TABLE 47: MIPS APM Measure List--Bundled Payments for Care Improvement Advanced Model

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
All-Cause Hospital Readmission	1789	Communication and Care Coordination	This measure estimates a hospital-level risk-standardized readmission rate (RSRR) of unplanned, all cause readmission after admission for any eligible condition within 30 days of hospital discharge.	CMS
Advanced Care Plan	0326 (adapted) [1]	Communication and Care Coordination	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	NCQA
Perioperative Care: Selection of Prophylactic Antibiotic: First or Second Generation Cephalosporin	0268	Patient Safety	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic who had an order for first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Elective Coronary Artery Bypass Graft (CABG) Surgery	2558	Patient Safety	The measure estimates a hospital-level, risk-standardized mortality rate (RSMR) for patients 18 years and older discharged from the hospital following a qualifying isolated CABG procedure. Mortality is defined as death from any cause within 30 days of the procedure date of an index CABG admission. The measure was developed using Medicare Fee-for-Service (FFS) patients 65 years and older and was tested in all-payer patients 18 years and older. An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the mortality outcome.	CMS
Excess Days in Acute Care After Hospitalization for Acute Myocardial Infarction	2881	Patient Safety	This measure assesses days spent in acute care within 30 days of discharge from an inpatient hospitalization for acute myocardial infarction (AMI) to provide a patient-centered assessment of the post-discharge period. This measure is intended to capture the quality of care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: emergency department (ED) visits, observation stays, and unplanned readmissions at any time during the 30 days post-discharge. To aggregate all three events, we measure each in terms of days. In 2016, CMS will begin annual reporting of the measure for patients who are 65 years or older, are enrolled in fee-for-service (FFS) Medicare, and are hospitalized in	CMS

Measure Name	NQF/ Quality ID #	National Quality Strategy Domain	Measure Description	Primary Measure Steward
			non-federal hospitals.	
AHRQ Patient Safety Measures	0531	Patient Safety	The modified PSI-90 Composite measure (name changed to Patient Safety and Adverse Events Composite) consists of ten component indicators: PSI-3 Pressure ulcer rate; PSI-6 Iatrogenic pneumothorax rate; PSI-8 Postoperative hip fracture rate; PSI-09 Perioperative hemorrage or hematoma rate; PSI-10 hysiologic and metabolic derangement rate; PSI-11 postoperative respiratory failure rate; PSI-12 Perioperative pulmonary embolism or Deep vein thrombosis rate; PSI-13 Postoperative sepsis rate; PSI-14 Postoperative wound dehiscence rate; and PSI-15 Accidental puncture or laceration rate.	AHRQ
Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty	1550	Patient Safety	The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and TKA in Medicare Fee-For-Service beneficiaries who are 65 years and older. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post date of the index admission (the admission included in the measure cohort).	CMS

1 The specifications used for the Advanced Care Plan quality measure in BPCI Advanced are not NQF endorsed, but have been created specifically for BPCI Advanced.

TABLE 48: MIPS APM Measure List—Maryland Total Cost of Care Model (Maryland Primary Care Program)

Measure Name	NQF/ Quality ID	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Controlling High Blood Pressure	0018	Effective / Clinical Care	Percentage of patients 18–85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9 percent)	0059	Effective Clinical Care	Percentage of patients 18–75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	0004	Effective / Clinical Care	Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported: a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
CG -CAHPS Survey 3.0 - modified for CPC+	Not Endorsed	Person and Family Engagement/ Patient and Caregiver Experience	CG–CAHPS Survey 3.0	AHRQ
Inpatient Hospital Utilization	Not Endorsed	Communication and Care Coordination	For members 18 years of age and older, the risk-adjusted ratio of observed to expected acute inpatient discharges during the measurement year reported by Surgery, Medicine, and Total.	National Committee for Quality Assurance
Emergency Department Utilization	Not Endorsed	Communication and Care Coordination	For members 18 years of age and older, the risk-adjusted ratio of observed to expected emergency department (ED) visits during the measurement year.	National Committee for Quality Assurance

TABLE 49: MIPS APM Measure List-- Independence at Home Demonstration

Measure Name	NQF/ Quality ID	National Quality Strategy Domain	Measure Description	Primary Measure Steward
Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months	Not Endorsed	N/A	Number of inpatient admissions for ambulatory-care sensitive conditions per 100 patient enrollment months.	CMS
Number of readmissions within 30 days per 100 inpatient discharges	Not Endorsed	N/A	Risk adjusted readmissions to a hospital within 30 days following discharge from the hospital for an index admission.	CMS
Emergency Department Visits for Ambulatory Care Sensitive Conditions	Not Endorsed	N/A	Risk adjusted emergency department visits for three ambulatory care sensitive conditions: diabetes, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD).	CMS
Contact with beneficiaries within 48 hours upon admission to the hospital and discharge from the hospital and/or ED	Not Endorsed	N/A	Percent of hospital admissions, hospital discharges, and emergency department (ED) visits for beneficiaries enrolled in IAH with a follow-up contact within 48 hours.	CMS
Medication reconciliation in the home	Not Endorsed	N/A	Percent of hospital discharges and emergency department (ED) visits for beneficiaries enrolled in IAH with medication reconciliation in the home within 48 hours.	CMS
Percentage with Documented Patient Preferences	Not Endorsed	N/A	Percent of beneficiaries enrolled in IAH with patient preferences documented in the medical record for a demonstration year.	CMS

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We proposed to update the MIPS APM measure sets that apply for purposes of the APM scoring standard (83 FR 35933 through 35934). The following is a summary of the public comments received on these measure sets and our responses:

Comment: Several commenters supported the measure sets set forth in the proposed rule. Other commenters recommended additional measures to be used in future years or suggested modifications to the measures themselves.

Response: We thank the commenters for their support and note that, consistent with § 414.1370(g)(1)(i)(A) and (ii)(A), we are using only measures that are included or that CMS intends to include in each APM measures set at the time of publication of this final rule. Should those measures be removed or revised from that measure set before the end of the performance year, we will not score APM Entities on their performance on those measures, but will include updated measures in future rulemaking.

Per our policy expressed in last year's final rule (82 FR 53695 and 53696), the measure sets on the MIPS APM measure list for the year will represent all possible measures which may contribute to an APM Entity's MIPS score for the MIPS quality performance category, and may include measures that are the same as or similar to those used by MIPS. However, a given measure ultimately might not be used for scoring, for example if its data becomes inappropriate or unavailable for scoring.

After consideration of the comments received, we are finalizing our proposal to update the MIPS APM measure sets that apply for purposes of the APM scoring standard and will score only measures that already have been included in the measure sets of their given APM, according to the terms of participation in that APM. We note that Table 48 has been updated to reflect the most current APM measure sets.

i. MIPS Final Score Methodology

(1) Converting Measures and Activities Into Performance Category Scores

(a) Background

For the 2021 MIPS payment year, we intend to build on the scoring methodology we finalized for the transition years, which allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. The rationale for our scoring methodology continues to be grounded in the understanding that the MIPS scoring system has many components and various moving parts.

As we continue to move forward in implementing the MIPS program, we strive to balance the statutory requirements and programmatic goals with the ease of use, stability, and meaningfulness for MIPS eligible clinicians. We do so while also emphasizing simplicity and the continued development of a scoring methodology that is understandable for MIPS eligible clinicians.

In the CY 2017 Quality Payment Program final rule, we finalized a unified scoring system to determine a final score across the 4 performance categories (81 FR 77273 through 77276). For the 2019 MIPS performance period, we proposed to build on the scoring methodology we previously finalized, focusing on encouraging MIPS eligible clinicians to meet data completeness requirements (83 FR 35948 through 35949). For quality performance category scoring, we proposed to extend some of the transition year policies to the 2019 MIPS performance period, and we also proposed several modifications to existing policies (83 FR 35947 through 35949). In the CY 2018 Quality Payment Program final rule (82 FR 53712 through 53714), we established a methodology for scoring improvement in the cost performance category. However, as required by section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018, we proposed that the cost performance category score would not take into account improvement until the 2024 MIPS payment year (83 FR 35956). In the CY 2018 Quality Payment Program final rule (82 FR 53753 through 53767), we finalized the availability of a facility-based measurement option for clinicians who met certain requirements, beginning with the 2019 MIPS performance period. As discussed in section III.I.3.i.(1)(d) of this final rule, we are finalizing our proposal to change the determination of facility-based measurement to include consideration of presence in the on-campus outpatient hospital. The policies for scoring the 4 performance categories are described in detail in section III.I.3.i.(1) of this final rule.

These policies will help eligible clinicians as they participate in the 2019 MIPS performance period/2021 MIPS payment year, and as we move beyond the transition years of the program. Section 51003 of the Bipartisan Budget Act of 2018 provides flexibility to continue the gradual ramp up of the Quality Payment Program and enables us to extend some of the transition year policies to the 2019 performance period.

Unless otherwise noted, for purposes of this section III.I.3.i. of this final rule, the term ''MIPS eligible clinician'' will refer to MIPS eligible clinicians who collect and submit data and are scored at either the individual or group level, including virtual groups; it will not refer to MIPS eligible clinicians who are scored by facility-based measurement, as discussed in section III.I.3.i.(1)(d) of this final rule. We also note that the APM scoring standard applies to MIPS eligible clinicians in APM Entities in MIPS APMs, and those policies take precedence where applicable. Where those policies do not apply, scoring for MIPS eligible clinicians as described in section III.I.3.h.(6) of this final rule will apply. We refer readers to section III.I.4. of this final rule for additional information about the APM scoring standard.

(b) Scoring the Quality Performance Category for the Following Collection Types: Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

Although we did not propose changing the basic scoring system that we finalized in the CY 2018 Quality Payment Program final rule for the 2021 MIPS payment year (82 FR 53712 through 53748), we proposed several modifications to scoring the quality performance category, including removing high-priority measure bonus points for CMS Web Interface measures and extending the bonus point caps, and adding a small practice bonus to the quality performance category score. The following section describes these previously finalized policies and our proposals (83 FR 35950 through 35952).

We also proposed updates to § 414.1380(b)(1) in an effort to more clearly and concisely capture previously established policies (83 FR 35946 through 35955). These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We will make note of the updated regulatory citations in their relevant sections below.

(i) Scoring Terminology

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77008 through 77831 and 82 FR 53568 through 54229, respectively), we used the term ''submission mechanisms'' in reference to the various ways in which a MIPS eligible clinician or group can submit data to CMS. As discussed in section III.I.3.h.(1)(b) of this final rule, it has come to our attention that the way we have described the various ways in which MIPS eligible clinicians, groups and third-party intermediaries can submit data to our systems does not accurately reflect the experience users have when submitting data to us. We refer readers to section III.I.3.h.(1)(b) of this final rule for further discussion on our finalized changes to the scoring terminology related to measure specification and data collection and submission. For additional discussion on the impact of the proposed terminology change on our benchmarking methodology, validation process, and end-to-end reporting bonus, we refer readers to sections III.I.3.i.(1)(b)(ii), (v), and (x) of this final rule.

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77282 and 82 FR 53718, respectively) for our previously established benchmarking policies. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(a)(i) of this final rule, our previously established benchmarking policies at § 414.1380(b)(1)(i) through (iii) would now be referenced at § 414.1380(b)(1)(i) through (ii).

When we developed the quality measure benchmarks, we sought to develop a system that enables MIPS eligible clinicians, beneficiaries, and other stakeholders to understand what is required for a strong performance in MIPS while being consistent with statutory requirements (81 FR 28249 through 28250). The feedback we have received thus far from stakeholders on our benchmarks is helping to inform our approach to the benchmarking methodology, especially as we look for possible ways of aligning with Physician Compare benchmarks. As described in section III.I.3.i.(1)(b)(xii) of this final rule, we solicited comment on potential future approaches to scoring the quality performance category to continue to promote value and improved outcomes.

We anticipate changes in scoring would be paired with potential modifications to measure selection and criteria discussed in section III.I.3.h.(2)(b) of this final rule. In the CY 2019 PFS proposed rule (83 FR 35947), we sought input on opportunities to further reduce confusion about our benchmarking methodology described in the CY 2017 Quality Payment Program final rule (81 FR 77277 through 77278), which includes further clarification of our benchmarking process and potential areas of alignment between the MIPS and Physician Compare benchmarking methodologies.

We thank commenters for their input and may take this input into consideration in future years.

(A) Revised Terminology for MIPS Benchmarks

We previously established at § 414.1380(b)(1)(iii) separate benchmarks for the following submission mechanisms: EHR; QCDR/registry, claims; CMS Web Interface; CMS-approved survey vendor; and administrative claims. In the CY 2019

PFS proposed rule, we did not propose to change our basic approach to our benchmarking methodology; however, we proposed to amend § 414.1380(b)(1)(ii) consistent with the proposed data submission terminology changes discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35947). Specifically, beginning with the 2021 MIPS payment year, we proposed to establish separate benchmarks for the following collection types: eCQMs; QCDR measures (as described at § 414.1400(e)); MIPS CQMs; Medicare Part B claims measures; CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. We would apply benchmarks based on collection type rather than submission mechanism. For example, for an eCQM, we would apply the eCQM benchmark regardless of submitter type (MIPS eligible clinician, group, third party intermediary). In addition, we would establish separate benchmarks for QCDR measures and MIPS CQMs since these measures do not have comparable specifications. In addition, we note that our proposed benchmarking policy allows for the addition of future collection types as the universe of measures continues to evolve and as new technology is introduced. Specifically, we proposed to amend § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

The following is a summary of the public comments on these proposals and our responses:

Comment: A few commenters expressed support for our proposal to establish separate benchmarks by collection types, citing the difference in measure performance across collection types. One commenter stated this update would maintain consistency when migrating between current MIPS terminology to proposed MIPS terminology.

Response: We thank commenters for their support as we continue to clarify and improve our benchmarking policies.

Comment: One commenter expressed concern about the proposal to update our regulatory text to state that benchmarks are based on collection types from all available sources, including APMs. Specifically, the commenter noted that incorporating APM data into benchmark calculations will set the benchmarks too high since APM participants tend to be high performers.

Response: We recognize commenter's concern; however, this is not a new policy, and we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77279) for additional discussion on the inclusion of APMs in the MIPS benchmarks. As measures and technology evolve, we are constantly reviewing and evaluating what data sources are appropriate for benchmarks.

Comment: One commenter requested clarification on whether QCDR measures that have an e-specified collection type and a manual collection type will also be considered separate collection types with distinct benchmarks.

Response: We expect that a QCDR measure for which data is abstracted through EHRs or manually (that is, paper records) would have to be approved as two separate measures. As a result, each measure would only be compared to its own benchmark.

After consideration of public comments, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to amend § 414.1380(b)(1)(ii) to establish separate benchmarks based on collection type and to remove the mention of each individual benchmark and state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(iii) Assigning Points Based on Achievement

In the CY 2017 Quality Payment Program final rule, we established the policies for scoring quality measures performance (81 FR 77286). We refer readers to § 414.1380(b)(1) for more on these policies.

(A) Floor for Scored Quality Measures

For the 2019 and 2020 MIPS payment years, we finalized at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable). In this way, MIPS eligible clinicians would receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements (81 FR 77286 through 77287; 82 FR 53719). For measures with a benchmark based on the performance period (rather than on the baseline period), we stated that we would continue to assign between 3 and 10 measure achievement points for performance periods after the first transition year (81 FR 77282, 77287; 82 FR 53719). For measures with benchmarks based on the baseline period, we stated that the 3-point floor was for the transition year and that we would revisit the 3-point floor in future years (81 FR 77286 through 77287; 82 FR 53719).

For the 2021 MIPS payment year, we proposed to again apply a 3-point floor for each measure that can be reliably scored against a benchmark based on the baseline period, and to amend § 414.1380(b)(1)(i) accordingly (83 FR 35947). We will revisit the 3-point floor for such measures again in future rulemaking.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters expressed support for the three-point floor for measures that can be reliably scored against a benchmark based on the baseline period because it would reduce confusion, help reduce burden, maintain stability, and encourage physicians to continue to participate in MIPS.

Response: We thank commenters for their support.

After consideration of public comments, we are finalizing our proposal, for the 2021 MIPS payment year, to apply a 3-point floor for each measure that can be reliably scored against a benchmark, and to amend § 414.1380(b)(1)(i) accordingly.

(B) Additional Policies for the CAHPS for MIPS Measure Score

Although participating in the CAHPS for MIPS survey is optional for all groups, some groups will be unable to participate in the CAHPS for MIPS survey because they do not meet the minimum beneficiary sampling requirements. CMS has sampling requirements for groups of 100 or more eligible clinicians, 25 to 99 eligible clinicians, and 2 to 24 eligible clinicians to ensure an adequate number of survey responses and the ability to reliably report data. Our sampling timeframes necessitate notifying groups of their inability to meet the sampling requirements late in the performance period (see 82 FR 53630 through 53632). As a result, we are concerned that some groups that expect and plan to meet the quality performance category requirements using the CAHPS for MIPS survey may find out late in the performance period that they are unable to meet the sampling requirements and, therefore, are unable to have their performance assessed on this measure. These groups may need to report on another measure to meet the

requirements of the quality performance category.

We want to encourage the reporting of the CAHPS for MIPS survey and do not want the uncertainty regarding sampling requirements to be a barrier to selecting the CAHPS for MIPS survey. To mitigate this concern, beginning with the 2021 MIPS payment year, we proposed to reduce the denominator (that is, the total available measure achievement points) for the quality performance category by 10 points for groups that register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements (83 FR 35948). By reducing the denominator instead of only assigning the group a score of zero measure achievement points (because the group would be unable to submit any CAHPS for MIPS survey data), we are effectively removing the impact of the group's inability to submit the CAHPS for MIPS survey. We believe this reduction in denominator would remove any need for groups to find another measure if they are unable to submit the CAHPS for MIPS survey. Therefore, we proposed to amend § 414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that registered for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters supported our proposed policy. One commenter believes this will encourage more groups to conduct the survey.

Response: We appreciate the commenters' support.

Comment: One commenter requested clarification on when groups would be notified that they did not meet the beneficiary sampling requirement. The commenter also requested clarification on what protections the agency will institute for groups who must cancel their contracts with survey vendors ''late in the performance period'' when they are notified that they did not meet the beneficiary sampling requirement. The commenter stated that CMS should not hold groups accountable for vendor costs that result from the agency's late notification process.

Response: We do not anticipate the notification process for minimum beneficiary sample requirements will change. CMS provides information on sample design and sample size requirements in the QPP Resource Library to aid groups in deciding whether or not to elect CAHPS for MIPS. CMS sends communication about sample size eligibility to the point of contact provided by each group during the registration process for CAHPS for MIPS. Providing more than one point of contact will help to promote timely delivery of the information on sample size eligibility to the group. Groups should coordinate with their vendors to address any questions regarding costs in the event the group does not meet the beneficiary sampling requirement. For any additional questions please visit the Quality Payment Program website at *qpp.cms.gov.*

Comment: One commenter sought clarification whether CMS would automatically apply the scoring policy or first provide groups with the option to report on an alternate quality measure or improvement activity.

Response: We will not automatically apply the scoring policy. Notifications will be sent twice to groups that have registered for the CAHPS for MIPS survey and who have an insufficient sample size, with the second notification usually occurring in September. These notifications also encourage groups to select other relevant measures that can be completed. We believe that this policy is necessary because the notification late in the performance period might not allow sufficient time for groups to collect and report a different quality measure, however, some practices may have other quality measures (beyond the 6 minimum) that they have been reporting on that could be submitted within the performance period. For groups that submitted 5 or fewer quality measures and do not meet the CAHPS for MIPS sampling requirements, the quality denominator will be reduced by 10 points. For groups that submitted 6 or more quality measures and do not meet the CAHPS for MIPS sampling requirements, we will score the 6 measures with the highest achievement points.

The notification will also encourage groups to select other relevant improvement activities that can be completed within the performance period. We refer readers to section III.I.3.h.(4)(b) of this final rule for further information on submission criteria for the improvement activities performance category.

After consideration of public comments, we are finalizing our proposal to amend § 414.1380 to add paragraph (b)(1)(vii)(B) to state that we will reduce the total available measure achievement points for the quality performance category by 10 points for groups that submit 5 or fewer quality measures and register for the CAHPS for MIPS survey, but do not meet the minimum beneficiary sampling requirements.

We do not want groups to register for the CAHPS for MIPS survey if they know in advance that they are unlikely to be able to meet the sampling requirement, so we solicited comments on whether we should limit this proposed policy to groups for only one MIPS performance period. For example, for the performance period following the application of this proposed policy, a notice could be provided to groups during registration indicating that if the sampling requirement is not met for a second consecutive performance period, the proposed policy will not be applied. This would provide notice to the group that they may not meet the sampling requirement needed for the CAHPS for MIPS survey and may need to look for alternate measures but does not preclude the group from registering for the CAHPS for MIPS survey if they expect to meet the minimum beneficiary sampling requirements in the second MIPS performance period.

We thank commenters for their suggestions and may consider them for future rulemaking.

(iv) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to CY 2017 Quality Payment Program final rule (82 FR 53721 through 53727) for our established policies for scoring topped out measures.

Under § 414.1380(b)(1)(xiii)(A), for the 2020 MIPS payment year, 6 measures will receive a maximum of 7 measure achievement points, provided that the applicable measure benchmarks are identified as topped out again in the benchmarks published for the 2018 MIPS performance period. Under § 414.1380(b)(1)(xiii)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727). As part of our technical updates to § 414.1380(b)(1) outlined in section III.I.3.i.(1)(b) of this final rule, our previously finalized topped out scoring policies are now referenced at § 414.1380(b)(1)(iv).

We refer readers to the 2018 MIPS Quality Benchmarks' file that is located on the Quality Payment Program resource library (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*) to determine which measure

benchmarks are topped out for 2018 and would be subject to the cap if they are also topped out in the 2019 MIPS Quality Benchmarks' file. We note that the final determination of which measure benchmarks are subject to the topped out cap will not be available until the 2019 MIPS Quality Benchmarks' file is released in late 2018.

We did not propose to apply our previously finalized topped out scoring policy to the CAHPS for MIPS survey (82 FR 53726). Because the CAHPS for MIPS survey was revised in 2018 (82 FR 53632), we do not have historical benchmarks for the 2018 performance period, so the topped out policy would not be applied for the 2019 performance period. Last year, we received limited feedback when we sought comment on how the topped out scoring policy should be applied to CAHPS for MIPS survey. In CY 2019 PFS proposed rule, we sought feedback on potential ways we can score CAHPS for MIPS Summary Survey Measures (SSM) (83 FR 35948). For example, we could score all SSMs, which means there would effectively be no topped out scoring for CAHPS for MIPS SSMs, or we could cap the SSMs that are topped out and score all other SSMs. We sought comment on these approaches and additional approaches to the topped out scoring policy for CAHPS for MIPS SSMs. We noted that we encourage groups to report the CAHPS for MIPS survey as it incorporates beneficiary feedback.

We thank commenters for their suggestions and will consider them for future rulemaking.

(v) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmarks Requirements

In the CY 2017 Quality Payment Program final rule (81 FR 77288 through 77289), we established scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement. As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously finalized scoring policies are now referenced at § 414.1380(b)(1)(i)(A) and (B).

A summary of the current and proposed policies is provided in Table 50. For more of the statutory background and details on current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77288 through 77289 and 82 FR 53727 through 53730, respectively).

TABLE 50: Quality Performance Category: Scoring Measures

Measure type	Description	Scoring rules
Class 1	For the 2018 and 2019 MIPS performance period: Measures that can be scored based on performance. Measures that were submitted or calculated that met the following criteria: (1) Has a benchmark; (2) Has at least 20 cases; and (3) Meets the data completeness standard (generally 60 percent.)	For the 2018 and 2019 MIPS performance period: 3 to 10 points based on performance compared to the benchmark.
Class 2*	For the 2018 and 2019 MIPS performance period: Measures that were submitted and meet data completeness, but do not have both of the following: (1) a benchmark (2) at least 20 cases.	For the 2018 and 2019 MIPS performance period: 3 points * This Class 2 measure policy does not apply to CMS Web Interface measures and administrative claims based measures
Class 3**	For the 2018 and 2019 MIPS performance period: Measures that were submitted, but do not meet data completeness criteria, regardless of whether they have a benchmark or meet the case minimum.	For the 2018 and 2019 MIPS performance period: 1 point except for small practices, which would receive 3 measure achievement points. Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero measure achievement points. Small practices will continue to receive 3 points. **This Class 3 measure policy would not apply to CMS Web Interface measures and administrative claims based measures

As the MIPS program continues to mature, we are looking to find ways to improve our policies, including what to do with measures that do not meet the case minimum. Although many MIPS eligible clinicians can meet the 20-case minimum requirement, we recognize that small practices and individual MIPS eligible clinicians may have difficulty meeting this standard. Although we process data from the CY 2017 MIPS performance period to determine how often submitted measures do not meet case minimums, we invited public comment on ways we can improve our case-minimum policy. In determining future improvements to our case minimum policy, our goal is to

balance the concerns of MIPS eligible clinicians who are unable to meet the case minimum requirement and for whom we cannot capture enough data to reliably measure performance, while not creating incentives for MIPS eligible clinicians to choose measures that do not meet case minimum even though other more relevant measures are available.

We thank commenters for their suggestions and will consider them for future rulemaking.

In the CY 2019 PFS proposed rule (83 FR 35949), we proposed to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and to amend § 414.1380(b)(1)(i) accordingly.

We also proposed to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend § 414.1380(b)(1)(i)(B)(*1*) accordingly (83 FR 35949). This policy is part of our effort to move toward complete and accurate reporting that reflects meaningful effort to improve the quality of care that patients receive. Measures submitted by small practices would continue to receive 3 points for all future CY MIPS performance periods, although we may revisit this policy through future rulemaking.

We requested comments on the proposals above. These comments and our responses are discussed below.

Comment: Several commenters supported the proposal to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period.

Response: We thank commenters for their support. However, we want to stress that these policies were not meant to be permanent and as clinicians continue to gain experience with the program we will revisit the appropriateness of these policies in future rulemaking.

Comment: A few commenters did not support our proposal to reduce points for measures that do not meet data completeness to zero starting with the CY 2020 MIPS performance period because of concerns that it would add complexity and burden as clinicians are continuing to learn the program. A few commenters suggested that CMS should return to assigning these measures 3 points or, at a minimum, continue to assign them 1 point or provide special scoring for MIPS eligible clinicians with significant administrative burdens. A few commenters recommended that clinicians should at least get some credit for attempting to report and, through no fault of their own, fail to meet the data completeness threshold, citing the difficulty of getting all the necessary data from hospitals and/or their billing companies to report on 60 percent of all applicable patients.

Response: We understand and recognize commenters' concerns. However, as the program is being fully implemented, we want to ensure that our policies align with our goal of improving quality. This scoring policy was intended to be temporary, and we believe that data completeness is something that is within the direct control of clinicians. Although we understand that many clinicians have administrative burdens and we continuously strive to reduce paperwork, we also believe that it is important to develop policies that align with the program's goal to improve quality of care. By the fourth year of implementation, we believe this policy is no longer needed and that removing this policy helps streamline our scoring policies.

After consideration of public comments, we are finalizing the proposal to maintain the policies finalized for the CY 2018 MIPS performance period regarding measures that do not meet the case-minimum requirement, do not have a benchmark, or do not meet the data-completeness criteria for the CY 2019 MIPS performance period, and the amending of § 414.1380(b)(1)(i) accordingly.

After consideration of public comments, we are finalizing our proposal to assign zero points for measures that do not meet data completeness starting with the CY 2020 MIPS performance period and to amend § 414.1380(b)(1)(i)(B)(1) accordingly. Measures submitted by small practices will continue to receive 3 points for all future MIPS performance periods.

(vi) Scoring Flexibility for Measures With Clinical Guideline Changes During the Performance Period

In the CY 2018 Quality Payment Program final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 updates based only on the first 9 months of the 12-month performance period (for example, January 1, 2018, through September 30, 2018, for the 2018 MIPS performance period). We noted that performance on measures that are not significantly impacted by changes to ICD–10 codes would continue to be assessed on the full 12-month performance period (January 1 through December 31). Lastly, we finalized that we will publish the list of measures requiring a 9-month assessment process on the CMS website by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period (for example, January 2, 2019, for the 2018 MIPS performance period). As part of our technical updates to § 414.1380(b)(1) outlined in section III.I.3.i.(1)(b) of this final rule, these previously finalized policies are now referenced at § 414.1380(b)(1)(viii).

We remain concerned about instances where clinical guideline changes or other changes to evidence supporting a measure occur during the performance period that may significantly impact a measure. Clinical guidelines and protocols developed by clinical experts and specialty medical societies often underpin quality measures. At times, measure stewards must amend quality measures to reflect new research and changed clinical guidelines, and sometimes, as a result of the change in these guidelines, adherence to guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. We sought comment in the CY 2018 Quality Payment Program final rule regarding whether we should apply scoring flexibility to measures significantly impacted by clinical guideline changes (82 FR 53716). We refer readers to the CY 2019 PFS proposed rule for a summary of the comments we received (83 FR 35949 through 35950).

We remain concerned that findings of evidence-based research, providing the basis for sound clinical practice guidelines and recommendations that are the foundation of a quality measure, may change outside of the rulemaking cycle. As the clinical evidence and guidelines change, approved measures may no longer reflect the most up-to-date clinical evidence and could be contrary to patient well-being. There may be instances in which changes to clinical guidelines are so significant, that an expedited review is needed outside of the rulemaking cycle because measures may result in a practice that is harmful to patients. To further align with policies adopted within other value based programs such as the Hospital VBP Program (83 FR 20409), we proposed to suppress a measure without rulemaking, if during the performance period a measure is

significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns (83 FR 35950). We would rely on measure stewards for notification in changes to clinical guidelines. We will publish on the CMS website suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

In the CY 2019 PFS proposed rule (83 FR 35950), we proposed policies to provide scoring flexibility in the event that we need to suppress a measure during a performance period. Scoring for a suppressed measure would result in a zero achievement points for the measure and a reduction of the total available measure achievement points by 10 points. We believe that this approach effectively removes the impact of the eligible clinician's inability to receive measure achievement points for the measure, if a submitted measure is later suppressed.

We also proposed to add a new paragraph at § 414.1380(b)(1)(vii) that, beginning with the 2019 MIPS performance period, CMS will reduce the total available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians that submit a measure significantly impacted by clinical guideline changes or other changes that CMS believes may pose patient safety concerns (83 FR 35950).

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: A few commenters supported the proposal because it holds the clinician harmless from clinical guideline changes that impact quality measures. One commenter noted that it is important that clinicians are protected from any adverse impacts on their scoring when they are following updated clinical guidelines to ensure proper patient care and safety.

Response: We appreciate the support of the proposal.

Comment: Several commenters did not support the proposal. Commenters questioned whether there would be an expectation that the clinician would continue collecting data on the measure, or whether they would be allowed to submit the measure with less than 12 months' data for the suppressed measure. A few commenters stated the policy should only be applied if the clinical guideline change relates to patient harm or patient safety, in which case data collection on the quality measure should cease immediately. A few commenters indicated that clinicians invest significant time and resources to assess and improve their performance over the course of the performance period, and thus suppressing the scoring of a quality measure, unless patient harm is involved, does not appropriately recognize these efforts. One commenter suggested that CMS establish an attestation process through the EIDM system to allow clinicians the option to attest their intent to report the measure, and CMS should adjust their scoring accordingly.

Response: We appreciate the commenters' suggestions. There are rare instances in which changes to clinical knowledge and guidelines can significantly impact measure specifications and the intent of the measure, which we believe requires suppression of scoring so as to encourage the clinicians to follow the guidelines that are best for the patient, rather than tracking the guidelines that were finalized in the measure set, which may negatively impact patient care. Clinical guideline changes that occur between rulemaking cycles would need to be significant enough that the change in the most up-to-date clinical evidence could result in patient harm if the clinician does not follow these new guidelines or otherwise provide misleading results as to what is measured as good quality care. We believe there are rare instances in which we should not delay our support of the use of the most current clinical evidence by continuing to require the collection of data and scoring the measure until the next rulemaking cycle. For example, a guideline may be updated because clinical evidence indicates that a new medication should replace a medication specified in a quality measure. If this occurs between rulemaking cycles, we would not want the scoring policy to disadvantage the clinicians adopting the updated guideline and using the recommended medication. We envision that this policy would be applied in two circumstances. First, there is a newly issued or updated guideline where there is wide consensus that would result in a significant change to a quality measure. In these cases, it would be expected that clinicians would adopt clinical processes to support the new guideline which may not be compatible with the existing measures and could provide misleading results or patient harm. In this case, we anticipate the quality measure would be reviewed and updated during the next rulemaking process. Second, we envision using this policy in rare cases where there is a new or revised guideline, even if there is no broad consensus within the specialty, because some clinicians will begin to adopt the new guideline which would not be consistent with the quality measures and scoring the measure could cause misleading results for those clinicians. We believe it important to suppress the measure until guideline and quality measure are reviewed by the Measures Application Partnership (MAP) and other processes to support the Annual List of Measures, including rulemaking. We do not envision using this policy solely based on indications that guideline revisions are anticipated but not completed. Until the guideline is updated, clinicians would be expected to follow the existing guideline and it would not be prudent to use the scoring policy. Nor would we activate the policy if the guideline change does not significantly impact the measure results.

In the event of the need for the special scoring policy, we would communicate to clinicians through multiple channels regarding the changes. We appreciate that clinicians invest significant time and resources to select measures, we also believe it is critical that the measure results do not cause patient harm or otherwise harm clinician performance by scoring potentially misleading data. We believe suppressing the measure and reducing the total possible achievement points by 10 would recognize this effort by not forcing clinicians in the middle of a performance to select a new measure to report.

We appreciate the time and resources clinicians expend to collect data for a quality measure; however, we believe the policy will only be used in rare occasions, which will limit disruption to clinicians. We also believe that the policy will not disadvantage the clinician and will ''hold harmless'' any clinician submitting data on the measure. Scoring would be suppressed for any clinician that submitted data on the measure prior to the announcement. Similarly, given how rarely we anticipate we will need to use this policy, we do not believe we require a process for attestation regarding which measures will be selected prior to the performance period.

Comment: A few commenters recommended regular communication between CMS and measure stewards and supported the proposal that it would be the responsibility of the measure steward to notify CMS of changes to the clinical guidelines that may impact existing quality measures. One commenter requested that CMS allow multiple sources, rather than just measure stewards, to identify potential significant changes to clinical guidelines that may pose patient safety

risks. Another commenter stated that only measure stewards should notify CMS of significant changes to clinical guidelines.

Response: We regularly monitor changes to quality measures and work closely with clinical organizations that maintain clinical guidelines and measure stewards to identify quality measures impacted by significant changes to clinical guidelines during the performance period. We will mainly rely on measure stewards to identify significant changes, especially those relating to potential patient harm. We clarify that measure stewards are not necessarily the owner and/or developer of the clinical guidelines. In many instances measure stewards defer to the clinical organizations or stakeholders who own, maintain and update the clinical guideline when changes are warranted. We intend to continue to work collaboratively with measure stewards, clinical organizations, measure owners and other key stakeholders responsible for the maintenance of these guidelines prior to deciding to suppress the scoring of a measure. As noted above, if we decide to suppress these measures, we would notify clinicians through multiple means.

After consideration of public comments, we are finalizing a modification of our proposal and adding a new paragraph at § 414.1380(b)(1)(vii) stating that, beginning with the 2021 MIPS payment year, we will reduce the denominator of available measure achievement points for the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise provide misleading results as to good quality care. To clarify, we regularly monitor changes to quality measures and clinical guidelines and we will rely mainly on measure stewards, who often defer to the clinical organizations or other stakeholders who own, maintain and update the clinical guideline when a guideline change is warranted, for notification in changes to clinical guidelines. We will publish on the CMS website suppressed measures whenever technically feasible, but by no later than the beginning of the data submission period.

(vii) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2018 Quality Payment Program final rule (82 FR 53732), we finalized that, beginning with the 2021 MIPS payment year, we will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. We will not apply the validation process to any data collection type that the MIPS eligible clinician does not utilize for the quality performance category for the performance period. We sought comment on how to modify the validation process for the 2021 MIPS payment year when clinicians may submit measures collected via multiple collection types.

As discussed in section III.I.3.h.(1)(b) of this final rule, we proposed to revise our terminology regarding data submission. This updated terminology will more accurately reflect our current submissions and validation policies. In the CY 2019 PFS proposed rule (83 FR 35950), we proposed to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, this policy would not apply to eCQMs even if they are submitted by a registry.

We note that a MIPS eligible clinician may not have available and applicable quality measures. If we are unable to score the quality performance category, then we may reweight the clinician's score according to the reweighting policies described in sections III.I.3.i.(2)(b)(ii) and III.I.3.i.(2)(b)(iii) of this final rule.

We did not receive any comments on this proposal.

We are finalizing our proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen.

(viii) Small Practice Bonus

In the CY 2018 Quality Payment Program final rule (82 FR 53788), we finalized at § 414.1380(c)(4) to add a small practice bonus of 5 points to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, APM Entities, and virtual groups that meet the definition of a small practice as defined at § 414.1305 and submit data on at least one performance category in the 2018 MIPS performance period.

We continue to believe an adjustment for small practices is generally appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap we have observed (based on historical PQRS data) for small practices in comparison to larger practices. We believe a small practice bonus specific to the quality performance category is preferable for the 2021 MIPS payment year and future years. We believe it is appropriate to apply a small practice bonus points to the quality performance category based on observations using historical data, which indicates that small practices are less likely to submit quality performance data, less likely to report as a group and use the CMS Web Interface, and more likely to have lower performance rates in the quality performance category than other practices. We want the final score to reflect performance, rather than the ability and infrastructure to support submitting quality performance category data.

We considered whether we should continue to apply the small practice bonus through bonus points in all 4 performance categories, but believe the need for doing so is less compelling. The improvement activities performance category already includes special scoring for small practices (please refer to § 414.1380(b)(3) and see section III.I.3.i.(1)(e) of this final rule for more information). In addition, for the Promoting Interoperability performance category, small practices can apply for a significant hardship exception if they have issues acquiring an EHR (see section III.I.3.h.(5) of this final rule). Finally, the cost performance category does not require submission of any data; therefore, there is less concern about a small practice being burdened by those requirements. For these reasons, we proposed to transition the small practice bonus to the quality performance category.

Starting with the 2021 MIPS payment year, we proposed at § 414.1380(b)(1)(v)(C) to add a small practice bonus of 3 points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure (83 FR 35950). Because MIPS eligible clinicians in small practices are not measured on the readmission measure and are not able to participate in the CMS Web Interface, they generally have a quality performance category denominator of 60 total possible measure achievement points. Thus, our proposal of 3 measure bonus points generally represents 5 percent of the quality performance category score. As described in section III.I.3.i.(2)(b)(iii) of this final rule, for clinicians in many small practices, the

quality performance category weight may be up to 85 percent of the final score. (For example, if a small practice applies for the Promoting Interoperability significant hardship application and does not meet the sufficient case minimum for cost measures, then the weights of Promoting Interoperability and cost performance categories are redistributed to quality and the quality performance category weight would be 85 percent.)

With a weight of 85 percent, a small practice bonus of 3 points added to the quality performance category will result in 4.25 bonus points added to the final score for clinicians in small practices.[29] We believe this is appropriate because it is similar to the impact of the small practice bonus we finalized for the 2020 MIPS payment year (5 points added to the final score). Although we recognize that the impact of the small practice bonus for MIPS eligible clinicians in small practices who do not receive reweighting for the cost and/or Promoting Interoperability performance categories will be less than 4.25 points added to the final score, we believe a consistent approach is preferable for simplicity, and we do not believe that a larger bonus is appropriate as that could potentially inflate the quality performance category score and the final score and mask poor performance.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Some commenters supported the proposal and recommended that CMS continue to evaluate the least complicated method to apply the small practice bonus in future years. One commenter indicated that a small practice bonus should be retained as long as possible to support small practices. A few commenters recommended stability over several performance periods for the small practice bonus, with incentives maintained over time with no changes from year-to-year. One commenter recommended that CMS codify the small practice bonus for at least 3 years.

Response: We will evaluate MIPS data to determine whether any future adjustment is still needed based on analysis of the performance of small group practices compared to larger practices. While we appreciate commenters' recommendations for stability in the bonus over time, we believe that we must be guided by the annual analysis of small practices' experience with the Quality Payment Program to determine if the adjustment is still warranted. Any extension to the small practice bonus would be proposed through future rulemaking.

Comment: One commenter recommended bonus points be applied evenly across the following performance categories: Quality; improvement activities; and Promoting Interoperability. Another commenter indicated that it did not support a bonus based on the size or location of the practice and recommended aligning the four performance categories and awarding bonuses for activities that apply across the performance categories. One commenter recommended that the clinician be allowed the option to have bonus points added to a performance category of his or her choice. A few commenters stated that small practices are consistently disadvantaged compared to large health systems for not only quality reporting, but also requirements of other performance categories including Promoting Interoperability and improvement activities.

Response: We considered dividing the small practice bonus between the performance categories; however, we believe that spreading the bonus across performance categories may not be appropriate, and the other performance categories already take small practices into account. As stated earlier, the improvement activities performance category already includes special scoring for small practices. The Promoting Interoperability performance category has a hardship exception for small practices. The cost performance category does not require submission of any data. For these reasons, we believe that it is appropriate for the small practice bonus to be in the quality performance category.

Comment: Many commenters did not support reducing the small practice bonus from 5 points in the final score to 3 measure bonus points in the quality performance category because of concerns that small practices will receive less points, which may not support small practices sufficiently. Several commenters stated that the bonus needs to be significant enough so that adjustments provide more equitable scoring to small practices. One commenter recommended that if the bonus is applied in the quality performance category, 5 points should be awarded.

Response: We understand commenters' concerns. We recently estimated quality performance category scores for the 2019 MIPS performance period using data from the 2017 MIPS performance period. This new data was not available before the publication of the proposed rule. In this new analysis, we found that the number of eligible clinicians whose quality performance category was reweighted to 85 percent of the final score was lower than we anticipated. We found that for approximately three-fourths of the clinicians in small practices (and those not subject to the APM scoring standard), quality was weighted between 45 and 60 percent when we applying our proposed CY 2019 performance period policies to MIPS year 1 data. Thus, the 3 bonus points proposed (which generally represents 5 percent of the quality performance category score for small practices) would represent a lower overall bonus when added to the final score than we had originally anticipated. While we still believe that the small practice bonus should be applied to the quality category performance score, it was not our intention to lower the overall impact on the final score.

With our updated impact analysis in this final rule, we discovered that trends identified when we originally established the small practice bonus still exist. For example, in the CY 2018 Quality Payment Program proposed rule (82 FR 30139 through 30140), we noted that clinicians in practices with more than 100 clinicians may perform better in the Quality Payment Program on average compared to clinicians in smaller practices. We believed this trend was due primarily to two factors: Participation rates and Web Interface reporting. While we estimate more clinicians in small practices are participating in MIPS in our updated model in this final rule compared to our estimates in the 2019 PFS proposed rule, we still see a gap in quality participation when comparing clinicians in small practices to clinicians in large practices (89.8 percent compared to 100.0 percent respectively). We also noticed a discrepancy in performance among those who submitted data for the quality performance category. Prior to applying a small practice bonus, the average quality score for submitters in small practices was 62 percent compared to 82 percent for clinicians in large groups. It is unclear whether the cause of the discrepancy is related to Web Interface reporting, to performance, or to factors related to data collection. While we continue to analyze the implications of these results, we believe increasing the small practice bonus from 3 to 6 measure bonus points for 1 year would be appropriate to ensure that we are correctly incentivizing participation

[29] We get 4.25 points using the following calculation: (3 measure bonus point/60 total measure points) * 85 percent * 100 = 4.25.

during the transition years without lowering the impact of the small practice bonus. The other bonuses in the quality performance category (for high-priority measures and end-to-end electronic reporting) are capped at 10 percent of the denominator of the quality performance category, which in almost all cases for small practices is 60 total possible measure achievement points. Setting the bonus at 6 points generally represents 10 percent of the quality performance category score. For those clinicians who have six measures and for whom the quality performance category weight is 45 percent, then the small practice bonus would equate to 4.5 final score points. For those with a quality performance category weight of 60 percent, the small practice bonus would equate to 6 final score points. We recognize that for some practices whose quality score is reweighted to 85 percent of their final score, this may account for a large part of the final score; however, based on the new CY 2017 MIPS performance period data, we do not believe this will be the case for a large proportion of small practices. On average, we estimate this change to the small practice bonus will add 4.4 points to the final score for clinicians in small practices who submit quality information to MIPS.

We want to remind readers that the small practice bonus was only meant to be temporary and as we further analyze CY 2017 MIPS performance period data we expect that the bonus will likely be reduced or removed in future rulemaking. While we currently believe that it is appropriate due to the unique challenges small practices experience related to financial and other resources, as well as the performance gap for small practices in comparison to larger practices, we believe that upon further analysis of CY 2017 MIPS performance period data the small practice bonus may not address the underlying reasons for the disparate performance between small practices and other clinicians. As a result, we intend to revisit this bonus during next year's rulemaking cycle.

Comment: Many commenters stated that the small practice bonus should not be embedded in the quality performance category and should be a standalone bonus at the final score level to reduce complication in scoring, provide greater flexibility, and reduce burden on small practices. Several commenters stated that the quality performance category is contributing less to the final score, since it is being reduced from 50 percent to 45 percent, and may be reduced in the future, which would continually reduce the small practice bonus. A few commenters noted that moving the bonus to the quality performance category provides additional scoring complexity and will not be equitable, since the bonus will be applied to small practices regardless of the number of measures submitted for the quality performance category. For example, the bonus of 3 points for a clinician being scored on one quality measure would translate to a higher contribution to the final score than applying a bonus of 3 points for a clinician being scored on 6 measures. One commenter was concerned that moving the small practices bonus to the quality performance category will remove the opportunity for a bonus from clinicians who do not, or cannot, report quality measures.

Response: We believe it is more appropriate for the small practice bonus to reside in the quality performance category because small practices have different reporting options than larger practices (for example, only small practices are able to submit data via Medicare Part B claims, but they cannot do so via the Web Interface), and burdens associated with submitting data could affect the quality performance category score. We also believe there is at least one quality measure that is relevant to the vast majority of clinicians in the Quality Payment Program. The small practice bonus is available to any small practice submitting at least one quality measure. We reiterate that we have special policies to assist small practices in the improvement activities and Promoting Interoperability performance categories, which limit the need for a small practice bonus in those performance categories. The cost performance category does not require additional burden to submit information and does not have the same reporting restrictions as the quality performance category. Over time, we will monitor the weight of the quality performance category and the small practice contribution to the final score to determine if the amount of the small practice bonus needs to be adjusted. We acknowledge that moving the small practice bonus may add to the complexity of scoring, but, on balance, we believe it is appropriate to encourage the submission of quality measures. Also, we note that previously the small practice bonus was added to the final score regardless of the number of quality measures that were submitted. Although the bonus is now in the quality category, the equity of the bonus does not change with this policy. In addition, we will continue to monitor data to evaluate the performance of small practices in the quality performance category to determine differences between small and large practices and propose any necessary changed in future rulemaking.

Comment: One commenter requested clarification on how CMS will extend the small practice bonus to MIPS APMs.

Response: The small practice bonus will be applied to the final quality performance category score for MIPS APMs at the MIPS APM entity-level. For further discussion on our MIPS APM scoring policies, we refer readers to section III.I.3.h.(6) of this final rule.

Comment: One commenter indicated that the bonus score changes based on the reweighting of certain performance categories for clinicians, which they believe gives an advantage to clinicians who have a higher percentage of the score weighed to the quality performance category. One commenter did not support moving the bonus to the quality performance category, because the potential to reweight performance categories results in a bonus that is not predictable during the performance period for clinicians, who do not know which performance categories will be reweighted.

Response: We appreciate that there might be differences in the reweighting of performance categories for small practices. As stated previously, we believe the quality performance category is an important component of the Quality Payment Program. While it was our intention to apply a bonus to the quality performance category with a cap approximately equal to the final score small practice bonus for the 2018 MIPS performance period/2020 MIPS payment year, we recognize that due to reweighting, the magnitude of the bonus will vary; however, in order to reduce complexity, we believe that a uniform bonus of 6 measure bonus points added to the numerator for quality is appropriate. As discussed in our response above, the policy is consistent with our other quality performance category bonuses because, for most clinicians, 6 measure bonus points is 10 percent of the 60-point denominator within the quality performance category. In addition, clinicians can predict whether their scores will be reweighted based on eligibility and special status information in the lookup tool. We will monitor the extent to which reweighting the quality performance category contribution to the final score affects quality measure bonus points awarded and so that we may keep the bonuses as equitable as possible.

Comment: A few commenters indicated that the small practice bonus should be extended to rural practices and different practice sizes. One

commenter recommended extending the bonus to all rural practices, regardless of practice size, because of the belief that all rural practices struggle with access to resources. One commenter indicated a belief that the program offers few bonus points and opportunities for high scores for small and rural practices, which may result in a skewed scoring system that rewards large groups with resources to support participation. One commenter recommended that the small practice bonus be available to groups with 10 or less participants, to align the definition with virtual group requirements. One commenter indicated that groups with more than 15 clinicians should be considered a small practice for purposes of the bonus.

Response: As discussed in the CY 2018 Quality Program final rule (82 FR 53778), we observed that performance for rural MIPS eligible clinicians is very similar to performance for non-rural MIPS clinicians once we account for practice size, so we do not believe a bonus for MIPS clinicians practicing in a rural setting is appropriate at this time. Additionally, we discussed in the CY 2018 Quality Payment Program final rule (82 FR 53777) that we believe it is important to maintain a consistent definition of small practices within the Quality Payment Program. In addition, we have not seen discrepancies between simulated MIPS final scores for practices of 16 to 24 clinicians and for practices of 15 or fewer clinicians. However, we will continue to monitor this issue and assess whether there are scoring differences between small rural and small urban practices and, if so, address it in future rulemaking.

Comment: One commenter requested that CMS articulate how the policies proposed align with other CMS efforts to support the long-term, sustainable transformation of small practices and those serving rural and underserved communities.

Response: We recognize the unique challenges that eligible clinicians in small practices face and have established a unique set of policies to reduce their participation burden and ease their transition into the program. The special policies include the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule; the significant hardship exception for Promoting Interoperability performance category and the associated reweighting policies available for small practices that do not have CEHRT (2018 Quality Payment Program final rule (82 FR 53683)); special scoring provisions available for the improvement activities performance category (82 FR 53656), and the provisions related to the low-volume threshold at section III.I.3.c. of this final rule. We are also continuing the Small, Underserved, and Rural Support initiative, which provides no-cost technical assistance to MIPS eligible clinicians in small practices. The initiative offers customized, one-on-one support to help MIPS eligible clinicians in small practices familiarize themselves with the program requirements, develop a strategy to successfully participate, and continue improving outcomes for beneficiaries. See: *https://qpp.cms.gov/about/small-underserved-rural-practices* for further information.

As discussed in the response above, we have estimated quality performance category scores using data from the 2017 MIPS performance period. As a result of this new data that was not available before the publication of the proposed rule we believe increasing the small practice bonus from 3 to 6 measure bonus points would be appropriate to ensure that we are correctly incentivizing participation without lowering the final score of small practices. The other bonuses in the quality performance category (for high-priority measures and end-to-end electronic reporting) are capped at 10 percent of the denominator of the quality performance category, which in almost all cases for small practices is 60 total possible measure achievement points. Setting the bonus at 6 points generally represents 10 percent of the quality performance category score.

After consideration of public comments, we are not finalizing as proposed the proposal to amend § 414.1380(b)(1)(v)(C) to add, beginning with the 2021 MIPS payment year, a small practice bonus of 3 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure. Instead, based on the rationale discussed previously, we are finalizing the amendment of § 414.1380(b)(1)(v)(C) to add, beginning with the 2021 MIPS payment year, a small practice bonus of 6 measure bonus points in the numerator of the quality performance category for MIPS eligible clinicians in small practices if the MIPS eligible clinician submits data to MIPS on at least 1 quality measure.

(ix) Incentives To Report High-Priority Measures

In the CY 2017 Quality Payment Program final rule, we established a cap on high-priority measure bonus points for the first 2 years of MIPS at 10 percent of the denominator (total possible measure achievement points the MIPS eligible clinician could receive in the quality performance category) of the quality performance category (81 FR 77294). As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policy on incentives to report high-priority measures is now referenced at § 414.1380(b)(1)(v)(A). In the CY 2019 PFS proposed rule, we proposed to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend § 414.1380(b)(1)(v)(A)(1)(ii), accordingly (83 FR 35951).

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: One commenter supported the proposal to maintain the cap on measure bonus points for reporting high-priority measures for the 2019 performance period/2021 MIPS payment year.

Response: We thank the commenter for its support of our proposal.

After consideration of public comments, we are finalizing our proposal to maintain the cap on measure bonus points for reporting high-priority measures for the 2021 MIPS payment year, and to amend § 414.1380(b)(1)(v)(A)(1)(ii), accordingly.

We established the scoring policies for high-priority measure bonus points in the CY 2017 Quality Payment Program final rule (81 FR 77293). We noted that, in addition to the required measures, CMS Web Interface reporters may also report the CAHPS for MIPS survey and receive measure bonus points for submitting that measure (81 FR 77293). We refer readers to § 414.1380(b)(1)(v)(A) for more details on the high-priority measure bonus points scoring policies.

For the 2021 MIPS payment year, we proposed to modify the policies finalized in the CY 2017 Quality Payment Program final rule (and amend § 414.1380(b)(1)(v)(A) accordingly) to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures (83 FR 35951). As we continue to move forward in implementing the MIPS program, we no longer believe that it is appropriate to award CMS Web Interface reporters measure bonus points to be consistent with other policies regarding selection of measures. Based on additional data analyses since the first-year policy was implemented,

we have found that practices that elect to report via CMS Web Interface generally perform better than other practices that select other collection types. Therefore, the benefit of the bonus points is limited and instead we believe will create higher than normal scores. Bonus points were created as transition policies which were not meant to continue through the life of the program. Measure bonus points are also used to encourage the selection of additional high-priority measures. As the program matures, we have established other policies related to measures selection, such as applying a cap of 7 measure achievement points if a clinician selects and submits a measure that has been topped out for 2 or more years; however, we have excluded CMS Web Interface reporters from the topped out policies because reporters have no choice in measures. By the same logic, since CMS Web Interface reporters have no choice in measures, we do not believe it is appropriate to continue to provide additional high-priority measure bonuses for reporting CMS Web Interface measures. We note the CMS Web Interface users may still elect to report the CAHPS for MIPS survey in addition to the CMS Web Interface, and if they do, they would receive the high priority bonus points for reporting the survey.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: A few commenters supported the proposal to discontinue awarding high-priority measure bonus points to CMS Web Interface reporters because it strengthens the incentive to report high-priority measures for those who actively elect to report these measures and reduces the advantage for the large practices that are able to report through CMS Web Interface. One commenter expressed support for the proposal because groups who report via Web Interface perform better than groups who use alternative data collection types, have an increased probability of earning higher quality performance category and overall higher MIPS scores, and can still earn bonus points for reporting CAHPS for MIPS survey measures.

Response: We thank the commenters for their support as we look for ways to improve our scoring policy.

Comment: Several commenters did not support the proposal to remove high-priority bonus points for CMS Web Interface reporters. One commenter stated it would disincentivize clinicians and groups from participating in APMs and stated that ACOs do not have an alternative submission method. Another commenter suggested that the bonus points should continue for non-MIPS APM participants because these submitters voluntarily choose a larger and more difficult and complex set of measures than are required. A few commenters stated that there is not an option to submit additional high-priority measures to earn these bonus points and that this proposal disadvantages ACOs which have demonstrated a high commitment to quality as evidenced by recent MIPS performance feedback reports. One commenter recommended that CMS should not remove all bonus points until it proposes to do the same for the other collection types. A few commenters suggested delaying removal of the bonus points to allow clinicians sufficient notice and until further information and insight is gained about performance in these measures. One commenter stated that the policy penalizes Web Interface reporters for their commitment to measures that truly reflects their practices.

Response: The high priority measure bonus points were intended to encourage the selection of certain measures. As we work towards improving our scoring policy to align with our goals of improving quality of care, we no longer believe we should award bonus points to CMS Web Interface reporters because they do not select individual measures to report, rather the Web Interface is a measurement set. This bonus policy was meant to be temporary, and we believe that as the MIPS program goes into its third year it is an appropriate time to begin to limit the assignment of high priority bonus points. While we recognize the commenters' concerns, the removal of the bonus was not intended to penalize Web Interface reporters and we still have several special policies available for Web Interface reporters. We have excluded CMS Web Interface reporters from the topped out measure cap (82 FR 53576), so although they are no longer able to receive this bonus, they are still able to receive maximum achievement points for all measures, even though some of the CMS Web Interface measures may be considered topped out. Additionally, CMS Web Interface reporters are still able to receive measure bonus points for reporting the CAHPS for MIPS survey and for end-to-end reporting.

We will consider commenters' concerns in future rulemaking.

After consideration of public comments, we are finalizing our proposal, beginning with the 2021 MIPS payment year, to discontinue awarding measure bonus points to CMS Web Interface reporters for reporting high-priority measures and to amend § 414.1380(b)(1)(v)(A) accordingly.

As part of our move towards fully implementing the high value measures as discussed in section III.I.3.h.(2)(b)(iv) of this final rule, we believe that bonus points for high priority measures for all collection types may no longer be needed, and as a result, we intend to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year (83 FR 35951).

We thank commenters for suggestions and may consider them for future rulemaking.

(x) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. Under § 414.1380(b)(1)(xv), 1 bonus point is available for each quality measure submitted with end-to-end electronic reporting, under certain criteria. In order to receive the bonus for end-to-end reporting, eligible clinicians must use the 2015 Edition CEHRT. We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77297) and section III.I.3.h.(2)(b)(i) of this final rule for further discussion on our certification requirements for the end-to-end reporting bonus. As part of our proposed technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established electronic end-to-end reporting bonus point scoring policy is now referenced at § 414.1380(b)(1)(v)(B).

In the CY 2019 PFS proposed rule, we proposed to maintain the cap on measure bonus points for end-to-end electronic reporting for the 2021 MIPS payment year (83 FR 35951). We also proposed to continue to assign bonus points for end-to-end electronic reporting for the 2021 MIPS payment year, as we have seen that this policy encourages electronic reporting. We proposed to amend § 414.1380(b)(1)(v)(B) accordingly.

We requested comments on the proposal above. These comments and our responses are discussed below.

Comment: Several commenters supported maintaining the bonus points for end-to-end electronic reporting for the 2021 MIPS payment year and requested that CMS continue to assign them in future years. One commenter

noted that continuing the bonus points beyond the 2021 MIPS payment year will allow clinicians in smaller practices who are not yet capable of end-to-end electronic reporting an opportunity to do so. Another commenter supported the bonus only if those that are not able to submit using end-to-end electronic reporting have access to CEHRT at no cost to the clinician. One commenter suggested that CMS continue the bonus points until the program is more mature and additional data on performance and reporting is gathered. A few commenters who supported maintaining the bonus points beyond the 2021 MIPS payment year, stated that the removal of the bonus points would result in increased administrative burden to CMS and clinicians, and would adversely affect the ability for clinicians with limited quality measures available to earn bonus points.

Response: While we signaled our intent to discontinue bonus points for end-to-end electronic reporting in the future (83 FR 35951), we are taking into consideration the suggestions we received on additional ways we can incentivize and encourage these reporting methods for future rulemaking.

After consideration of public comments, we are finalizing our proposals to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2021 MIPS payment year and to amend § 414.1380(b)(1)(v)(B) accordingly.

We also proposed to modify our end-to-end reporting bonus point scoring policy based on the changes to the submission terminology discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35951). We proposed that the end-to-end reporting bonus can only apply to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298). However, the end-to-end reporting bonus would not be applied to the claims submission type because it does not meet the criteria discussed above. This is not a policy change but rather a clarification of our current process in light of the proposed terminology changes.

We did not receive any comments on this proposal.

After consideration of public comments, we are finalizing our proposals to modify our end-to-end reporting bonus point scoring policy based on the changes to the submission terminology and only apply the bonus to the subset of data submitted by direct, log in and upload, and CMS Web Interface that meet the criteria finalized in the CY 2017 Quality Payment Program final rule (81 FR 77297 through 77298).

As discussed in section III.I.3.i.(1)(b)(x) of this final rule, we believe that in the future, bonus points for end-to-end reporting for all submission types will no longer be needed as we move towards fully implementing the program, and as a result we intend to consider in future rulemaking modifying our scoring policy to no longer offer end-to-end reporting bonus points after the 2021 MIPS payment year (83 FR 35951). Consistent with the section 1848(q)(5)(B)(ii) of the Act, which requires the Secretary to encourage the use of CEHRT for quality reporting, we will continue to be committed to ways that we can incentivize and encourage these reporting methods. We invited comment on other ways that we can encourage the use of CEHRT for quality reporting.

We thank commenters for suggestions and will consider them for future rulemaking.

(xi) Calculating Total Measure Achievement and Measure Bonus Points

(A) Calculating Total Measure Achievement and Measure Bonus Points for Non-CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77300, and 82 FR 53733 through 53736, respectively), we established the policy for calculating total measure achievement and measure bonus points for Non-CMS Web Interface reporters. We refer readers to § 414.1380(b)(1) for more details on these policies.

We did not propose any changes to the policy for scoring submitted measures collected across multiple collection types; however, we provided a summary of how this policy will be scored using our new terminology (83 FR 35952). We noted that CMS Web Interface and facility-based measurement each have a comprehensive set of measures that meet the proposed MIPS category requirements. As a result, we did not combine CMS Web Interface measures or facility-based measurement with other ways groups can be scored for data submitted for MIPS (other than CAHPS for MIPS, which can be submitted in conjunction with the CMS Web Interface). We refer readers to section III.I.3.i.(1)(d) of this final rule for a description of our policies on facility-based measurement (83 FR 35956 through 35963).

Although we have established a policy to account for scoring in circumstances when the same measure is collected via multiple collection types, we anticipate that this will be a rare circumstance and do not encourage clinicians to submit the same measure collected via multiple collection types. Table 51 is included in this final rule for illustrative purposes and clarity due to the changes in terminology discussed in section III.I.3.h.(1)(b) of this final rule (83 FR 35893 through 35895). For further discussion of this example, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53734).

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TABLE 51: Example Assigning Total Measure Achievement and Bonus Points for an Individual MIPS Eligible Clinician Who Submits Measures Collected Across Multiple Collection Types

	Measure Achievement Points	Six Scored Measures	High-Priority Measure Bonus Points	Incentive for CEHRT Measure Bonus Points
MIPS CQMs				
Measure A (Outcome)	7.1	7.1 (Outcome measure with highest achievement points)	(required outcome measure does not receive bonus points)	
Measure B	6.2 (points not considered because it is lower than the 8.2 points for the same claims measure)			
Measure C (high priority patient safety measure that meets requirements for additional bonus points)	5.1 (points not considered because it is lower than the 6.0 points for the same claims measure)		1	
Claims				
Measure A (Outcome)	4.1 (points not considered because it is lower than the 7.1 points for the same MIPS CQM)		No bonus points because the MIPS CQM of the same measure satisfies requirement for outcome measure.	
Measure B	8.2	8.2		
Measure C (High priority patient safety measure that meets requirements for additional bonus points)	6.0	6.0	No bonus (Bonus applied to the MIPS CQMs)	
Measure D (outcome measure <50% of data submitted)	1.0		(no high priority bonus points because below data completeness)	
EHR (direct submission using end-to-end)				***Reporting that meets CEHRT /bonus point criteria***
Measure E	5.1	5.1		1
Measure F	5.0	5.0		1
Measure G	4.1			1
Measure H	4.2	4.2		1
Measure I (high priority patient safety measure that is below case minimum)	3.0		(no high priority bonus points because below	1

	Measure Achievement Points	Six Scored Measures	High-Priority Measure Bonus Points	Incentive for CEHRT Measure Bonus Points
			case minimum)	
		35.6	1 (below 10% cap[1])	5 (below 10% cap)
Quality Performance Category Percent Score Prior to Improvement Scoring		(35.6 + 1 + 5) / 60 = 69.33%		

[1] In this example, the cap would be 6 points, which is 10 percent of the total available measure achievement points of 60.

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We did not propose any changes to our policy regarding scoring measure achievement points and bonus points when using multiple collection types for non-Web Interface MIPS eligible clinicians in the quality performance category for the 2019 MIPS performance period.

(B) Calculating Total Measure Achievement and Measure Bonus Points for CMS Web Interface Reporters

In the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77302 through 77306, and 82 FR 53736 through 82 FR 53737, respectively), we finalized the scoring policies for CMS Web Interface reporters. As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policies for CMS Web Interface reporters are now referenced at § 414.1380(b)(1)(i)(A)(*2*)(*i*) and (b)(1)(v)(A).

(xii) Future Approaches To Scoring the Quality Performance Category

As we discuss in section III.I.3.h.(2)(b)(iv) of this final rule, we anticipate making changes to the quality performance category to reduce burden and increase the value of the measures we are collecting. We discussed that existing measures have differing levels of value and our approaches for implementing a system where points are awarded based on the value of the measure. Should we adopt these approaches, we anticipate needing to modify our scoring approaches accordingly. In addition, we have received stakeholder feedback requesting that we simplify scoring for the quality performance category. Therefore, we solicited comment on the following approaches to scoring that we may consider in future rulemaking and whether these approaches move the clinicians towards reporting high value measures and more accurate performance measurement (83 FR 35954 through 35955).

One option for simplification is restructuring the quality requirements with a pre-determined denominator, for example, 50 points, but no specific requirements regarding the number of measures that must be submitted. Further, we would categorize MIPS and QCDR measures by value, because we recognize that not all measures are created equal. We seek to ensure that the collection and submission of data is valuable to clinicians and worth the cost and burden of collection of information. A system to classify measures as a particular value (for example, gold, silver, or bronze) is discussed in section III.I.3.h.(2)(b)(iv) of this final rule. In this approach, the highest tier would include measures that are considered ''gold'' standard, such as outcome measures, composite measure, or measures that address agency priorities (such as opioids). The CAHPS for MIPS survey, which collects patient experience data, may also be considered a high-value measure. Measures considered in the second tier, or at a ''silver'' standard, would be process measures that are directly related to outcomes and have a good gap in performance (there is no high, unwavering performance) and demonstrate room for improvement, or topped out outcome measures. Lower value measures, such as standard of care process measures or topped out process measures, would have scoring caps in place that would reflect the measure's status as a ''bronze measure.'' In this scenario, we could envision awarding points for achievement as follows: Up to 15 to 20 points in the top tier; up to 10 points in the next tier; and up to 5 points in the lowest tier. Similar to the structure of the improvement activities performance category, a clinician that chooses a top-tier measure would not have to submit as many measures to MIPS. We would still want to ensure the submission of high value measures and might include requirements that restrict the number of lower tier measures that could be submitted; alternatively, we could add a requirement that a certain number of higher tier measures would need to be submitted. With this approach, we could still incentivize reporting on high-priority measures by classifying them as ''gold'' standard measures which would be eligible for up to 15 to 20 achievement points.

Alternatively, we could keep our current approach for the quality performance category requiring 6 measures including one outcome measure, with every measure worth up to 10 measure achievement points in the denominator but change the minimum number of measure achievement points available to vary by the measure tier. For example, high-tier measures could qualify for high priority bonus and/or have a higher potential floor (for example, 5 measure achievement points instead of the floor of 3 measure achievement points for ''gold'' standard measures, which would be eligible for up to 10 measure achievement points.); whereas low-tier measures could have a lower floor (for example, 1 measure achievement point instead of the floor of 3 measure achievement points for ''bronze standard' measures).

Taking into consideration the potential future quality performance category change, we also believe that removing the validation process to determine whether the eligible clinician has measures that are available and applicable would simplify the quality performance category significantly. Several stakeholders have expressed their confusion with the validation process. A move to sets of measures in the quality performance category, potentially with some criteria to define the clinicians for whom these measures are applicable, would eliminate the need for a validation process for measures that are available and

applicable. Moving to sets of measures would also enable us to develop more robust benchmarks. We also believe that in the next few years, we could remove the validation process for measures that are available and applicable if we set the denominator at a pre-determined level (as outlined in the example above at 50 points) and let clinicians determine the best method to achieve 50 points. For the 2019 and 2020 MIPS payment years, MIPS eligible clinicians and groups who report on QCDR measures that do not have an available benchmark based on the baseline or performance period but meet data completeness are assigned a score of 3 measure achievement points (small practices receive 3 points regardless of whether they meet data completeness). Through stakeholder engagement, particularly feedback provided by QCDRs who have developed their own measures, we have heard that MIPS eligible clinicians are hesitant to report QCDR measures without established benchmarks. Eligible clinicians have voiced concern on reporting on QCDR measures without benchmarks because they are not certain that a benchmark could be calculated and established for the MIPS performance period, and they would therefore be limited to a 3-point score for that QCDR measure. In addition, QCDRs have inquired about the possibility of creating QCDR benchmarks. To encourage reporting of QCDR measures, we sought comment on an approach to develop QCDR measure benchmarks based off historical measure data. This may require QDCRs to submit historical data in a form and manner that meets benchmarking needs as required by CMS. We anticipate that the historical QCDR measure data would need to be submitted at the time of self-nomination of the QCDR measure, during the self-nomination period. Detailed discussion of the self-nomination period timeline and requirements can be found in section III.I.3.k of this final rule. Our concern with utilizing historical data provided by QCDRs to develop benchmarks is whether QCDRs have the capability to filter through their historical measure data to extract only data from MIPS eligible clinicians and groups prior to submitting the historical data to CMS for QCDR measure benchmarking consideration. Furthermore, once the historical data is submitted by the QCDR, CMS would analyze the data to ensure that it met benchmarking standards prior to it being accepted to form a benchmark. However, to perform this analysis CMS may need additional data elements such as the sources of the data, data completeness, and the collection period. In addition to seeking comment on developing QCDR measure benchmarks from historical data, we also solicited comment as to how our aforementioned concerns may be addressed in future rulemaking.

We also recognize that improving the electronic capture, calculation, and reporting of quality measures is also an important component of reducing provider burden. We invited comment on how we can incorporate incentives for the use of electronic clinical quality measurement into the future approaches described under this section, as well as other ways to encourage more efficient technology-enabled measurement approaches.

We solicited comment on these approaches and other approaches to simplify scoring, provide incentives to submit more impactful measures that assess outcomes rather than processes, and develop data that can show differences in performance and determine clinicians that provide high value care (83 FR 35954 through 35955).

We thank commenters for suggestions and will consider them for future rulemaking.

(xiii) Improvement Scoring for the MIPS Quality Performance Category Percent Score

Section 1848(q)(5)(D)(i) of the Act stipulates that, beginning with the second year to which the MIPS applies, if data sufficient to measure improvement is available, the improvement of the quality performance category score for eligible clinicians should be measured. To measure improvement, we require a direct comparison of data from one Quality Payment Program year to another (82 FR 52740). For more descriptions of our current policies, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53737 to 53747). As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established improvement scoring policies are now referenced at § 414.1380(b)(1)(vi).

In the CY 2018 Quality Payment Program final rule, we adopted a policy that MIPS eligible clinicians must fully participate to receive a quality performance category improvement percent score greater than zero (82 FR 53743 through 53745). In § 414.1380(b)(1)(vi)(F), we determined ''participation'' to mean compliance with § 414.1330 and § 414.1340 in the current performance period. We issued a technical correction for the CY 2018 Quality Payment Year final rule, replacing § 414.1330 with § 414.1335 since § 414.1335 is more specific because it discusses the quality performance category requirements.

We finalized at § 414.1380(b)(1)(vi)(C)(4) that we would compare the 2018 performance to an assumed 2017 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year (82 FR 53744 through 53745). In the CY 2019 PFS proposed rule, we proposed to continue this policy for the 2019 MIPS performance period and amend § 414.1380(b)(1)(vi)(C)(4), accordingly (83 FR 35955). We proposed to compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent.

The following is a summary of the public comments on the proposal and our responses:

Comment: One commenter supported the proposal.

Response: We thank the commenter for its support.

After consideration of public comments, we are finalizing the proposal to continue our previously established policy for the 2019 MIPS performance period and amend § 414.1380(b)(1)(vi)(C)(4), accordingly. Specifically, we will compare the 2019 performance to an assumed 2018 quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(xiv) Calculating the Quality Performance Category Percent Score Including Achievement and Improvement Points

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77300 and 82 FR 53747 through 53748, respectively), we finalized the policies on incorporating the improvement percent score into the quality performance category percent score. As part of our technical updates to § 414.1380(b)(1) discussed in section III.I.3.i.(1)(b) of this final rule, our previously established policies are now referenced at § 414.1380(b)(1)(vii).

(c) Scoring the Cost Performance Category

(i) Scoring Achievement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring achievement in the cost performance

category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311) and the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53749). In the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77309), we established that we will determine cost measure benchmarks based on cost measure performance during the performance period. We also established that at least 20 MIPS eligible clinicians or groups must meet the minimum case volume that we specify for a cost measure in order for a benchmark to be determined for the measure, and that if a benchmark is not determined for a cost measure, the measure will not be scored. We proposed to codify these final policies at § 414.1380(b)(2)(i) (83 FR 35955 through 35956).

While we did not receive any public comments for this proposal, we are finalizing our proposal to codify these final policies at § 414.1380(b)(2)(i).

(ii) Scoring Improvement in the Cost Performance Category

For a description of the statutory basis and our existing policies for scoring improvement in the cost performance category, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53749 through 53752). Section 51003(a)(1)(B) of the Bipartisan Budget Act of 2018 modified section 1848(q)(5)(D) of the Act such that the cost performance category score shall not take into account the improvement of the MIPS eligible clinician for each of the second, third, fourth, and fifth years for which the MIPS applies to payments. We do not believe this change requires us to remove our existing methodology for scoring improvement in the cost performance category (see 82 FR 53749 through 53752), but it does prohibit us from including an improvement component in the cost performance category percent score for each of the 2020 through 2023 MIPS payment years. Therefore, we proposed to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points (83 FR 35955). Under our existing policy (82 FR 53751 through 53752), the maximum cost improvement score for the 2020 MIPS payment year is 1 percentage point, but due to the statutory changes and under our proposal, the maximum cost improvement score for the 2020 MIPS payment year would be zero percentage points. We also proposed at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year (83 FR 35956). The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters supported the proposals to set the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years at zero percentage points.

Response: We thank the commenter for their support.

Comment: Several commenters requested that the cost performance category score be determined in a different manner because of the proposed inclusion of episode-based measures. A few commenters recommended that the new measures have a lower weight in determining the cost performance category score than the previously-established MSPB and total per capita cost measures. A few commenters recommend that similar to the quality performance category, only the 6 measures with the highest scores among those for which the clinician or group met the case minimum should be included in calculating the cost performance category score. Likewise, a few commenters recommended that similar to the quality performance category, scores for cost measures should not be below 3 out of 10 points. One commenter recommended that a cost performance category score not be calculated if a clinician or group only meets the case minimum for a single cost measure.

Response: We do not believe that the inclusion of new measures in the cost performance category necessitates a change in the determination of the cost performance category score. Measures in the cost performance category differ from quality measures because they do not require reporting on the part of the clinicians outside of the usual claims submission process. Therefore, there is no choice of measures for clinicians nor burden of reporting. We believe that this is an important consideration in maintaining a simpler scoring mechanism in the cost performance category and scoring all measures for which an individual or group meets the case minimum. Some groups due to their size and comprehensiveness will meet the case minimum for all cost measures. Other individuals and groups will meet the case minimum for fewer measures. A scoring policy that would only score the top 6 measures in the cost performance category would provide an advantage for those groups with more than 6 measures because it would disregard those measures on which performance was poorest. For example, a group that met the case minimum for 10 measures and scored in the lowest decile for the total per capita cost score and the highest decile for all other measures, would have the score for the total per capita measure dropped and would receive the highest possible score in the cost performance category. A group that met the case minimum for only 6 measures, and also performed in the lowest decile for the total per capita cost score and the highest decile for the other 5 cost measures for which it met the case minimum, would not have performance on this measure disregarded and receive a lower score.

We believe that not scoring clinicians and groups that meet the case minimum for only a single measure would fail to recognize that a single measure, such as total per capita cost, could reflect care provided to a large number of patients.

After consideration of the public comments, we are finalizing as proposed our proposal to revise § 414.1380(b)(2)(iv)(E) to provide that the maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points. We are also finalizing as proposed our proposal at § 414.1380(a)(1)(ii) to modify the performance standards to reflect that the cost performance category percent score will not take into account improvement until the 2024 MIPS payment year.

(d) Facility-Based Measures Scoring Option for the 2021 MIPS Payment Year for the Quality and Cost Performance Categories

(i) Background

In the CY 2018 Quality Payment Program final rule, we established a facility-based measurement scoring option for clinicians that meet certain criteria beginning with the 2019 MIPS performance period/2021 MIPS payment year (82 FR 53752 through 53767). We originally proposed a facility-based measurement scoring option for the 2018 MIPS performance period. We did not finalize the policy because we were concerned that we would not have the operational ability to inform clinicians early enough in the 2018 MIPS performance period to allow them to consider the consequences and benefits of participation (82 FR 53755).

(ii) Facility-Based Measurement Applicability

(A) General

In the CY 2018 Quality Payment Program final rule, we limited facility-based reporting to the inpatient hospital in the first year for several reasons,

including because a more diverse group of clinicians (and specialty types) provide services in an inpatient setting than in other settings, and because the Hospital Value-Based Purchasing (VBP) Program adjusts payment to hospitals for inpatient services in connection with their performance under that program (82 FR 53753 through 53755). We also limited measures applicable for facility-based measurement to those used in the Hospital VBP Program because the Hospital VBP Program compares hospital performance on a series of different measures intended to capture the breadth of inpatient care in the facility (82 FR 53753). We noted that we were open to the consideration of additional facility types in the future but recognized that adding a facility type would be dependent upon whether CMS has established a value-based purchasing program for that facility type, the applicability of measures, and our ability to appropriately attribute a clinician to a facility (82 FR 53754). Please note that when we use the term value-based purchasing, we are referring in general to value-based purchasing programs or scores, and not specifically the Hospital VBP Program, unless specifically stated.

We did not propose to add additional facility types for facility-based measurement, but we are interested in potentially expanding to other settings in future rulemaking. Therefore, in section III.I.3.i.(1)(d)(vii) of this final rule, we outline several issues on which we requested feedback and would need to be resolved in order to expand this option to a wider group of facility-based clinicians in future years.

(B) Facility-Based Measurement by Individual Clinicians

In the CY 2018 Quality Payment Program final rule, we established individual eligibility criteria for facility-based measurement at § 414.1380(e)(2)(i). We established that a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital or emergency room based on claims for a period prior to the performance period as specified by CMS (82 FR 53756 through 53757) is eligible as an individual for facility-based measurement. We had noted, as a part of our proposal summary, that we would use the definition of professional services in section 1848(k)(3)(A) of the Act in applying this standard (82 FR 53756). For purposes of determining eligibility for facility-based measurement, we discussed CMS using data from the period between September 1 of the calendar year, 2 years preceding the MIPS performance period, through August 31 of the calendar year preceding the MIPS performance period, with a 30-day claims run out but did not finalize that as part of the applicable regulation (82 FR 53756 through 53757). Because we are using the quality measures associated with the inpatient hospital to determine the MIPS quality and cost performance category score, we wanted to ensure that eligible clinicians contributed to care in that setting during that time period.

We indicated that CMS will use POS code 21 (inpatient) and POS code 23 (emergency department) for this purpose (82 FR 53756). Commenters on our proposal (as summarized in the CY 2018 Quality Payment Program final rule (82 FR 53756 through 53757)) expressed concern that adopting the definition that we did for facility-based clinicians would limit the number of clinicians who would be eligible.

In the CY 2019 PFS proposed rule, we proposed to modify our determination of a facility-based individual at § 414.1380(e)(2)(i) in four ways (83 FR 35957). First, we proposed to add on-campus outpatient hospital (as identified in the POS code in the HIPAA standard transaction, that is, POS code 22) to the settings that determine whether a clinician is facility-based. Second, we proposed that a clinician must have at least a single service billed with the POS code used for the inpatient hospital or emergency room. Third, we proposed that, if we are unable to identify a facility with a value-based purchasing score to attribute as a clinician's performance, that clinician is not eligible for facility-based measurement. Fourth, we proposed to align the time period for determining eligibility for facility-based measurement with changes to the dates used to determine MIPS eligibility and special status detailed in section III.I.3.b. of this final rule. We explain these four proposals from the proposed rule in this section. In the CY 2019 PFS proposed rule, we stated our belief that these proposals will further expand the opportunity for facility-based measurement and eliminate issues associated with the provision of observation services while still restricting eligibility to those who work in an inpatient setting.

First, we proposed to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement (83 FR 35957). We agree with commenters that limiting the eligibility to our current definition may prevent some clinicians who are largely hospital-based from being eligible. However, expanding eligibility without taking into account the relationship between the clinician and the facility and facility's performance could result in unfairly attributing to a clinician performance for which the clinician is not responsible or has little to no role in improving. We do believe that a significant provision of services in the on-campus outpatient hospital are reflected in the quality captured by the Hospital VBP Program. For example, patients in observation status are typically treated by the same staff and clinicians as those who meet the requirements for inpatient status. Although there are some clinical differences that may result in a patient having observation status, we believe that the quality of care provided to these patients in this same setting would be comparable, reflecting the overall healthcare system at that particular location. In the CY 2019 PFS proposed rule, we stated our conviction, based on this that a sufficient nexus exists for attributing the hospital's VBP Total Performance Score to clinicians that provide services in on-campus outpatient hospital settings.

Second, we proposed to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement (83 FR 35957). Although we generally believe that clinicians who provide services in the outpatient hospital can affect the quality of care for inpatients, we noted in the CY 2019 PFS proposed rule our belief that a clinician who is measured according to the performance of a hospital should at least have a minimal presence in the inpatient or emergency room setting. We explained our concern about attributing inpatient facility performance to clinicians who provide at least 75 percent of their services at on-campus outpatient hospitals (with POS code 22) when such clinicians exclusively provide outpatient services that are unrelated to inpatient hospital service by describing an example: A dermatologist who provides office-based services in a hospital-owned clinic but who never admits or treats patients within the inpatient or emergency room setting does not meaningfully contribute to the quality of care for patients measured under the Hospital VBP Program.

We stated in the CY 2019 PFS proposed rule how we had considered different ways to best identify those who contribute to the quality of care in the inpatient setting while keeping the

facility-based scoring option as simple as possible. We provided one explanation of an alternative we had considered: Separately measuring the HCPCS codes for observation services; however, as also noted in the proposed rule, we believe that such a measurement may not fairly consider services provided by clinicians for whom observations services may be embedded in a global code for a procedure rather than billed as a separate observation service. We also considered requiring a clinician to provide a certain percentage of services with the inpatient hospital POS. We described how we had not identified a threshold (other the one claim threshold we proposed) that would more meaningfully differentiate clinicians who provide services with the outpatient hospital POS code versus those who do not contribute to the services that would be measured under the Hospital VBP Program. We identified our goal of ensuring that the program rules are clear and easily applied to clinicians, so as to both avoid confusion on program participation requirements and to meet overall agency goals to increase transparency in the agency's activities. Our proposal of using a single service as the threshold would provide a simple, bright-line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services as well as outpatient services. We explained in the proposed rule that this would limit the chance of clinicians who exclusively practice in the outpatient setting being measured on the Hospital VBP Program's performance of an unrelated hospital. We recognized this requirement of one service with the inpatient or emergency department POS may not demonstrate a significant presence in a particular facility and solicited comment on whether a better threshold could be used to identify those who are contributing to the quality of care for patients in the inpatient setting without creating unnecessary or inappropriate barriers to eligibility for facility-based measurement.

We explained in the proposed rule our rationale and reasoning for these first two proposals as being based in large part on our analysis of the previously finalized policy for eligibility for the facility-based measurement scoring option. Using claims data, we had identified all clinicians that would be MIPS eligible as either an individual or group, and identified the POS codes submitted for PFS services provided by those clinicians. We then modeled the existing final policy based on inpatient and ER services. Although almost all ER physicians would be scored under facility-based measurement, a relatively small percentage of clinicians in other specialties, even those which we expected to have significant presence in the hospital, would be eligible for the facility-based measurement scoring option. For example, only 13.45 percent of anesthesiologists would be eligible for the facility-based measurement scoring option under the policy finalized in the CY 2018 Quality Payment Program final rule. Adding the on-campus outpatient hospital POS code substantially increased eligibility for the facility-based measurement scoring option in our modeling, even after we adjusted for requiring one service with the inpatient or emergency department POS. Under our proposal, our model illustrated that 72.55 percent of anesthesiologists would be eligible. However, the model did not show that the proposal would substantially increase the number of clinicians eligible for the facility-based measurement scoring option who, based on specialty identification, may not have a significant presence in the hospital. For example, the modeling of the proposed policy projected an increase in the percentage of family physicians eligible for the facility-based measurement scoring option from 11.34 percent to 13.86 percent, which is still a very small percentage of those clinicians.

Third, we proposed to add a new criterion (to be codified at § 414.1380(e)(2)(i)(C)) that stated to be eligible for facility-based measurement, we must be able to attribute a clinician to a particular facility that has a value-based purchasing score (83 FR 35957 through 35958). We explained in the proposed rule how, for facility-based measurement to be applicable, we must be able to attribute a clinician to a facility with a value-based purchasing score. Based on our definition of facility-based measurement, we stated that this means a clinician must be associated with a hospital with a Hospital VBP Program Total Performance Score. We explained our concern that the proposed expansion of eligibility for facility-based measurement would increase the number of clinicians eligible for facility-based measurement but to whom we would be unable to attribute the performance of a particular facility that has a value-based purchasing score. As we noted in the CY 2018 Quality Payment Program final rule (82 FR 53766), some hospitals do not have a Hospital VBP Program Total Performance Score that could be used to determine a MIPS quality and cost performance category score, such as hospitals in the state of Maryland. Hence, clinicians associated with those hospitals would not be able to use facility-based measurement but could report quality measures through another method and have cost measures calculated if applicable. We explained that, under our proposal, a similar result, although relatively rare, would happen if we could not attribute a clinician identified as facility-based to a specific facility; those clinicians who are identified as facility-based but whom we cannot attribute to a hospital would have to participate in MIPS quality reporting through another method, or they would receive a score of zero in the quality performance category. Therefore, we proposed to add the requirement to § 414.1380(e)(2)(i)(C) that a clinician must be able to be attributed to a particular facility with a value-based purchasing score under the methodology specified in § 414.1380(e)(5) to be eligible for facility-based measurement. The cross-reference to paragraph (e)(5) is to the methodology we also proposed for determining the applicable facility score to be used. Our proposed new regulatory text at § 414.1380(e)(2)(i)(C) addresses both attribution to a facility and the need for that facility to have a value-based purchasing score by conditioning eligibility for facility-based scoring for an individual clinician on the clinician being attributed under the methodology in paragraph (e)(5) to a facility with a value-based purchasing score.

Fourth, we proposed to change the dates of determining eligibility for facility-based measurement (83 FR 35958). In section III.M.3.b. of the proposed rule, we proposed to modify the dates of the MIPS determination period that would provide eligibility determination for small practice size, non-patient facing, low-volume threshold, ASC, hospital-based, and facility-based determination periods. To align this regulation controlling facility-based scoring with these other determination periods, we proposed that CMS would use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, with a 30-day claims run out, in determining eligibility for facility-based measurement.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters supported the four proposed changes to the determination of a facility-based individual.

Response: We appreciate the commenters' support.

Comment: One commenter recommended that CMS include the place of service code used for the off-campus outpatient hospital (POS code 19) in determining individual eligibility for facility-based measurement, noting that many clinicians work in both on-campus and off-campus outpatient hospital settings. The commenter further suggested the inclusion of the measures from the Hospital Outpatient Quality Reporting Program.

Response: While we are finalizing our proposal to add on the on-campus outpatient code (POS code 22), we disagree that the off-campus outpatient hospital setting (POS code 19) indicates that a clinician has a significant impact on the quality and cost within an inpatient hospital setting in the way that POS code 22 might. A clinician may work at an off-campus outpatient hospital setting that is miles from the hospital and not have any involvement with patients that are hospitalized. We do not believe the Hospital VBP Program measures, which reflect the quality of care furnished to patients in hospitals in inpatient settings, are applicable to (or relate to the performance of) those clinicians who primarily bill within the off-campus outpatient hospital setting; therefore, we do not believe such clinicians should be eligible for facility-based measurement.

While the measures used in the Hospital Outpatient Quality Reporting Program do reflect quality for the off-campus outpatient hospital, section 1848(q)(2)(C)(ii) of the Act provides that we may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. Our determination of facility-based measurement does not consider the specialty of clinicians, so we therefore do not believe it is appropriate or consistent with the statutory authority to add this setting or these measures at this time.

Comment: One commenter recommended that the threshold of services required to be provided in facilities to be eligible for facility-based measurement be reduced from 75 percent to more than 50 percent of services, because clinicians often work in multiple settings.

Response: As we stated in the CY 2018 Quality Payment Program final rule (82 FR 53757), we believe the 75 percent threshold is appropriate to use because it is similar to our determination of hospital-based eligible clinicians in the Promoting Interoperability performance category. In the context of our proposal to change the eligibility criteria for facility-based measurement, we still believe that a 75 percent threshold indicates that a clinician is spending much of their clinical time working in a hospital and the quality of their work is reflected in that setting. Clinicians who work in more varied settings may be better measured through another method of participating in MIPS.

Comment: One commenter recommended that CMS not include the requirement to bill at least a single service with the POS code used for the inpatient hospital or emergency room as this requirement could easily be gamed.

Response: We continue to believe that that using a single service as the threshold provides a simple, bright line to differentiate those who never provide inpatient services from clinicians that do provide inpatient services, as well as outpatient services. We will monitor this requirement and may consider changing it in future rulemaking if we find evidence or examples of gaming, such as that clinicians are providing services in the inpatient setting primarily so they may meet the requirements of facility-based measurement.

Comment: Several commenters supported the facility-based measurement and the proposed policies because this option would reduce burden and recognize the joint accountability for measures in the hospital environment.

Response: We appreciate the commenters' support as we begin to implement facility-based measurement in the 2019 MIPS performance period/2021 MIPS payment year.

Comment: Several commenters requested that CMS provide more data analysis on the implementation of facility-based measurement. A few commenters noted concerns with how the facility-based scoring option could contribute to an uneven playing field. Commenters' concerns highlighted that automatically applying a quality and cost score eliminates incentives to coordinate care which may place these clinicians at an unfair advantage over those who must report on measures and take steps to perform well on those measures. Hence, commenters encouraged CMS to closely monitor the impact of the facility-based scoring option policy. One commenter suggested that CMS provide more data on how MIPS eligible clinicians might score in the facility-based scoring option. Another commenter suggested that CMS provide data on the percentage of certain specialists who would be eligible. A few commenters suggested that CMS should closely monitor how facility-based measurement impacts total MIPS scores between specialties and groups working within the same hospital, as well as the effect of facility-based measurement on those who are not eligible. One commenter suggested that CMS provide more information via educational resources; another commenter requested that CMS explain how the Hospital VBP Program Total Performance Score is converted into MIPS scoring and requirements for group reporting options.

Response: We recognize the value of data analysis when developing additional scoring options for MIPS eligible clinicians. We continue to believe that the facility-based scoring option will reduce administrative burden by streamlining reporting and allowing clinicians to focus on quality improvement. We disagree that clinicians have an advantage under facility-based scoring option given that we have established an eligibility threshold to identify those clinicians that have a significant impact on the care delivered within the facility and the facility's performance under the Hospital VBP Program. The scoring methodology developed for facility-based measurement translates scores in the Hospital VBP Program to scores in the Quality and Cost performance category. Because that translation takes into account the distribution of scores in the Hospital VBP program, which is analogous to the distribution of scores in MIPS, clinicians who are scored using facility-based measurement will have a similar range of scores as those who are not eligible for facility-based measurement. We will continue to monitor the impact of the finalized facility-based scoring policies in efforts to avoid unfair advantages within the MIPS program.

Comment: Several commenters expressed concern about the availability of facility-based measurement beginning in the 2019 MIPS performance period/2021 MIPS payment year. The commenters expressed concern that the measures included in the Hospital VBP Program were not representative of the care provided by clinicians and would distract from efforts to focus on measures on which these clinicians could have an effect. A few commenters

supported facility-based measurement as a short-term solution to reducing administrative burden for clinicians who primarily work within an inpatient setting but encouraged movement towards measures that are more meaningful for certain specialists who also predominantly work within an inpatient setting.

Response: We recognize that the Hospital VBP Program was not designed to measure clinicians' performance but rather hospitals' performance. However, we believe that by using the established 75 percent threshold to identify clinicians as eligible for facility-based scoring, we are distinguishing between those clinicians who ultimately have a significant impact on the hospital's performance score for the care and cost rendered within that facility versus those who do not. We therefore believe that the Hospital VBP Program measures do reflect the performance of the clinicians in a team-based environment. We note that there may be more opportunities for clinicians, particularly specialists who wish to report on more clinically meaningful measures, to participate in MIPS using qualified registries or QCDRs that may be related to care provided to those specific patients in a facility setting, and we encourage clinicians who find the MIPS measures more meaningful in the context of their patient population to report in that manner.

After consideration of the public comments, we are finalizing our proposals to add the on-campus outpatient hospital (POS code 22) to the list of sites of service used to determine eligibility for facility-based measurement and to require that clinicians bill at least a single service with the POS codes for inpatient hospital or the emergency room in order to be eligible for facility-based measurement as reflected in the regulation text at § 414.1380(e)(2)(i)(A) and (B). We are also finalizing our proposal that we must be able to attribute a clinician to a particular facility that has a value-based purchasing score under the methodology specified in § 414.1380(e)(5) to meet eligibility for facility-based measurement as codified at § 414.1380(e)(2)(i)(C). We are also finalizing our proposed policy that CMS would use data from the initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, with a 30-day claims run out to determine eligibility for facility-based measurement.

(C) Facility-Based Measurement by Group

In the CY 2018 Quality Payment Program final rule (82 FR 53757), we finalized at § 414.1380(e)(2)(ii) that a MIPS eligible clinician is eligible for facility-based measurement under MIPS if they are determined to be facility-based as part of a group. We established at § 414.1380(e)(2)(ii) that a facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements at § 414.1380(e)(2)(i) (82 FR 53758). We did not propose any changes to the determination of a facility-based group but acknowledged that our proposal to change how individual clinicians are determined to be eligible for facility-based measurement will necessarily have a practical impact for practice groups. For more of the statutory background and descriptions of our current policies on determining a facility-based group, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53757 through 53758).

(iii) Facility Attribution for Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53759), we finalized at § 414.1380(e)(5) a method to identify the hospital whose scores would be associated with a MIPS eligible clinician or group for purposes of facility-based measurement scoring. However, because of a discrepancy in the preamble and the proposed regulation text in the CY 2018 Quality Payment Program proposed rule (82 FR 53759), we indicated we would address this issue as part of the next Quality Payment Program rulemaking cycle. Under the current regulation text § 414.1380(e)(5), a facility-based clinician or group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the clinician or group provided services to the most Medicare beneficiaries during the year claims are drawn (that is, the 12-month period described in paragraph (e)(2)). Although we did not propose any changes, we are revising this section to replace the word ''segment'' with ''period'' for clarity purposes.

If an equal number of Medicare beneficiaries are treated at more than one facility, then we will use the value-based purchasing score for the highest-scoring facility (82 FR 53759 through 53760). For more of the statutory background and descriptions of our current policies for attributing a facility to a MIPS eligible clinician, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53759 through 53760).

In considering the issue of facility attribution for a facility-based group, we stated in the CY 2019 PFS proposed rule that we believe that a change to facility-based attribution is appropriate to better align the policy with the determination of a facility-based group at § 414.1380(e)(2)(ii). A facility-based group is one in which 75 percent or more of the eligible clinician NPIs billing under the group's TIN are eligible for facility-based measurement as individuals. Additionally, under the current regulation, the value-based purchasing score for the highest scoring facility would be used in the case of a tie among the number of facilities at which the group provided services to Medicare beneficiaries. We proposed to revise § 414.1380(e)(5) to differentiate how a facility-based clinician or group receives a score based on whether they participate as a clinician or a group (83 FR 35958).

We proposed to remove ''or group'' from § 414.1380(e)(5) and redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians (83 FR 35958). Under our proposal, newly redesignated paragraph (e)(5)(i) would retain the rule for facility attribution for an individual MIPS eligible clinician as finalized in the CY 2018 Quality Payment Program final rule; we also proposed a few minor edits to the paragraph for grammar and to improve the sentence flow. We also proposed to add a new paragraph (e)(5)(ii) to provide that a facility-based group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in § 414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as individuals (83 FR 35958). We made this proposal because of our wish to emphasize the connection between an individual clinician and a facility. We explained in the CY 2019 PFS proposed rule that using the plurality of clinicians reinforces the connection between an individual clinician and facility and is more easily understandable for larger groups.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters suggested that CMS consider additional rules or standards for attribution of a

clinician or group to a facility for purposes of using that facility's Total Performance Score. One commenter requested that CMS consider using an eligible clinician's/group's second most utilized facility in cases where the top utilized facility does not have a Hospital VBP Program Total Performance Score. Another commenter encouraged CMS develop a group level attribution methodology to account for groups that practice in multiple sites and the commenter believed that an accountability model will be more meaningful and actionable for these groups.

Response: We are finalizing our proposal that if we are unable to identify a particular facility with a value-based purchasing score under the methodology specified in § 414.1380(e)(5), such as those facilities in the state of Maryland, to attribute for use as an individual clinician's performance, then that clinician is not eligible for facility-based measurement. We are concerned that using a hospital other than the most utilized could result in assigning a score based on a hospital at which the clinician rarely works. For example, in the case of using the second most utilized facility, an individual clinician may have primarily worked in the facility without a Hospital VBP Program Total Performance Score and then only have seen a single patient at the second most utilized hospital with a Hospital VBP Total Performance Score. However, we will consider looking into this issue in future rulemaking, including whether it may be appropriate to allow for the score to be based upon a facility other than the one at which a clinician provides services to the most patients.

We understand that some groups that may be facility-based include clinicians that practice in a number of different facilities. However, we believe this issue is similar to that experienced in other clinician groups that may have a diversity of clinicians and settings. In section III.I.3.e of the proposed rule (83 FR 35891), we requested comments on developing an opportunity for clinicians to participate in MIPS as subgroups. We believe that our consideration of that issue could inform the determination of members of a group that practice in a single TIN but who serve patients in many different facilities.

After consideration of the public comments, we are finalizing our proposals to remove ''or group'' from § 414.1380(e)(5); redesignate that paragraph as (e)(5)(i) so that it only applies to individual MIPS eligible clinicians; and add a new paragraph (e)(5)(ii) to § 414.1380(e)(5) regarding group scoring methodologies in which a facility-based group receives a score under the facility-based measurement scoring standard derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under the methodology described in § 414.1380(e)(5)(i) if the clinicians had been scored under facility-based measurement as individuals.

(iv) No Election of Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule (82 FR 53760), we did not finalize our proposal for how individual MIPS eligible clinicians or groups who wish to have their quality and cost performance category scores determined based on a facility's performance would elect to do so through an attestation. We did finalize, and reflect in the introductory text at § 414.1380(e), that an individual clinician or group would elect to use a facility-based score. In the CY 2019 PFS proposed rule (82 FR 53760), we specified that such clinicians or groups would be required to submit their election during the data submission period through the attestation submission mechanism established for the improvement activities and the Promoting Interoperability performance categories. An alternative approach, which likewise was not finalized, did not require an election process, but instead would have automatically applied a facility-based measurement to MIPS eligible clinicians and groups who met the eligibility criteria for facility-based measurement, if such an application were technically feasible (82 FR 53760). We noted in the CY 2018 Quality Payment Program final rule (82 FR 53760) that we would examine both the attestation process and the opt-out process, and work with stakeholders to identify a new proposal in future rulemaking. We explained in the CY2018 Quality Payment Program final rule (82 FR 53760) our interest in a process that would impose less burden on clinicians than an attestation requirement and requested comment on automatically assigning a clinician or group a facility-based score, but with a notice and opportunity to opt-out of facility-based measurement. We summarized those comments in the CY 2019 PFS proposed rule (83 FR 35958).

After further considering the advantages and disadvantages of an opt-in or an opt-out process, we proposed a modified policy that would not require an election process. We proposed to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score (83 FR 35959). Under our proposal, if the MIPS eligible clinician or group is eligible for facility-based measurement, we would calculate a combined quality and cost performance category score. We proposed to use the facility-based score to determine the MIPS quality and cost performance category scores, unless we received another submission of quality data for or on behalf of that clinician or group and the combined quality and cost performance category score for the other submission results in a higher combined quality and cost performance score. If the other submission has a higher combined quality and cost performance score, then we would not apply the facility-based performance scores for either the quality or cost performance categories (83 FR 35959). Under our proposal, the combined score for the quality and cost performance categories would determine the scores to be used for both the quality and cost performance categories, for both individual clinicians and for groups that meet the requirements of paragraph (e)(2). We did not propose to adopt a formal opt-out process because, under our proposal, the higher of the combined quality and cost performance scores for the clinician or clinician group would be used, which would only benefit the clinician or group. We explained in the proposed rule our strong commitment to reducing burden as part of the Quality Payment Program and that we believe that requiring a clinician or group to elect a measurement process (or to opt-out of a measurement process) based on facility performance would add unnecessary burden.

In MIPS, we score clinicians as individuals unless they submit data as a group. We stated in the proposed rule that the same policy should apply to facility-based measurement, even though there are no submission requirements for the quality performance category for individuals under facility-based measurement. We proposed to revise § 414.1380(e)(4) to state that there are no submission requirements for individual clinicians in facility-based measurement, but a group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be measured as a group under facility-based measurement. We explained how, if a group does not

submit improvement activities or Promoting Interoperability measures, we would apply facility-based measurement to the individual clinicians and such clinicians would not be scored as a group under our proposal. In the case of virtual groups, MIPS eligible clinicians will have formed virtual groups prior to the MIPS performance period; as a result, virtual groups eligible for facility-based measurement will always be measured as a virtual group (83 FR 35959). Although we can calculate a score for a TIN without the submission of data by the TIN, we would not be certain if the clinicians in that group actually wanted to be measured as a group without an active submission (in other words, if the group did not submit data as a group). As we explained in the proposed rule, we view submission of data on the improvement activities or Promoting Interoperability measures as an indication by the clinicians in that group that they want to be scored as a group; using the choice to submit data as a group to identify a group in the context of facility-based scoring would preserve and respect choices made by clinicians and groups while avoiding the burden of an election process to be scored as a group solely for the purpose of facility-based scoring. We solicited comment specifically on this proposal and other means to achieve the same ends.

In the CY 2018 Quality Payment Program final rule, we established that if a clinician or group elects facility-based measurement but also submits MIPS quality data, then the clinician or group would be measured on the method that results in the higher quality score (82 FR 53767). We proposed to adopt this same scoring principle in conjunction with our proposal not to use (or require) an election process. Therefore, we proposed at § 414.1380(e)(6)(vi) that the MIPS quality and cost score for clinicians and groups eligible for facility-based measurement would be based on the facility-based measurement scoring methodology described in § 414.1380(e)(6) unless the clinician or group receives a higher combined score for the MIPS quality and cost performance categories through data submitted to CMS for MIPS (83 FR 35959). We stated in the proposed rule that this policy is not applicable to any MIPS eligible clinicians scored under the APM scoring standard described at § 414.1370; we further clarify here that this includes Shared Savings Program participant TINs in ACOs that have failed to complete web interface reporting, unless these measures are specifically required under the terms of the applicable APM.

We also proposed conforming changes in two other sections of regulatory text. We proposed to revise the introductory text at § 414.1380(e) to remove ''elect to,'' and therefore, reflect that clinicians and groups who are determined to be facility-based will receive MIPS quality and cost performance categories under the methodology in paragraph (e) (83 FR 35959 through 35960). Because of our proposal to not require clinicians to opt-in into facility-based measurement, we acknowledged that there may be clinicians that will continue to submit data via other methods. We explained that these clinicians and groups are not prohibited from submitting quality measures to CMS for purposes of MIPS. However, under our proposal, if a higher combined quality and cost score is achieved using data submitted to CMS for purposes of MIPS, then we will use the MIPS scores based on the submission. We also proposed to revise § 414.1380(e)(4) and (e)(6)(v)(A) to reflect that facility-based measurement does not require election and to replace the phrase ''clinicians that elect facility-based measurement'' with ''clinicians and groups scored under facility-based measurement'' (83 FR 35960) as part of this policy.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Many commenters supported our proposal to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score.

Response: We thank the commenters for their support.

Comment: A few commenters opposed our proposal to require a group to submit information in the improvement activities or Promoting Interoperability performance categories to be measured as a facility-based group. A few of these commenters requested that rather than requiring the submission of information in these categories, CMS offer an election process. One commenter questioned how a group that was excluded from both the improvement activities and Promoting Interoperability performance categories could participate as a facility-based group. One commenter suggested that it would be difficult to complete an improvement activity if members of the group practice at more than one facility.

Response: We continue to believe that our proposal of a clinician receiving the higher of the quality and cost performance score available would only benefit the individual MIPS eligible clinician or group. If we do not require groups to submit data in the improvement activity or Promoting Interoperability performance categories, then we will be unable to tell whether the clinician should be measured as part of a group. We will consider whether there would be an opportunity for a facility-based group to elect to participate without submitting data on another performance category in the future as feasible. We do not believe that we would need to establish additional policies for groups that would have their improvement activities performance score re-weighted specifically because we generally expect reweighting to occur for the improvement activities performance category only in rare cases of extreme and uncontrollable events. We do note that the clinicians in a facility-based group who meet the requirements for facility-based measurement as individuals will have scores in the quality and cost performance categories determined for them as individuals if there is no data submission from the group in the improvement activity or Promoting Interoperability performance categories.

Comment: Commenters encouraged CMS to provide as much information as possible to eligible clinicians including information on eligibility for facility-based measurement, clinician type, potential performance score under facility-based scoring, and to which facility the eligible clinician will be attributed. Several commenters noted that more information would give clinicians the opportunity to assess the advantages and disadvantages of various reporting options under MIPS. One commenter stated that more information will avoid confusion as to how the facility-based scoring option will work during the performance period. A few commenters noted concerns with the timing of receiving information about facility-based measurement. Some commenters noted the risk of a clinician assuming that he or she will meet the criteria for facility-based measurement when that may not be the case. Another commenter noted that the timing is important in making decisions as to whether to report as a group or an individual under the facility-based scoring option.

Response: We intend to provide as much information as possible as early as possible to clinicians about their eligibility and the hospital performance upon which a MIPS eligible clinician's score would be based. We acknowledge

that clinicians may want to consider this information to make financial and operational decisions, regardless of not having to be required to opt-in to facility-based scoring. We intend to provide additional information to clinicians regarding their status with facility-based measurement eligibility, facility attribution, and a preview score based on data from the previous performance period. We anticipate that this information will be released during the first quarter of the performance period, if technically feasible, beginning with the 2019 performance period, and we aim to notify clinicians as soon as this information is available.

Comment: Many commenters expressed concern with our proposal to not require an opt-in or offer an opt-out for facility-based measurement. A few commenters noted that performing this calculation automatically would reduce the control that clinicians have over their participation in MIPS. A few commenters suggested that automatically calculating a score for facility-based clinicians would reduce the incentive to participate in clinical data registries. A few commenters suggested that not requiring an opt-in would provide a performance advantage to facility-based clinicians over those who are not eligible for facility-based measurement. One commenter expressed concern that clinicians could have measures displayed on Physician Compare from facility-based measurement.

Response: Receiving the higher of the combined quality and cost performance scores available would only benefit the applicable individual MIPS eligible clinician or group; however, we are uncertain that facility-based clinicians would necessarily perform better than those who submit MIPS data, because the opportunity to submit data via other methods provides individual clinicians or groups the opportunity to select quality measures. We continue to believe that adding a formal opt-in or opt-out process would add unnecessary burden for both individual clinicians and groups. Additionally, we believe that those MIPS eligible clinicians who will not be required to submit MIPS data will benefit from a reduction in administrative burden while being measured in a facility in which their care has a significant impact on the facility's performance. We note that clinicians who wish to better control their performance in MIPS may submit measures through another method. Hence, we are finalizing our proposal to not require an opt-in or opt-out for facility-based measurement. Additionally, we did not propose any policies for how facility-based measures, other than the scores derived from those measures and included as quality and cost performance category scores, will be displayed on Physician Compare, but we thank commenters for their input and will take this input into consideration in future years.

Comment: One commenter requested clarification on how CMS would score a facility-based clinician who submits data on the quality performance category but does not have a cost performance category score, and thus, the cost performance category weight would need to be redistributed to the quality performance category.

Response: The cost performance category can be reweighted to 0 percent if there are not sufficient cost measures applicable and available (for example, if the clinician does not meet the minimum case requirements for the cost measures). In cases in which a clinician or group does not have a score in the cost performance category, in general, the weight of the cost performance category would be redistributed to the quality performance category. In that case, the points assigned under § 414.1380(b) for purposes of calculating/assigning the MIPS final score in the cost and quality categories will be compared to the points that contribute to the final score from the quality and cost scores established under facility-based measurement. For example, a clinician whose data was submitted on their behalf by a third-party intermediary and received a MIPS quality performance category percent score of 50 percent but did not meet the case minimum for cost measures, would have a total of 30 points as the combined score for the quality and cost performance categories. If that same clinician were eligible for facility-based measurement, the score based on that third party intermediary submission would be used unless the combination of the quality and cost scores established under facility-based measurement (as calculated under § 414.1380(e)(6)) resulted in more than 30 points towards the final score.

Comment: One commenter requested guidance and language as to how to account for MIPS eligible clinicians who wish to use their facility's Hospital VBP Program Total Performance Score for the quality and cost performance categories, yet still use a QCDR to report.

Response: Our proposed policy to not require an opt-in or offer an opt-out for facility-based measurement anticipates that there may be some clinicians and groups who will both receive a score based upon facility-based measurement and submit quality measures via various collection types. These clinicians may believe these quality measures better represent their performance or that they will perform better submitting these measures. In all cases, under the policy we are finalizing here, we will compare combined performance in these two categories and assign the clinician or group the higher combined score, whether based on the facility-based measurement or through another submission type. We note that facility-based measurement only applies to the quality and cost performance categories; the Promoting Interoperability and improvement activity performance categories would still require reporting on the part of the clinicians or group.

After consideration of the public comments, we are finalizing our proposal to automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and those who have a higher combined quality and cost performance category score. Additionally, we are finalizing our proposal to revise § 414.1380(e)(4) to state that there are no submission requirements for individual clinicians in facility-based measurement and that a group must submit data in the improvement activities or Promoting Interoperability performance categories to be measured as a group under facility-based measurement. Additionally, we are also revising the proposed regulation text for § 414.1380(e)(4) by adding ''to be'' between ''clinicians'' and ''scored'' to clarify that this paragraph is establishing the data submissions necessary for facility-based scoring to be possible as opposed to a provision governing MIPS reporting as a whole for all categories. We are also finalizing the conforming changes at § 414.1380(e)(4) and (e)(6) to revise text that referred to an election by the clinician or group to use facility-based scoring. Additionally, while we did not propose any changes, we are revising § 414.1380(e) to state, for the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories under the methodology described in this paragraph (e). These technical changes are made to conform to our policy in this section to not require or offer an election and to improve readability.

(v) Facility-Based Measures

(A) Background

Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use

measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. However, the Secretary may not use measures for hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists. In the CY 2018 Quality Payment Program proposed rule, we proposed to include for the 2020 MIPS payment year all the measures adopted for the FY 2019 Hospital VBP Program on the MIPS list of quality measures and cost measures for purposes of facility-based measurement (82 FR 30125). We noted how these measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act (82 FR 30125). In the CY 2018 Quality Payment Program final rule, we did not finalize our proposal that the facility-based measures available for the 2018 MIPS performance period would be the measures adopted for the FY 2019 Hospital VBP Program; nor did we finalize our proposal that, for the 2020 MIPS payment year, facility-based individual MIPS eligible clinicians or groups that were attributed to a facility would be scored on all measures on which the facility is scored via the Hospital VBP Program's Total Performance Score methodology (82 FR 53762).

We did finalize a facility-based measurement scoring standard but not the specific instance of using the FY 2019 Hospital VBP Program Total Performance Score methodology (82 FR 53755). We expressed our belief that using all measures from the Hospital VBP Program is appropriate; nevertheless, because we did not finalize the facility-based measurement scoring option for the 2018 MIPS performance period/2020 MIPS payment year, it was not appropriate to adopt these policies at that time (82 FR 53762 through 53763). We noted that we intended to propose measures that would be available for facility-based measurement for the 2019 MIPS performance period/2021 MIPS payment year in future rulemaking (82 FR 53763).

(B) Measures in Facility-Based Scoring

As we noted in the proposed CY 2019 PFS rule, we continue to believe it is appropriate to adopt all the measures for the Hospital VBP Program into MIPS for purposes of facility-based scoring; these Hospital VBP Program measures meet the definition of additional system-based measures provided in section 1848(q)(2)(C)(ii) of the Act. We also stated how it is appropriate to adopt the performance periods for the measures, which generally are consistent with the dates that we use to determine eligibility for facility-based measurement.

Beginning with the 2019 MIPS performance period, we proposed at § 414.1380(e)(1)(i) to adopt for facility-based measurement, the measure set that we finalize for the fiscal year Hospital VBP Program for which payment begins during the applicable MIPS performance period. For the 2019 MIPS performance period (which runs on the 2019 calendar year), we proposed to adopt the FY 2020 Hospital VBP Program measure set, for which payment begins on October 1, 2019. The performance period for these measures varies but performance ends in 2018 for all measures.

We also proposed at § 414.1380(e)(1)(ii) that, starting with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period. Additionally, we note a typographical error in the CY 2019 PFS proposed rule (83 FR 35960) in which we state FY 2019 instead of FY 2020, which we believe commenters have likely understood given the comments we have received on FY 2020 measures. However, we provide additional clarification in this final rule.

We noted in the proposed rule that this approach of adopting all the measures in the Hospital VBP Program can be applied to other value-based purchasing programs in the future, should we decide to expand facility-based measurement to settings other than hospitals.

In the CY 2018 Quality Payment Program final rule we also established at § 414.1380(e)(6)(i) that the available quality and cost measures for facility-based measurement are those adopted under the value-based purchasing program of the facility for the year specified. We established at § 414.1380(e)(6)(ii) that we will use the benchmarks adopted under the value-based purchasing program of the facility program for the year specified (82 FR 53763 through 53764). We noted that we would determine the particular value-based purchasing program to be used for facility-based measurement in future rulemaking but would routinely use the benchmarks associated with that program (82 FR 53764). Likewise, at § 414.1380(e)(6)(iii), we established that the performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year specified (82 FR 53755). We noted that these provisions referred to the general parameters of our method of facility-based measurement and that we would address specific programs and years in future rulemaking (82 FR 53763). For the CY 2019 performance period, we proposed regulation text for these three provisions to specify that the measures, performance period, and benchmark period for facility-based measurement are the measures, performance period, and benchmark period established for the value-based purchasing program used to determine the score as described in § 414.1380(e)(1) (83 FR 35960). We provided an example in the proposed rule to illustrate this policy: For the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2019 Hospital VBP Program along with the associated benchmarks and performance periods. As explained earlier, we intended this to mean that for the 2019 MIPS performance period and 2021 MIPS payment year, the measures used would be those for the FY 2020 Hospital VBP Program along with the associated benchmarks and performance periods.

The following is a summary of the public comments received on these proposals and our responses:

Comment: Several commenters noted their appreciation of the facility-based scoring option but requested that CMS consider additional measures that are more relevant to specific specialties as that would capture clinically meaningful information. One commenter suggested CMS develop episode-based risk adjusted measures even if they are not used in the Hospital VBP Program. Another commenter suggested that CMS consider additional avenues to collect more meaningful information.

Response: Section 1848(q)(2)(C)(ii) of the Act provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories. Based on this statutory requirement and because we want to align incentives between clinicians and hospitals, we proposed to use measures that are developed and implemented in other programs, as opposed to new measures that reflect a facility's performance. Due to this limitation, we note that there may be additional avenues for clinicians to participate in MIPS using qualified

registries or QCDRs that measure quality for services that may be provided in a facility setting, such as inpatient surgeries, without being measured in facility-based measurement.

After consideration of the public comments, we are finalizing the proposed regulation text at § 414.1380(e)(1)(i) that the measures for facility-based measurement will be the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period. We are also finalizing the proposed regulation text at § 414.1380(e)(1)(ii) that, beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program for the fiscal year for which payment begins during the applicable MIPS performance period. This means that for the 2021 MIPS payment year, the Total Performance Score for FY 2020 will be applied for the MIPS performance year 2019. Additionally, while we did not propose any changes, we are revising the regulation text at § 414.1380(e)(1)(i) to stated that the measures used for facility-based measurement are the measure set finalized for the fiscal year VBP program for which payment begins during the applicable MIPS performance period. This update is not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We have also made a technical revision in which we revise § 414.1380(e)(6)(ii), (iv), and (v) to reference only (e)(1) rather than (e)(1)(i) for improvements in readability and clarity of the regulation.

(C) Measures for MIPS 2019 Performance Period/2021 MIPS Payment Year

For informational purposes, we provided a list of measures included in the FY 2020 Hospital VBP Program that would be used in determining the quality and cost performance category scores for the 2019 MIPS performance period/2021 MIPS payment year. The FY 2020 Hospital VBP Program has adopted 12 measures covering 4 domains (83 FR 20412 through 20413). The performance period for measures in the Hospital VBP Program varies depending on the measure, and some measures include multi-year performance periods. We noted in the proposed rule that these measures are determined through separate rulemaking (83 FR 38244); the applicable rulemaking is usually the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System rule. We are using these measures, benchmarks, and performance periods for the purposes of facility-based measurement based on § 414.1380(e)(1) as finalized here. We repeat the list of measures finalized for the FY 2020 Hospital VBP measure set and Total Performance Score in Table 52.

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TABLE 52: FY 2020 Hospital VBP Program Measures

Short Name	Domain/Measure Name	NQF #	Performance Period
Person and Community Engagement Domain			
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)	January 1, 2018 – December 31, 2018
Clinical Outcomes Domain			
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization	0230	July 1, 2015 – June 30, 2018
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization	0229	July 1, 2015 – June 30, 2018
MORT-30-PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468	July 1, 2015 – June 30, 2018
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550	July 1, 2015 – June 30, 2018
Safety Domain			
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138	January 1, 2018 – December 31, 2018
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139	January 1, 2018 – December 31, 2018
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753	January 1, 2018 – December 31, 2018
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716	January 1, 2018 – December 31, 2018
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717	January 1, 2018 – December 31, 2018
PC-01	Elective Delivery	0469	January 1, 2018 – December 31, 2018
Efficiency and Cost Reduction Domain			
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158	January 1, 2018 – December 31, 2018

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(vi) Scoring Facility-Based Measurement

(A) Scoring Achievement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we adopted certain scoring policies for clinicians and groups in facility-based measurement. We established at § 414.1380(e)(6)(iv) and (v) that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the value-based purchasing program for the specified year, then awarding scores associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not scored using facility-based measurement for the MIPS payment year (82 FR 53764). We also finalized at § 414.1380(e)(6)(v)(A) that clinicians scored under facility-based measurement would not be scored on other cost measures (82 FR 53767).

For detailed descriptions of the current policies related to scoring achievement in facility-based measurement, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53763). Because we proposed to not require or allow an opt-in process for facility-based measurement, we proposed a change to the determination of the quality and cost performance category scores. We proposed that the quality and cost performance category percent scores would be established by determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year (83 FR 35961). Under our proposal, the determination of percentile performance would be independent of those clinicians who would not have their quality or cost scores determined until we make the determination of their status under facility-based measurement.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters supported our proposal that the quality and cost performance category percent scores for clinicians in facility-based measurement would be established by

determining the percentile performance of the facility in the Hospital VBP Program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal to change the determination of the quality and cost performance category scores at § 414.1380(e)(6)(iv) and (v) to establish both scores by determining the percentile performance of the facility in value-based purchasing program for the specified year, then awarding a score associated with that same percentile performance in the MIPS quality and cost performance categories for those MIPS eligible clinicians who are not eligible to be scored under facility-based measurement for the MIPS payment year. Also, we have revised the last sentence in paragraphs (e)(6)(iv) and (v) to more clearly state that a clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality or cost categories.

(B) Scoring Improvement in Facility-Based Measurement

In the CY 2018 Quality Payment Program final rule, we finalized that we would not give a clinician or group participating in facility-based measurement the opportunity to earn improvement points based on prior performance in the MIPS quality and cost performance categories; we noted that the Hospital VBP Program already takes improvement into account in determining the Total Performance Score (82 FR 53764 through 53765). We proposed to add this previously finalized policy to regulatory text at § 414.1380(e)(6)(iv) and (v) (83 FR 35961).

We did not address in the CY 2018 Quality Payment Program final rule a policy for a clinician or group who participates in facility-based measurement for one performance period, and then does not participate in facility-based measurement in a subsequent performance period (for example, a clinician who is scored using facility-based measurement in the 2019 MIPS performance period and is not eligible for facility-based measurement in the 2020 MIPS performance period). After further considering the issue, we stated in the CY 2019 PFS proposed rule our position that it is not possible to assess improvement in the quality performance category for those who are measured under facility-based measurement in 1 year and then through another method in the following year. Our method of assessing and rewarding improvement in the MIPS quality performance category separates points awarded for measure performance from those received for bonus points (82 FR 53745). Our method of determining the quality performance category score using facility-based measurement does not allow for the separation of achievement from bonus points. For this reason, we proposed at § 414.1380(b)(1)(vi)(A)(4) [30] to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year (83 FR 39561).

We did not receive any public comments on this proposal, so we will finalize our proposal to add regulatory text at § 414.1380(e)(6)(iv) and (v) and our proposal at § 414.1380(b)(1)(vi)(A)(4) to not assess improvement for MIPS-eligible clinicians who are scored in MIPS through facility-based measurement in 1 year but through another method in the following year.

(vii) Expansion of Facility-Based Measurement To Use in Other Settings

We initiated the process of facility-based measurement focusing on the inpatient hospital setting, but have noted in the past our policy goal of expanding the concept into other facilities and programs and future, in particular to use the post-acute care (PAC) and the end-stage renal disease (ESRD) settings as the basis for facility-based measurement and scoring. In the proposed rule, we summarized a number of issues and topics related to the use of PAC and ESRD facilities (83 FR 35962 through 35963). We solicited comment on these topics, including:

- How to attribute the quality and cost of care for patients in PAC settings to clinicians;
- Whether using a value-based purchasing program, that is, a similar approach to § 414.1380(e)(1), could work for PAC given the number and variation of PAC settings and clinicians;
- The level of influence MIPS-eligible clinicians have in determining performance on quality measures for individual settings and programs in the PAC setting;
- Which PAC QRP measures may be best utilized to measure clinician performance;
- Methods to identify the appropriate measures for scoring, and what measures would be most influenced by clinicians;
- Whether all measures that are reported as part of the PAC QRPs should be included or whether we should identify a subset of measures;
- Whether we should limit facility-based measurement to specific PAC settings and programs such as the IRF QRP or LTCH QRP, or whether we should consider all PAC settings in the facility-based measurement discussion;
- The extent to which the quality measures of dialysis centers reflect clinician performance; and
- Practical and policy considerations related to whether we could to attribute the performance of a specific ESRD facility to an individual clinician.

We appreciate the comments received in response to these considerations and may consider these suggestions in policies that will be proposed as part of future rulemaking.

(e) Scoring the Improvement Activities Performance Category

For our previously established policies regarding scoring the improvement activities performance category, we refer readers to § 414.1380(b)(3) and the CY 2018 Quality Payment Program final rule (82 FR 53767 through 53769). We also refer readers to § 414.1355 and the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53662) and CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) for previously established policies regarding the improvement activities performance category generally.

(i) Regulatory Text Updates

In the CY 2019 PFS proposed rule, we proposed updates to both §§ 414.1380(b)(3) and 414.1355 to more clearly and concisely capture previously established policies (83 FR 35963). We also proposed one substantive change with respect to patient-centered medical homes and comparable specialty practices (83 FR 35963). These are discussed in more detail in this section.

[30] The codification was misidentified in the preamble of the proposed rule as § 414.1380(b)(1)(xi)(A)(4) but the regulation text was proposed, at 83 FR 36081, to be codified at § 414.1380(b)(1)(vi)(A)(4), where we are finalizing it.

(A) Improvement Activities Performance Category Score and Total Required Points

In an effort to more clearly and concisely capture previously established policies, we proposed updates to § 414.1380(b)(3) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963). We also clarified that the improvement activities performance category score cannot exceed 100 percent (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1380(b)(3) as proposed.

(B) Weighting of Improvement Activities

In an effort to more clearly and concisely capture previously established policies, we proposed updates to § 414.1380(b)(3) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1380(b)(3) as proposed.

(C) APM Improvement Activities Performance Category Score

In an effort to more clearly and concisely capture previously established policies, we proposed updates to § 414.1380(b)(3)(i) and refer readers to the CY 2019 PFS proposed rule for more details (83 FR 35963).

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1380(b)(3)(i) as proposed.

(D) Patient-Centered Medical Homes and Comparable Specialty Practices

In the CY 2019 PFS proposed rule (83 FR 35963), we proposed to modify our regulations at § 414.1380(b)(3)(ii) to more clearly and concisely capture our previously established policies for patient-centered medical homes and comparable specialty practices and refer readers to the CY 2019 PFS proposed rule for more details.

In addition, it had come to our attention that in the preamble of the CY 2017 Quality Payment Program final rule (81 FR 77186 and 77179), the terminology ''automatic'' was used in reference to patient-centered medical home or comparable specialty practice improvement activities scoring credit. In that rule (81 FR 77186), in response to one comment, we stated, ''. . . any MIPS eligible clinician or group that does not qualify by October 1st of the performance year as a certified patient-centered medical home or comparable specialty practice cannot receive automatic credit as such for the improvement activities performance category.'' In response to another comment in that rule (81 FR 77179), we stated, ''Other certifications that are not for patient-centered medical homes or comparable specialty practices would also not qualify automatically for the highest score.''

While we used the term ''automatic'' then, we have since come to realize it is inaccurate because an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive full credit for the improvement activities performance category. In the CY 2018 Quality Payment Program final rule (82 FR 53649), in response to comments we received regarding patient-centered medical homes or comparable specialty practices receiving full credit for the improvement activities performance category for MIPS, we stated that we would like to make clear that credit is not automatically granted; MIPS eligible clinicians and groups must attest in order to receive the credit.

Therefore, in the CY 2019 PFS proposed rule (83 FR 35963), we proposed codifying at § 414.1380(b)(3)(ii) to require that an eligible clinician or group must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. Specifically, MIPS eligible clinicians who wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice for a continuous 90-day minimum during the performance period.

We solicited comments on the above proposal. We received the following comment on this proposal.

Comment: One commenter supported the proposal to modify current regulations to more clearly and concisely capture previously established policies for patient-centered Medical Homes and comparable specialty practices.

Response: We thank the commenter for your support.

After consideration of the comment we received, we are finalizing our changes to regulation text at § 414.1380(b)(3)(ii) as proposed.

(E) Improvement Activities Performance Category Weighting for Final Scoring

In the CY 2019 PFS proposed rule (83 FR 35963), in an effort to more clearly and concisely capture previously established policies, we proposed to make technical changes to § 414.1355(b) to state that unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises 15 percent of a MIPS eligible clinician's final score for the 2019 MIPS payment year and for each MIPS payment year thereafter). We stated that we believe these changes would better align the regulation text with the text of the statute.

We solicited comments on the above proposal. We did not receive any comments on this proposal. We are finalizing our changes to regulation text at § 414.1355(b) as proposed.

(ii) CEHRT Bonus

In the CY 2017 Quality Payment Program final rule (81 FR 77202 through 77209) and the CY 2018 Quality Payment Program final rule (82 FR 53664 through 53670), we established that certain activities in the improvement activities performance category will qualify for a bonus under the Promoting Interoperability performance category if they are completed using CEHRT. This bonus is applied under the Promoting Interoperability performance category and not under the improvement activities performance category. In the CY 2019 PFS proposed rule (83 FR 35932), we proposed a new approach for scoring the Promoting Interoperability performance category that is aligned with our MIPS program goals of flexibility and simplicity. We refer readers to section III.I.3.h.(5)(g) of this final rule for a summary of the comments we received regarding this proposal and our responses.

(f) Scoring the Promoting Interoperability Performance Category

We refer readers to section III.I.3.h.(5) of this final rule, where we discuss our proposals for scoring the Promoting Interoperability performance category.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c), the discussion in the CY 2017 Quality Payment Program final rule (81 FR 77319 through 77329), and the discussion in the CY 2018 Quality Payment Program final rule (82 FR 53769 through 53785). In this final rule, we discuss our proposal to continue the complex patient bonus for the 2021 MIPS payment year, as well as a

modification to the final score calculation for the 2021 MIPS payment year. Finally, we discuss refinements to reweighting policies.

(a) Accounting for Risk Factors

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on individuals' health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) and, as appropriate, other information, including information collected before completion of such studies and recommendations.

(i) Considerations for Social Risk

In the CY 2019 PFS proposed rule (83 FR 35964), we summarized our efforts related to social risk and the relevant studies conducted under section 2(d) of the IMPACT Act. We received several comments suggesting various approaches to adjust for social risk factors in the Quality Payment Program going forward. We thank commenters for their input and will take this input into consideration in future years. We also plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

(ii) Complex Patient Bonus for the 2021 MIPS Payment Year

In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we finalized at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. Our overall goal for the complex patient bonus was two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We noted that we would assess on an annual basis whether to continue the bonus and how the bonus should be structured (82 FR 53771). For a detailed description of the complex patient bonus finalized for the 2020 MIPS payment year, please refer to the CY 2018 Quality Payment Program final rule (82 FR 53771 through 53776).

For the 2019 MIPS performance period/2021 MIPS payment year, we proposed in the CY 2019 PFS proposed rule to continue the complex patient bonus as finalized for the 2018 MIPS performance period/2020 MIPS payment year and to revise § 414.1380(c)(3) to reflect this policy (83 FR 35964 through 35965). Although we intended to maintain the complex patient bonus as a short-term solution, we did not believe we had sufficient information available at the time of the proposed rule to develop a long-term solution to account for patient risk factors in MIPS such that we would be able to propose a different approach for the 2019 MIPS performance period/2021 MIPS payment year. At the time of the proposed rule, we did not believe additional data sources were available that would be feasible to use as the basis for a different approach to account for patient risk factors in MIPS. In the CY 2019 PFS proposed rule, we noted our intention to analyze data when feasible from the 2017 MIPS performance period to identify differences in performance that are consistent across performance categories and that we may, in the future, shift the complex patient bonus to specific performance categories (83 FR 35965). In the absence of data analysis from the first year of MIPS, we did not believe that a change was appropriate at that time. Therefore, we stated that while we work with stakeholders to identify a long-term approach to account for patient risk factors in MIPS, we believed it was appropriate to continue the complex patient bonus for another year to support MIPS eligible clinicians who treat patients with risk factors, as well as to maintain consistency with the 2020 MIPS payment year and minimize confusion. We had received significant feedback from MIPS eligible clinicians that consistency in the MIPS program over time is valued when possible in order to minimize confusion and to help MIPS eligible clinicians predict how they will be scored under MIPS. Therefore, we stated our belief that it is appropriate to maintain consistent policies for the complex patient bonus in the 2021 MIPS payment year until we have sufficient evidence and new data sources that support an updated approach to account for patient risk factors.

Although we did not propose changes to the complex patient bonus for the 2021 MIPS payment year, we stated that the dates used in the calculation of the complex patient bonus may change as a result of other proposals we made in the CY 2019 PFS proposed rule (83 FR 35885 through 35886). For the 2020 MIPS payment year, we finalized that we will use the second 12-month segment of the eligibility determination period to calculate average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians (82 FR 53771 through 53772). We proposed to change the dates of the eligibility determination period (now referred to as the MIPS determination period) beginning with the 2021 MIPS payment year (83 FR 35885 through 35886). Specifically, the second 12-month segment would begin on October 1 of the calendar year preceding the applicable performance period and end on September 30 of the calendar year in which the applicable performance period occurs. We indicated that if this proposed change to the MIPS determination period is finalized, then beginning with the 2021 MIPS payment year, the second 12-month segment of the MIPS determination period (beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs) would be used when calculating average HCC risk scores and proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposal to continue the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. Commenters stated that the bonus helps to create fairer scoring for MIPS eligible clinicians. Some commenters requested that we continue the bonus beyond the 2019 MIPS performance period/2021 MIPS payment year. A few commenters supported the complex patient bonus but requested that we increase the complex patient bonus above the proposed 5 points, stating that 5 points

will have a minimal impact on the final score.

Response: We thank commenters for their support of our proposal to maintain the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year. We plan to review available information, including any updated data, in future years to determine if it is appropriate to modify our approach to adjusting for social risk factors. As we stated in the CY 2018 Quality Payment Program final rule (82 FR 53775), we believe a complex patient bonus of 5 points added to the final score is appropriate and is justified by information currently available at this time.

Comment: Several commenters did not support our approach for the complex patient bonus. Commenters pointed out limitations in the use of HCC and dual-eligibility to calculate the complex patient bonus. For instance, commenters stated that these indicators are not sufficient to adjust for differences in performance and suggested other indicators that might be more appropriate (such as income or education). Commenters urged us to continue to explore alternative methods to adjust for patient complexity in future years.

Response: We understand that both HCC risk scores and dual eligibility have some limitations as proxies for social risk factors. However, we are not aware of data sources for indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. We have decided to pair the HCC risk score with the proportion of dual eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional options in future years based on any updated data or additional information in order to better account for social risk factors while minimizing unintended consequences.

Comment: One commenter recommended that we use the 12-month performance period to determine the complex patient bonus, stating that it is the most accurate representation of the patient population of a MIPS eligible clinician.

Response: We believe that aligning the time period for assigning beneficiaries for purposes of calculating the complex patient bonus with the MIPS determination period is preferable for simplicity. In addition, when we designed our systems, we incorporated user feedback that requested eligibility information be connected to data submission. In order to be able to provide this information on the complex patient bonus at or near the time of data submission, it is necessary to use the second 12-month segment of the MIPS determination period as proposed to identify beneficiaries for purposes of assigning HCC risk scores and full benefit or partial benefit dual eligible beneficiaries to MIPS eligible clinicians, rather than the performance period. We note that this second 12-month segment begins 3 months before the year in which the performance period occurs and ends 9 months into the year in which the performance period occurs, creating a considerable overlap between the MIPS determination period and the year in which the performance period occurs (9 months).

After consideration of public comments, we are finalizing our proposal to continue the complex patient bonus for the 2019 MIPS performance period/2021 MIPS payment year as proposed. We are also finalizing the changes to the regulation text at § 414.1380(c)(3) as proposed. We are also modifying the timing used to calculate the complex patient bonus based on our changes to the MIPS determination period finalized in III.I.3.b. of this final rule. The second 12-month segment of the MIPS determination period will be used when calculating average HCC risk scores and the proportion of full benefit or partial benefit dual eligible beneficiaries for MIPS eligible clinicians.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability (formerly advancing care information) performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77320 and 82 FR 53779, respectively). Under the proposals we are finalizing in sections III.I.3.h.(3)(a) and III.I.3.h.(2)(a)(ii) of this final rule, for the 2021 MIPS payment year, the cost performance category will make up 15 percent and the quality performance category will make up 45 percent of a MIPS eligible clinician's final score. Table 53 summarizes the weights specified for each performance category.

TABLE 53—FINALIZED WEIGHTS BY MIPS PERFORMANCE CATEGORY AND MIPS PAYMENT YEAR

Performance category	2019 MIPS payment year (previously finalized) (percent)	2020 MIPS payment year (previously finalized) (percent)	2021 MIPS payment year (finalized) (percent)
Quality	60	50	45
Cost	0	10	15
Improvement Activities	15	15	15
Promoting Interoperability	25	25	25

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as

achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Assigning a scoring weight of zero percent and redistributing the weight to the other performance categories differs from the scenario of a MIPS eligible clinician failing to report on an applicable measure or activity that is required to be reported.

(A) Scenarios Where the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories Would Be Reweighted

In the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77322 through 77325 and 82 FR 53779 through 53780, respectively), we explained our interpretation of what it means for there to be sufficient measures applicable and available for the quality and cost performance categories, and we finalized policies for the 2019 and 2020 MIPS payment years under which we would assign a scoring weight of zero percent to the quality or cost performance category and redistribute its weight to the other performance categories in the event there are not sufficient measures applicable and available, as authorized by section 1848(q)(5)(F) of the Act. For the quality performance category, we stated that having sufficient measures applicable and available means that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician (82 FR 53780). For the cost performance category, we stated that having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures that adequately captures and reflects the performance of a MIPS eligible clinician (82 FR 53780). We established that if a MIPS eligible clinician is not attributed enough cases for a cost measure (in other words, has not met the required case minimum for the measure), or if a cost measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). We stated that if we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score (82 FR 53780).

In the CY 2019 PFS proposed rule, we proposed to codify these policies for the quality and cost performance categories at § 414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year (83 FR 35966).

For the Promoting Interoperability performance category, in the CY 2017 Quality Payment Program final rule (81 FR 77238 through 77245) and the CY 2018 Quality Payment Program final rule (82 FR 53680 through 53687), we established policies for assigning a scoring weight of zero percent to the Promoting Interoperability performance category and redistributing its weight to the other performance categories in the final score. We proposed to codify those policies under § 414.1380(c)(2)(i) and (iii) (83 FR 35966).

For the improvement activities performance category, we stated in the CY 2019 proposed rule (83 FR 35967 through 35968) that we continue to believe that all MIPS eligible clinicians will have sufficient activities applicable and available, except for limited extreme and uncontrollable circumstances, such as natural disasters, where a clinician is unable to report improvement activities, and circumstances where a MIPS eligible clinician joins a practice in the final 3 months of the performance period as discussed in the CY 2019 PFS proposed rule (83 FR 35967 through 35968). We stated that, barring these circumstances, we believe that all MIPS eligible clinicians will have sufficient improvement activities applicable and available (82 FR 53780).

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: One commenter supported our reweighting policies, stating that they provide flexibility for MIPS eligible clinicians who are unable to participate in specific performance categories.

Response: We thank this commenter for its support.

Comment: One commenter expressed concern with our reweighting policies, because the commenter believes MIPS eligible clinician may expend resources to submit data to us, and then receive reweighting based on our determination that there are not sufficient measures or activities applicable and available.

Response: Our reweighting policies would not lead us to reweight a MIPS eligible clinician after they submit data for a given performance category. Rather, we would consider whether these policies are applicable in the event that we do not receive any data for a MIPS eligible clinician for a particular performance category. If we determine that the clinician is eligible for reweighting under our policies, then we would redistribute the weight of the performance category, rather than awarding a score of zero to the clinician for that performance category.

After consideration of public comments, we are finalizing our proposal to codify the reweighting policies for the quality and cost performance categories at § 414.1380(c)(2)(i)(A)(1) and (2), respectively, and to continue them for the 2021 MIPS payment year and each subsequent MIPS payment year, as proposed. We are also finalizing our proposal to codify the Promoting Interoperability reweighting policies under § 414.1380(c)(2)(i) and (iii) as proposed.

(B) Reweighting the Quality, Cost, and Improvement Activities Performance Categories for Extreme and Uncontrollable Circumstances

For a summary of the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances, we refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53780 through 53783). In the proposed rule (83 FR 35966), we proposed to codify this policy at § 414.1380(c)(2)(i)(A)(*5*), but we inadvertently referred to the wrong paragraph of the regulation text, and the citation should have read § 414.1380(c)(2)(i)(A)(6).

We proposed a few minor modifications to our extreme and uncontrollable circumstances policy (83 FR 35967). First, beginning with the 2019 MIPS performance period/2021 MIPS payment year, we proposed at § 414.1380(c)(2)(i)(A)(5) (which should have read § 414.1380(c)(2)(i)(A)(6)) that, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with § 414.1325, he or she would be scored on the submitted data like all other MIPS eligible clinicians, and the categories would not be reweighted (83 FR 35967). We proposed this modification to align with a similar policy for the Promoting Interoperability performance category (82 FR 53680 through 53682). We stated that if a MIPS eligible clinician reports on measures or activities specified for the quality or improvement activities performance categories, then we assume the clinician

believes there are sufficient measures or activities applicable and available to the clinician.

For most quality measures and improvement activities, the data submission occurs after the end of the MIPS performance period, so clinicians would know about the extreme and uncontrollable circumstance prior to submission. However, for the quality performance category, measures submitted via the Medicare Part B claims collection type are submitted by adding quality data codes to a claim. As a result, it is possible that a MIPS eligible clinician could have submitted some Medicare Part B claims collection type data prior to the submission of a reweighting application for extreme and uncontrollable events. Under our proposal, we would score the quality performance category because we have received data. However, we previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). If a clinician experiences an extreme and uncontrollable event that affects all of the performance categories, then under our proposal, the clinician would only be scored on the quality performance category if they submit data for only that category. The clinician would also have to submit data for the improvement activities or the Promoting Interoperability performance categories in order to be scored on two or more performance categories and receive a final score different than the performance threshold.

This proposal did not include administrative claims data that we receive through the claims submission process and use to calculate the cost measures and certain quality measures. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095), and as we are codifying in this final rule at § 414.1325(a)(2), there are no data submission requirements for the cost performance category and for certain quality measures used to assess performance in the quality performance category. Please see section III.I.3.h.(1)(b) of this final rule for a description of collection types, submission types, and submitter types. We calculate performance on these measures using administrative claims data, and clinicians are not required to submit any additional data for these measures. Therefore, we stated that we did not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We also proposed to apply the policy we finalized for virtual groups in the CY 2018 Quality Payment Program final rule (82 FR 53782 through 53783) to groups submitting reweighting applications for the quality, cost, or improvement activities performance categories based on extreme and uncontrollable circumstances (83 FR 35967). For groups, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances. In the CY 2019 PFS proposed rule (83 FR 35967), we stated that although we did not specifically propose to apply this policy to groups in the CY 2018 Quality Payment Program proposed rule, our intention was to apply the same policy for groups and virtual groups, and thus if we adopt this proposal, we would apply the policy to groups beginning with the 2018 performance period/2020 MIPS payment year.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: One commenter supported our proposal for groups, stating that all MIPS eligible clinicians in the group will likely be facing the same barriers and a group application will reduce administrative burden and redundancy.

Response: We thank the commenter for its support of our proposal to apply the same policy we established for virtual groups to groups. Under the proposed policy, we would evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided for the individual clinicians and practice location(s) affected by extreme and uncontrollable circumstances and the nature of those circumstances.

Comment: One commenter expressed concern that MIPS eligible clinicians who submit an application for reweighting based on extreme and uncontrollable circumstances, but who also report via Medicare Part B claims collection type may be unfairly penalized if claims data is received prior to the extreme and uncontrollable event. Another commenter suggested that we should score data received from MIPS eligible clinicians who submit a reweighting application only if they would receive a score that would result in a payment adjustment no lower than a neutral adjustment.

Response: If a MIPS eligible clinician reports via Medicare Part B claims collection type for the quality performance category, and we receive an application for reweighting for the clinician based on extreme and uncontrollable circumstances, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or the improvement activities performance categories. We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). The clinician's cost performance category score would not contribute to their final score because as we discuss above, there are no data submission requirements for the cost performance category, and we do not believe that it would be appropriate to void a reweighting application based on administrative claims data we receive for measures that do not require data submission for purposes of MIPS.

We assume that if a MIPS eligible clinician submits data to us following the submission of an application for reweighting based on extreme and uncontrollable circumstances, the clinician believes there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score. However, once the data is submitted, it will be scored based on performance in accordance with our policies, and the clinician could receive a negative payment adjustment.

After consideration of public comments, we are finalizing our proposal to codify the final policy we adopted beginning with the 2018 MIPS performance period/2020 MIPS payment year to reweight the quality, cost, and improvement activities performance categories based on a request submitted by a MIPS eligible clinician, group, or virtual group that was subject to extreme and uncontrollable circumstances. We are finalizing our proposal that, beginning with the 2019 performance period/2021 MIPS payment year, if a MIPS eligible clinician submits an application for reweighting based on extreme and uncontrollable circumstances, but also

submits data on the measures or activities specified for the quality or improvement activities performance categories in accordance with § 414.1325, he or she will be scored on the submitted data like all other MIPS eligible clinicians, and the categories will not be reweighted. We are also finalizing our proposal, beginning with the 2018 performance period/2020 MIPS payment year, that, for groups, we will evaluate whether sufficient measures and activities are applicable and available to MIPS eligible clinicians in the group on a case-by-case basis and determine whether to reweight a performance category based on the information provided. We are finalizing the regulation text at § 414.1380(c)(2)(i)(A)(6) as proposed.

(C) Reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability Performance Categories for MIPS Eligible Clinicians Who Join a Practice in the Final 3 Months of the Performance Period Year

Beginning with the 2019 MIPS performance period, we proposed that a MIPS eligible clinician who joins an existing practice (existing TIN) during the final 3 months of the calendar year in which the MIPS performance period occurs (the performance period year) that is not participating in MIPS as a group would not have sufficient measures applicable and available (83 FR 35967 through 35968). We also proposed that a MIPS eligible clinician who joins a practice that is newly formed (new TIN) during the final 3 months of the performance period year would not have sufficient measures applicable and available, regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group (83 FR 35967 through 35968). In each of these scenarios, we proposed to reweight all four of the performance categories to zero percent for the MIPS eligible clinician and, because he or she would be scored on fewer than two performance categories, the MIPS eligible clinician would receive a final score equal to the performance threshold and a neutral MIPS payment adjustment under the policy at § 414.1380(c) (83 FR 35967 through 35968). We proposed to codify these policies at § 414.1380(c)(2)(i)(A)(3).

We proposed this policy because we are not currently able to identify these MIPS eligible clinicians (or groups if the group is formed in the final 3 months of the performance period year) at the start of the MIPS submission period. When we designed our systems, we incorporated user feedback that requested eligibility information be connected to the submission process. In order to submit data, an individual TIN/NPI or the group TIN must be in the files generated from the MIPS eligibility determination periods. As discussed in the CY 2019 PFS proposed rule (83 FR 35885 through 35886), we have two 12-month determination periods for eligibility. We proposed and are finalizing in section III.II.3.b. of this final rule that the second 12-month segment of the MIPS eligibility determination period will end on September 30 of the calendar year in which the applicable MIPS performance period occurs; therefore, we will have no eligibility information about clinicians who join a practice after September 30 of the performance period year. MIPS eligible clinicians who join an existing practice (existing TIN) in the final 3 months of the performance period year that is not participating in MIPS as a group will not be identified by our systems, and we will not have the ability to inform them that they are eligible or to receive MIPS data from them. Similarly, practices that form (new TIN) in the final 3 months of the performance period year will not be in the MIPS determination files. Accordingly, we stated that the measures and activities would not be available because any data from these MIPS eligible clinicians would not be accessible to us.

If a MIPS eligible clinician joins a practice (existing TIN) in the final 3 months of the performance period year, and the practice is not newly formed and is reporting as a group for the performance period, the MIPS eligible clinician will be able to report as part of that group. In this case, we are able to accept data for the group because the TIN would be in our MIPS eligibility determination files. Therefore, we stated that we believe the measures and activities would be available in this scenario, and reweighting would not be necessary for the MIPS eligible clinician. We noted that, if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination will not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available. Please see section III.I.3.j.(1) of this final rule for more information about assigning group scores to MIPS eligible clinicians.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposal to reweight MIPS eligible clinicians who form a new practice in the final 3 months of the performance period year or join an existing practice that does not participate in MIPS as a group.

Response: We thank commenters for their support of our proposal.

Comment: One commenter requested that we extend this policy to the 2018 performance period as well.

Response: We note that we did not propose to apply the policy to the 2018 performance period, and as such, we will not be extending it in this final rule.

Comment: One commenter did not support our proposal to treat MIPS eligible clinicians who join a new or existing practice in the final 3 months of the performance period year differently depending on whether the practice reports as a group. The commenter also requested that we reweight MIPS eligible clinicians who switch practices at any time during the performance period, because a MIPS eligible clinician's previous practice may not report on their behalf and because clinicians are impacted by training and other requirements associated with switching practices that may impact performance.

Response: A MIPS eligible clinician who joins an existing practice that is participating in MIPS as a group would have the opportunity to contribute to the group's performance and final score. We refer readers to section III.I.3.j.(1) of this final rule for a discussion of which MIPS eligible clinicians may receive a group final score. We do not believe it would be appropriate to reweight the performance categories for MIPS eligible clinicians who change practices at any time during the performance period year because, consistent with our discussion in the CY 2019 PFS proposed rule (83 FR 35967 through 35968), we would be able to identify these clinicians at the beginning of the MIPS submission period if they change practices prior to the final 3 months of the performance period year. We also believe MIPS eligible clinicians who change practices prior to the final 3 months of the performance period year generally should have sufficient time to prepare for MIPS reporting, in the event that their prior practice does not submit data for them.

After consideration of public comments, we are finalizing as

proposed our proposal to reweight the quality, cost, improvement activities, and Promoting Interoperability performance categories to zero percent for MIPS eligible clinicians who join an existing practice (existing TIN) during the final 3 months of the performance period year that is not participating in MIPS as a group, or a practice that is newly formed (new TIN) during the final 3 months of the performance period year regardless of whether the clinicians in the practice report for purposes of MIPS as individuals or as a group. We are finalizing the proposed regulation text at § 414.1380(c)(2)(i)(A)(3) as proposed.

(D) Automatic Extreme and Uncontrollable Circumstances Policy Beginning With the 2020 MIPS Payment Year

In conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/ 2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900).

In the CY 2019 PFS proposed rule (83 FR 35968), we stated that we believe that a similar automatic extreme and uncontrollable circumstances policy would be appropriate for any year of the MIPS program to account for natural disasters and other extreme and uncontrollable circumstances that impact an entire region or locale. As we discussed in the interim final rule (82 FR 53897), we believe such a policy would reduce burden on clinicians who have been affected by widespread catastrophes and would align with existing policies for other Medicare programs. We proposed at § 414.1380(c)(2)(i)(A)(7) and (c)(2)(i)(C)(3) to apply the automatic extreme and uncontrollable circumstances policy we adopted for the transition year to subsequent years of the MIPS program, beginning with the 2018 MIPS performance period and the 2020 MIPS payment year, with a few additions to address the cost performance category (83 FR 35968). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read § 414.1380(c)(2)(i)(A)(8) instead of § 414.1380(c)(2)(i)(A)(7). For a description of the policy we adopted for the MIPS transition year, we refer readers to the discussion in the interim final rule (82 FR 53895 through 53900).

In the interim final rule (82 FR 53897), we stated that we were not including the cost performance category in the automatic extreme and uncontrollable circumstances policy for the transition year because the cost performance category is weighted at zero percent in the final score for the 2017 MIPS performance period/2019 MIPS payment year. We finalized a 10 percent weight for the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year (82 FR 53643) and are finalizing a 15 percent weight for the 2019 performance period/ 2021 MIPS payment year (see section III.I.3.h.(3)(a) of this final rule). In the CY 2019 PFS proposed rule (83 FR 35968), we stated that for the reasons discussed in the CY 2018 Quality Payment Program final rule (82 FR 53781), we believe a MIPS eligible clinician's performance on measures calculated based on administrative claims data, such as the measures specified for the cost performance category, could be adversely affected by a natural disaster or other extreme and uncontrollable circumstance, and that the cost measures may not be applicable to that MIPS eligible clinician. Therefore, we proposed to include the cost performance category in the automatic extreme and uncontrollable circumstances policy beginning with the 2018 MIPS performance period/2020 MIPS payment year (83 FR 35968). Under our policy for the transition year, if a MIPS eligible clinician in an affected area submits data for any of the MIPS performance categories by the applicable submission deadline for the 2017 MIPS performance period, he or she will be scored on each performance category for which he or she submits data, and the performance category will not be reweighted to zero percent in the final score (82 FR 53898). Our policy for the transition year did not include measures that are calculated based on administrative claims data (82 FR 53898). As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77094 through 77095), and as we are codifying in this final rule at § 414.1325(a)(2), there are no data submission requirements for the cost performance category, and we will calculate performance on the measures specified for the cost performance category using administrative claims data. We proposed for the cost performance category, if a MIPS eligible clinician is located in an affected area, we would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if we receive administrative claims data that would enable us to calculate the cost measures for that clinician (83 FR 35968).

In the interim final rule (82 FR 53897), we did not include an automatic extreme and uncontrollable circumstances policy for groups or virtual groups, and we stated in the CY 2019 PFS proposed rule (83 FR 35968) that we continue to believe such a policy is not necessary. Unless we receive data from a TIN indicating that the TIN would like to be scored as a group for MIPS, performance by default is assessed at the individual MIPS eligible clinician level. Similarly, performance is not assessed at the virtual group level unless the member TINs submit an application in accordance with § 414.1315. We stated that if we receive data from a group or virtual group, we would score that data, even if individual MIPS eligible clinicians within the group or virtual group are impacted by an event that would be included in our automatic extreme and uncontrollable circumstances policy. Regardless of whether we receive data from a group or virtual group, we would have no mechanism to determine whether the group or virtual group did not submit data, or submitted data and performed poorly, because it had been affected by an extreme and uncontrollable event unless the group notifies us of its circumstances. Instead of establishing a threshold for groups or virtual groups to receive automatic reweighting based on the number of clinicians in the group or virtual group impacted by extreme and uncontrollable events, we stated that we believe it is preferable that these groups and virtual groups submit an application for reweighting based on extreme and uncontrollable circumstances under our existing policy (82 FR 53780 through 53783) where they may be eligible for reweighting if they establish that the group or virtual group was sufficiently impacted by the extreme and uncontrollable event.

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: Several commenters supported our proposed application of the automatic extreme and uncontrollable policy starting with the 2018 MIPS performance period/2020 MIPS payment year to reduce burden on

impacted MIPS eligible clinicians. A few commenters supported our proposal to extend the automatic extreme and uncontrollable policy to include the cost performance category for the 2018 MIPS performance period/2020 MIPS payment year and future years.

Response: We thank commenters for their support of our proposals.

Comment: One commenter suggested that we only score performance categories (including the cost performance category) for MIPS eligible clinicians impacted by the automatic extreme and uncontrollable policy if they would receive a positive or neutral payment adjustment.

Response: If a MIPS eligible clinician reports via Medicare Part B claims collection type for the quality performance category, and we receive data for the clinician prior to a triggering event for the automatic extreme and uncontrollable circumstances policy, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or the improvement activities performance categories. We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779). We assume that if a MIPS eligible clinician submits data to us following a triggering event, the clinician believes there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score. However, once the data is submitted, it will be scored based on performance in accordance with our policies, and the clinician could receive a negative payment adjustment.

Comment: One commenter disagreed with our decision to not propose an automatic extreme and uncontrollable circumstances policy for groups, because clinicians who choose to report as group for purposes of MIPS conduct all aspects of MIPS at a group level.

Response: We continue to believe that a group policy is not necessary and that there are barriers to implementing such a policy. For example, because group reporting is optional, we would have no mechanism to determine who would have been intending to report without receiving a data submission. Additionally, some groups may be split between areas that are impacted by the triggering event and areas that are not. We do not believe that it would be appropriate to make a decision about how the group is impacted without additional information. We believe our application-based extreme and uncontrollable circumstances policy provides the mechanism for such an assessment. Finally, we note that if all the MIPS eligible clinicians in a group are located in an area affected by the extreme and uncontrollable circumstance, and the group is not able to submit for MIPS as a group, then all the MIPS eligible clinicians in the group would be considered as individuals and covered by the automatic extreme and uncontrollable circumstances policy.

After consideration of public comments received, we are finalizing these proposals and the regulation text at § 414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3) as proposed.

iii. Extreme and Uncontrollable Circumstance Policy for the 2017 Performance Period/2019 MIPS Payment Year

As discussed in the preceding section III.I.3.i.(2)(b)(ii)(D), in conjunction with the CY 2018 Quality Payment Program final rule, and due to the impact of Hurricanes Harvey, Irma, and Maria, we issued an interim final rule with comment period (IFC) in which we adopted on an interim final basis a policy for automatically reweighting the quality, improvement activities, and advancing care information (now referred to as Promoting Interoperability) performance categories for the transition year of MIPS (the 2017 performance period/2019 MIPS payment year) for MIPS eligible clinicians who are affected by extreme and uncontrollable circumstances affecting entire regions or locales (82 FR 53895 through 53900). In the CY 2019 PFS proposed rule (83 FR 35968), we proposed to codify this policy for the quality and improvement activities performance categories at § 414.1380(c)(2)(i)(A)(6) and for the advancing care information (now Promoting Interoperability) performance category at § 414.1380(c)(2)(i)(C)(3). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read § 414.1380(c)(2)(i)(A)(7) instead of § 414.1380(c)(2)(i)(A)(6).

A summary of the comments we received on the IFC and our responses are included below.

Comment: Many commenters supported the automatic extreme and uncontrollable circumstance policy for the 2017 MIPS performance period. Several commenters stated that the policy is appropriate given the burden these events have had on impacted MIPS eligible clinicians. Several commenters supported the flexibility afforded by this policy and noted that the policy will allow impacted MIPS eligible clinicians to focus on providing patient care during natural disasters without having to focus on MIPS reporting. Several commenters supported our policy to allow clinicians impacted by extreme and uncontrollable events to report for MIPS if they choose because commenters believe some MIPS eligible clinicians may be less impacted by natural disasters and may have interest in reporting for MIPS. One commenter supported including events that have been designated by FEMA in the automatic extreme and uncontrollable circumstance policy. Another commenter supported using the practice location listed in PECOS to determine eligibility for the automatic extreme and uncontrollable policy.

Response: We believe that the automatic extreme and uncontrollable circumstance policy is appropriate to provide relief to MIPS eligible clinicians experiencing natural disasters and will help to ensure they are able to focus on providing patient care. In the CY 2018 Quality Payment Program final rule, we noted that we anticipate the types of events that could trigger this policy would be events designated as FEMA major disasters or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis (82 FR 53897).

Comment: One commenter urged CMS to develop a clear communications plan for alerting MIPS eligible clinicians that they are eligible for the automatic extreme and uncontrollable circumstance policy.

Response: We agree that it will be important to effectively alert MIPS eligible clinicians who we determine are covered by the automatic extreme and uncontrollable circumstance policy. Similar to other CMS programs, we communicated applicability information through routine communication channels, including, but not limited to, issuing memos, emails, and notices on the QPP website, *qpp.cms.gov*.

Comment: One commenter stated that providing MIPS eligible clinicians who are impacted by extreme and uncontrollable events with a final score that is equal to the performance threshold if they report on only one performance category does not recognize their efforts for that performance category. Instead, commenter stated CMS should score the MIPS eligible clinician on that category.

Response: We continue to believe that the final score for MIPS should be a composite score. Therefore, for MIPS

eligible clinicians who are subject to the automatic extreme and uncontrollable circumstance policy, we will continue to apply our general MIPS policy codified at § 414.1380(c) that MIPS eligible clinicians who are scored on fewer than 2 performance categories receive a score equal to the performance threshold (82 FR 53958). MIPS eligible clinicians who are located in an area affected by extreme and uncontrollable circumstances who submit data for the quality performance category would also have to submit data for the Promoting Interoperability or improvement activities performance categories in order for the data submitted to contribute to their final score.

Comment: One commenter stated that scoring data that are submitted by impacted MIPS eligible clinicians is unfair because they are being assessed against MIPS eligible clinicians who were not impacted by natural disasters.

Response: Because the performance threshold is set very low (at 3 points) for the 2017 MIPS performance period, we believe that MIPS eligible clinicians who are eligible for the automatic extreme and uncontrollable circumstance policy but submit data will easily exceed the performance threshold and thus will not be negatively impacted. Furthermore, we assume that MIPS eligible clinicians who are located in an area affected by extreme and uncontrollable circumstances but then submit data for more than one performance category believe there are sufficient measures or activities applicable and available to them and would like their data to contribute to their final score.

Comment: One commenter suggested that CMS should not score Medicare Part B claims measures that are submitted by MIPS eligible clinicians impacted by extreme and uncontrollable events.

Response: If a MIPS eligible clinician reports via Medicare Part B claims for the quality performance category and we receive data prior to the extreme and uncontrollable event, their Medicare Part B claims data would only contribute to their final score if they also submit data for either the Promoting Interoperability or improvement activities performance categories. We previously finalized at § 414.1380(c) that if a MIPS eligible clinician is scored on fewer than two performance categories, he or she will receive a final score equal to the performance threshold (81 FR 77320 through 77321 and 82 FR 53778 through 53779).

Comment: One commenter suggested that CMS consider providing a positive payment adjustment for MIPS eligible clinicians who are eligible for the automatic extreme and uncontrollable circumstance policy instead of providing a neutral payment adjustment because this will help to incentivize MIPS eligible clinicians to return to affected areas.

Response: It is unclear to us how a positive payment adjustment would incentivize clinicians to return to affected areas, or how we would go about verifying whether and why they have returned, since many factors influence clinician choice in practice location.

After consideration of the public comments, we are adopting the IFC as a final rule without any modifications. We are finalizing the regulation text at § 414.1380(c)(2)(i)(A)(7) and § 414.1380(c)(2)(i)(C)(3) as proposed.

(iv) Redistributing Performance Category Weights

In the CY 2017 and CY 2018 Quality Payment Program final rules, we established policies for redistributing the weights of performance categories for the 2019 and 2020 MIPS payment years in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories (81 FR 77325 through 77329; 82 FR 53783 through 53785, 53895 through 53900). We proposed to codify these policies under § 414.1380(c)(2)(ii) (83 FR 35969).

For the 2021 MIPS payment year, we proposed at § 414.1380(c)(2)(ii)(B) to apply similar reweighting policies as finalized for the 2020 MIPS payment year (83 FR 35969). We note that we inadvertently referred to the wrong paragraph of the regulation text in the proposed rule, and the citation should have read § 414.1380(c)(2)(ii)(C) instead of § 414.1380(c)(2)(ii)(B). In general, we would redistribute the weight of a performance category or categories to the quality performance category. We stated that redistributing weight to the quality performance category is appropriate because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. We proposed to continue to redistribute the weight of the quality performance category to the improvement activities and Promoting Interoperability performance categories (83 FR 35969). However, for the 2021 MIPS payment year, based on our proposal to weight the cost performance category at 15 percent, we proposed to reweight the Promoting Interoperability performance category to 45 percent and the improvement activities performance category to 40 percent when the quality performance category is weighted at zero percent (83 FR 35969). We chose to weigh Promoting Interoperability higher in order to align with goals of interoperability and for simplicity because we generally have avoided assigning partial percentage points to performance category weights. Reweighting scenarios under the proposal are presented in Table 54.

TABLE 54: Performance Category Redistribution Policies Proposed for the 2021 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Cost	60%	0%	15%	25%
-No Promoting Interoperability	70%	15%	15%	0%
-No Quality	0%	15%	40%	45%
-No Improvement Activities	60%	15%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	50%	50%
-No Cost and no Improvement Activities	75%	0%	0%	25%
-No Promoting Interoperability and no Quality	0%	15%	85%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%

We stated that we have heard from stakeholders in previous years that our reweighting policies place undue weight on the quality performance category, and, although we continue to believe the policies are appropriate, we solicited comment on alternative redistribution policies in which we would also redistribute weight to the improvement activities performance category (see Table 55). Under the alternative redistribution policy we considered, we would redistribute the weight of the Promoting Interoperability performance category to the quality and improvement activities performance categories (83 FR 35969 through 35970). We would redistribute 15 percent of the Promoting Interoperability performance category weight to the quality performance category, and 10 percent to the improvement activities performance category. We stated that redistributing more of the weight of the Promoting Interoperability performance category to the quality performance category is appropriate because MIPS eligible clinicians have had more experience reporting on quality measures under other CMS programs than reporting on improvement activities. We would redistribute the cost performance category weight equally to the quality and improvement activities performance categories (5 percent to each) under this alternative policy.

TABLE 55: Alternative Performance Category Redistribution Policies Considered for the 2021 MIPS Payment Year

	Alternative Redistribution Policy: Reweight Promoting Interoperability and Cost to Quality and Improvement Activities			
Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	45%	15%	15%	25%
Reweight One Performance Category				
-No Promoting Interoperability	60%	15%	25%	0%
-No Cost	55%	0%	20%	25%
-No Quality	0%	15%	40%	45%
-No Improvement Activities	60%	15%	0%	25%
Reweight Two Performance Categories				
-No Cost and No Promoting Interoperability	70%	0%	30%	0%
-No Cost and no Quality	0%	0%	50%	50%
-No Cost and no Improvement Activities	75%	0%	0%	25%
-No Promoting Interoperability and no Quality	0%	15%	85%	0%
-No Promoting Interoperability and no Improvement Activities	85%	15%	0%	0%
-No Quality and no Improvement Activities	0%	15%	0%	85%

We solicited comments on the above proposals. These comments and our responses are discussed below.

Comment: A few commenters supported our proposed reweighting policies for the 2019 MIPS performance period/2021 MIPS payment year.

Response: We thank commenters for their support of our proposal.

Comment: Several commenters supported the alternative policy we considered to reweight to both quality and improvement activities, and stated our primary proposal which generally reweights to quality, places undue weight on the quality performance category. Some commenters stated that reweighting to the improvement activities performance category is appropriate given the importance of practice improvement. A few commenters stated that the quality performance category is particularly challenging, and therefore, placing additional weight on this performance category would not be fair to MIPS eligible clinicians who receive reweighting for the cost or Promoting Interoperability performance categories. A few commenters also mentioned that our reweighting policies place undue burden on small and rural practices who have particular difficulty performing well on the quality performance category. A few commenters requested that we redistribute all of the weight of the Promoting Interoperability or cost performance categories to the improvement activities performance category, in order to avoid placing undue focus on quality and due to the importance of quality improvement.

Response: We continue to believe reweighting to the quality performance category is appropriate as the quality performance category is a critical component of value-based care, and therefore, we believe performance on quality measures is important. While there is variation in performance for the quality performance category, for the improvement activities we are only assessing whether the MIPS eligible clinician completed activities. We believe that reweighting to the quality performance category will encourage MIPS eligible clinicians to report on the quality performance category due to the higher category weight (that is, a zero score for this performance category would have more significant impact), particularly those clinicians who may have only reported to the improvement activities performance category, and will minimize complexity. We believe it is important to encourage MIPS eligible clinicians to report on quality while the performance threshold is still relatively low. In regards to the concern on small and rural practice performance in the quality performance category, we note that small practices that report quality measures can receive the small practice bonus we are finalizing in section III.I.3.i.(1)(b)(viii) of this final rule and we have not seen differences in performance for rural practices. We plan to review available approaches to reweighting in future years including impact on small and rural practices and may revisit our policies to ensure they are fair and not overly complex.

Comment: One commenter disagreed with our proposal to reweight the quality performance category to the improvement activities and Promoting Interoperability performance categories, because the commenter noted concern with our discussion of available and applicable measures for the quality performance category and reweighting this category would place greater weight on other performance categories. Another commenter noted that reweighting the quality performance category may lead to MIPS eligible clinicians inaccurately receiving a positive, neutral, or negative payment adjustment.

Response: We believe reweighting to the improvement activities and Promoting Interoperability performance categories in the rare cases when the quality performance category is reweighted is appropriate because MIPS eligible clinicians have limited experience being scored on the cost performance category. We also expect the cases when a MIPS eligible clinician does not have any quality measures to be very rare.

After consideration of public comments, we are finalizing these proposals and the regulation text at § 414.1380(c)(2)(ii)(A) through (C) as proposed.

Because the cost performance category was zero percent of a MIPS eligible clinician's final score for the 2017 MIPS performance period, we stated in the CY 2019 PFS proposed rule (83 FR 35970) that it is not appropriate to redistribute weight to the cost performance category for the 2019 MIPS performance period because MIPS eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. In addition, we were concerned that there would be limited measures in the cost performance category under our proposals for the 2019 MIPS performance period and stated that it may be appropriate to delay shifting additional weight to the cost performance category until additional measures are developed. However, we also noted that cost is a critical component of the Quality Payment Program and believe placing additional emphasis on the cost performance category in future years may be appropriate. Therefore, we solicited comment on redistributing weight to the cost performance category in future years.

We thank commenters for their input and will take this input into consideration in future years.

(c) Final Score Calculation

We proposed to revise the formula at § 414.1380(c) for calculating the final score (83 FR 35970). We did not propose to continue to add the small practice bonus to the final score for the 2021 MIPS payment year and proposed to add a small practice bonus to the quality performance category score instead starting with the 2021 MIPS payment year (83 FR 35950 through 35951). Therefore, we proposed to revise the formula to omit the small practice bonus from the final score calculation beginning with the 2021 MIPS payment year (83 FR 35970). We requested public comments on this proposal.

Although we received several comments on the small practice bonus, we did not receive any comments on our proposed revisions to the formula to calculate the final score. We discuss our policy for our revised small practice bonus in the quality performance category in section III.I.3.i.(1)(b)(viii) of this final rule.

After consideration of public comments, we are finalizing our proposed revisions to § 414.1380(c) as proposed.

In the CY 2019 PFS proposed rule, we solicited comments on approaches to simplify calculation of the final score (83 FR 35970). We thank commenters for their input and will take this input into consideration in future years.

j. MIPS Payment Adjustments

(1) Final Score Used in Payment Adjustment Calculation

For our previously established policies regarding the final score used in payment adjustment calculations, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77330 through 77332) and the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787). Under our policies, for groups submitting data using the TIN identifier, we will apply the group final score to all the TIN/NPI combinations that bill under that TIN during the performance period (82 FR 53785). We proposed to modify this policy for the application of the group final score, beginning with the 2019

performance period/2021 MIPS payment year (83 FR 35971). We proposed a 15-month window that starts with the second segment of the MIPS determination period (October 1 prior to the MIPS performance period through September of the MIPS performance period) and also includes the final 3 months of the calendar year of the performance period (October 1 through December 31 of the performance period year) (83 FR 35971). We proposed for groups submitting data using the TIN identifier, we would apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the proposed 15-month window (83 FR 35971). We stated that we believe that partially aligning with the second segment of the MIPS determination period creates consistency with our eligibility policies that informs a group or eligible clinician of who is eligible. We refer readers to the CY 2019 PFS proposed rule (83 FR 35884 through 35886) where we discuss our proposals related to MIPS determination periods.

We noted that, if a MIPS eligible clinician's TIN/NPI combination was not part of the group practice during the MIPS determination period, the TIN/NPI combination would not be identified in our system at the start of the MIPS data submission period; however, if the MIPS eligible clinician qualifies to receive the group final score under our proposal, we would apply the group final score to the MIPS eligible clinician's TIN/NPI combination as soon as the information becomes available.

We solicited comments on the above proposal.

Comment: One commenter supported the concept of assigning a group score to clinicians who are in a group during the final 3 months of the calendar year of the performance period, stating that it is administratively burdensome for large organizations to track clinicians who join their practice during the last 3 months of the calendar year of the performance period and determine whether or not their previous practice intends to submit data on their behalf for the same calendar year of the performance period.

Response: We thank the commenter for their support.

Comment: One commenter expressed concern with the 15-month gap between the end of the first segment of the MIPS determination period and the end of the calendar year of the MIPS performance period for clinicians in groups who qualify for a group final score. The commenter stated that many clinicians move from one TIN to another and recommended we allow groups to report both on behalf of individual clinicians or as a group for all clinicians who have assigned their billing rights to the TIN during the calendar year of the performance period.

Response: We realize that the first segment of the MIPS determination period, as codified in this final rule at § 414.1305, ends 15 months before the end of the calendar year of the performance period; however, we believe the performance of a group should coincide, to the extent possible, with clinicians who are in the group during the performance period. Therefore, we believe it is appropriate to use the 15-month window which includes the second segment of the MIPS determination period and the last 3 months of the calendar year of the performance period. We note that group reporting is an option and practices may elect to submit for individual eligible clinicians, rather than as a group, as long as eligible clinicians are identified prior to end of the second segment of the MIPS determination period. As discussed in section III.I.3.i.(2)(b)(ii)(C) of this final rule, we do not have the ability to accept data for new group practices formed in the last 3 months of the calendar year of the performance period, or for individual MIPS eligible clinicians who switch practices in the last 3 months of the calendar year of the performance period if their new practice is not participating in MIPS as a group.

Comment: One commenter did not support the proposed 15-month window, citing the need for additional clarity and guidance to avoid complexity and confusion, and suggested that CMS provide examples of how this policy would apply in different scenarios. This commenter also recommended that CMS consider the implications of the proposal on clinician employment and how the proposal may negatively impact the ability of clinicians to switch practices.

Response: We do not agree that this proposal would cause confusion or add complexity. We believe the 15-month window aligns with our eligibility policies and better informs clinicians about their eligibility, streamlining the program. For example, for the 2019 MIPS performance period, if an eligible clinician joins a group practice in November of 2019 and that group practice existed prior to the last 3 months of the year (that is, prior to October 1, 2019) and submits MIPS data as a group, we would apply the group final score to that eligible clinician if the clinician bills under the group's TIN during the proposed 15-month window. Another example is a MIPS eligible clinician who joins a group practice in October of 2018 and that group practice submits MIPS data as a group for the 2019 MIPS performance period; for the 2019 performance period, we would apply the group final score to that eligible clinician if the clinician bills under the group's TIN during the proposed 15-month window. We appreciate the suggestion to consider the policy's implications on clinician employment and will take this into consideration in future rulemaking.

After consideration of the comments we received, we are finalizing our proposed 15-month window that starts with the second segment of the MIPS determination period (October 1 prior to the calendar year of the performance period through September 30 of the calendar year of the performance period) and also includes the final 3 months of the calendar year of the performance period (October 1 through December 31 of the calendar year of the performance period). We are also finalizing that for groups submitting data using the TIN identifier, we will apply the group final score to all of the TIN/NPI combinations that bill under that TIN during the 15-month window. We refer readers to section III.I.3.i.(2)(b)(ii)(C) of this final rule for a detailed discussion of the reweighting of the quality, cost, improvement activities and Promoting Interoperability performance categories for MIPS eligible clinicians who join a group practice in the final 3 months of the calendar year of the performance period.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of

which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

To determine a performance threshold to propose for the third year of MIPS (2019 MIPS performance period/2021 MIPS payment year), in the CY 2019 PFS proposed rule (83 FR 35971), we again relied upon the special rule in section 1848(q)(6)(D)(iii) of the Act, as amended by 51003(a)(1)(D) of the Bipartisan Budget Act of 2018. As required by section 1848(q)(6)(D)(iii) of the Act, we considered data available from a prior period with respect to performance on measures and activities that may be used under the MIPS performance categories. In accordance with newly added clause (iv) of section 1848(q)(6)(D) of the Act, we also considered which data could be used to estimate the performance threshold for the 2024 MIPS payment year to ensure a gradual and incremental transition from the performance threshold we would establish for the 2021 MIPS payment year. In the CY 2019 PFS proposed rule (83 FR 35971), we noted that we considered using the final scores for the 2017 MIPS performance period/2019 MIPS payment year; however, the data used to calculate the final scores was submitted through the first quarter of 2018, and final scores for MIPS eligible clinicians were not available in time for us to use in our analyses. We noted that if technically feasible, we would consider using the actual data used to determine the final scores for the 2019 MIPS payment year to estimate a performance threshold for the 2024 MIPS payment year in the final rule.

Because the final scores for MIPS eligible clinicians were not yet available at the time of the CY 2019 PFS proposed rule, we reviewed the data relied upon for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536) as we believed it was the best data available to us to estimate the actual data for the 2017 MIPS performance period/2019 MIPS payment year (83 FR 35971). Please refer to the CY 2019 PFS proposed rule (83 FR 35971 through 35973) for more details about the data we used.

In accordance with section 1848(q)(6)(D)(i) of the Act, the performance threshold for the 2024 MIPS payment year would be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. In the CY 2019 PFS proposed rule (83 FR 35972), we stated that when we analyzed the estimated final scores for the first year of the program (the 2019 MIPS payment year), the mean final score was between 63.50 and 68.98 points and the median was between 77.83 and 82.5 points based on the different participation assumptions. For purposes of estimating the performance threshold for the 2024 MIPS payment year, we used the mean final score based on data used for the CY 2017 Quality Payment Program final rule regulatory impact analysis (81 FR 77514 through 77536), which resulted in an estimated performance threshold between 63.50 and 68.98 points for the 2024 MIPS payment year. We noted that this is only an estimation we are providing in accordance with section 1848(q)(6)(D)(iv) of the Act, and we will propose the actual performance threshold for the 2024 MIPS payment year in future rulemaking.

We proposed a performance threshold of 30 points for the 2021 MIPS payment year to be codified at § 414.1405(b)(6) (83 FR 35972). A performance threshold of 30 points would be a modest increase over the performance threshold for the 2020 MIPS payment year (15 points), and we stated that we believe it would provide a gradual and incremental transition to the performance threshold we will establish for the 2024 MIPS payment year, which we have estimated would be between 63.50 and 68.98 points.

We stated that we want to encourage continued participation and the collection of meaningful data by MIPS eligible clinicians. A higher performance threshold would help MIPS eligible clinicians strive to achieve more complete reporting and better performance and prepare MIPS eligible clinicians for the 2024 MIPS payment year. However, a performance threshold set too high could also create a performance barrier, particularly for MIPS eligible clinicians who did not previously participate in PQRS or the EHR Incentive Programs. Additionally, we stated that we believe a modest increase from the performance threshold for the 2020 MIPS payment year would be particularly important to reduce the burden for MIPS eligible clinicians in small or solo practices. We stated that we believe that active participation of MIPS eligible clinicians in MIPS will improve the overall quality, cost, and care coordination of services provided to Medicare beneficiaries.

In the CY 2019 PFS proposed rule (83 FR 35972), we noted that we heard from stakeholders requesting that we continue a low performance threshold and from stakeholders that requested we ramp up the performance threshold to help MIPS eligible clinicians prepare for a future performance threshold of the mean or median of final scores and to meaningfully incentivize higher performance. We also noted that we heard from stakeholders who stated a higher performance threshold may incentivize higher performance by MIPS eligible clinicians through higher positive MIPS payment adjustments for those who exceed the performance threshold. We noted our belief that a performance threshold of 30 points for the 2021 MIPS payment year would provide a gradual and incremental increase from the performance threshold of 15 points for the 2020 MIPS payment year and could incentivize higher performance by MIPS eligible clinicians.

We also noted our belief that a performance threshold of 30 points represents a meaningful increase compared to 15 points, while maintaining flexibility for MIPS eligible clinicians in the pathways available to achieve this performance threshold, and we provided examples to support our belief in the CY 2019 PFS proposed rule (83 FR 35972). We invited public comment on the proposal to set the performance threshold for the 2021 MIPS payment year at 30 points (83 FR 35972). Alternatively, we considered whether the performance threshold should be set at a higher or lower number, for example, 25 points or 35 points, and also sought comment on

alternative numerical values for the performance threshold for the 2021 MIPS payment year (83 FR 35972).

We solicited comments on the above proposal.

Comment: Many commenters supported the proposed performance threshold of 30 points, indicating that the increase is reasonable; is aligned with what they believe to be Congress's intent to ensure that clinicians continue to be held accountable for quality and cost; is not a significant change from the prior year; encourages clinicians to increase their engagement and performance in MIPS; and is low enough to protect eligible clinicians who may not have experience reporting in MIPS from negative payment adjustments. One commenter stated that raising the performance threshold may help limit the flattening impact of the overall cost performance category score. One commenter stated the modest increase would not disadvantage small practices if the small practice bonus and other special scoring policies remain available to them and is reasonable considering that a fair portion of clinicians are excluded from MIPS under the low-volume threshold.

Response: We thank the commenters for their support.

Comment: Many commenters did not support the proposed performance threshold of 30 points and stated it is too high, is not gradual enough, would be unduly taxing, and many eligible clinicians are still adapting to the complexities of the MIPS program. Several commenters did not support the performance threshold citing the number of policy changes to the MIPS program and stated that group practices and clinicians, including newly eligible clinicians, should gain experience with MIPS policy changes, including changes to episode-based cost measures and the restructuring of the Promoting Interoperability performance category, before the performance threshold is raised. Several commenters recommended a performance threshold of 20 points given the number of changes being proposed. Commenters also indicated 20 points would help newly eligible clinicians adjust to program reporting requirements and that it could be met or exceeded by reporting on 6 quality measures that receive at least 3 points per measure and one high weighted improvement activity or 2 medium weighted improvement activities to avoid a negative MIPS payment adjustment. A few commenters indicated that clinicians need more time to be educated about the MIPS program.

Response: We acknowledge the concerns submitted by many commenters. We recognize that many requirements and scoring policies in the MIPS program have changed since the 2017 MIPS performance period/2019 MIPS payment year, but we believe the proposed performance threshold of 30 points is an appropriate increase that encourages increased participation and engagement in the MIPS program and that incentivizes clinicians to transition to value-based care with a focus on the delivery of high-value care.

We also do not believe that increasing the performance threshold to 30 points is unreasonable or too steep, but is rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. In the CY 2019 PFS proposed rule, we estimated the performance threshold we would establish for the 2024 MIPS payment year would be between 63.50 and 68.98 points. This information was based on year 1 estimates from the regulatory impact analysis (83 FR 35972; 81 FR 77514 through 77536). When we looked at the actual final scores for MIPS eligible clinicians for the 2017 MIPS performance period/2019 MIPS payment year, we found the mean final score was 74.01 points and the median final score was 88.97 points. As discussed in section VII.F.8.d. of the Regulatory Impact Analysis (RIA) of this final rule, we also estimated the potential final scores for the 2019 MIPS performance period/2021 MIPS payment year. In the RIA, we updated our estimates by using data submitted for the first year of MIPS (2017 MIPS performance period/2019 MIPS payment year) and applying the scoring and eligibility policies for the third year of MIPS (the 2019 MIPS performance period/2021 MIPS payment year). In the RIA, we estimated the mean final score for the 2019 performance period/2021 MIPS payment year at 69.53 points and the median final score at 78.72 points. Based on these numbers, we estimate the performance threshold that we would establish for the 2024 MIPS payment year would likely be over 65 points. We believe that if we set the performance threshold at 20 points (or another number lower than 30 points) for the 2021 MIPS payment year, then the increases in the performance threshold for each of the 2022 and 2023 MIPS payment years would have to be steeper to ensure a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year, in accordance with 1848(q)(6)(D)(iv) of the Act.

Additionally, we recognize that some policy changes, such as those finalized in this final rule for the Promoting Interoperability performance category, the impact of topped out measures on the quality performance category, the increased weighting of the cost performance category, and the introduction of episode-based cost measures may dampen final scores because it will be more difficult to achieve a perfect performance category score of 100 percent. However, we believe there are also many options for a MIPS eligible clinician, including a newly eligible clinician, to earn a final score at or above a performance threshold of 30 points that do not require a perfect score in every performance category and that these policies do not preclude a MIPS eligible clinician from performing well. For example, a MIPS eligible clinician that submits the maximum number of improvement activities (achieving 40 points out of a possible 40 points) that is weighted at 15 percent of the final score (100 percent improvement activities performance category score × 15 percent × 100 equals 15 points toward the final score) and achieves a quality performance category score of 35 percent [31] that could be achieved through a minimum of complete reporting of quality measures at varying levels of performance (35 percent quality performance category score × 45 percent × 100 equals 15.75 points toward the final score) would qualify for 30.75 points and exceed the performance threshold. When we also consider the cost and Promoting Interoperability performance categories scores, clinicians have even more options to exceed a 30-point performance threshold. While the performance threshold could be met or exceeded without clinician participation in the quality performance category, we encourage clinicians to participate in multiple performance categories, including the quality performance category, to help facilitate successful participation in MIPS when the performance threshold will be increased in future years and to align with the MIPS program's focus on value-based care and the delivery of high quality care for Medicare beneficiaries.

We agree with commenters about the need to educate clinicians, including newly eligible clinicians, about MIPS program policies and policy changes from year to year and encourage

[31] The score for the quality performance category would be (6 measure achievement points × 1 measure plus 3 measure achievement points × 5 measures)/60 total possible achievement points or 35 percent. This assumes an outcome measure is submitted. That score could be higher if the clinician qualifies for bonuses in the quality performance category.

clinicians to utilize the resources available to educate clinicians about the MIPS program at the CMS Quality Payment Program Resource library at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Resource-library.html*.

Comment: Several commenters recommended a lower performance threshold specifically for eligible clinicians in their first year of MIPS eligibility, citing that this flexibility is more equitable and allows for a greater chance of successful participation, is a reasonable approach, and that 30 points creates an unlevel playing field. A few commenters recommended 25 points and other scoring accommodations for newly eligible clinicians, including occupational therapists and physical therapists. A few commenters suggested alternative performance thresholds for newly eligible clinicians including 3 points and a modified ''pick your pace'' threshold for these clinicians. One commenter recommended a performance threshold of 20 points and stated a 30-point performance threshold is a very high standard for eligible clinicians in their first year of eligibility.

Response: As described in section III.I.3.j.(2) of this final rule, the MIPS program is still ramping up, and we will continue to increase the performance threshold to ensure a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year (year 6). Therefore, a clinician who is a MIPS eligible clinician beginning with the 2021 MIPS payment year would have 4 years in the program to ramp up to year 6. Conversely, a clinician who first becomes a MIPS eligible clinician in a later year would be afforded less time to ramp up the closer the program gets to year 6. We refer readers to section III.I.3.a. of this final rule for our discussion of new eligible clinician types.

Comment: Many commenters stated that CMS should not increase the performance threshold until there is actual MIPS participation data available to analyze and share with clinicians, indicating that there is insufficient historical MIPS data on which to set benchmarks and determine the feasibility of the current performance threshold, the program is still in its early stages, and that use of actual data would provide eligible clinicians a greater sense of how they performed in the program overall.

Response: We appreciate the commenters' concerns with the proposed performance threshold and their request for a delay in increasing the performance threshold until we have more information about how clinicians are actually performing under MIPS. As discussed earlier in this section, we estimate that we would likely set the performance threshold for the 2024 MIPS payment year at over 65 points. We did analyze the actual final scores for the 2019 MIPS payment year and found the mean final score was 74.01 points and the median final score was 88.97 points for MIPS eligible clinicians. We believe that setting the performance threshold at 30 points for the 2019 performance period/2021 MIPS payment year is appropriate because it encourages increased participation and prepares clinicians for the additional participation requirements to meet or exceed the performance thresholds that will be set for later years. Additionally, we do not believe that keeping the performance threshold at 15 points (which was the performance threshold for the 2020 MIPS payment year) would provide the gradual and incremental transition to the performance threshold for the 2024 MIPS payment year required by section 1848(q)(6)(D)(iv) of the Act.

We also note that eligible clinicians have received performance feedback based on their performance in year 1 of MIPS. As previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53801 through 53802), on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories for the 2017 performance period, and if technically feasible, for the improvement activities and advancing care information (now known as Promoting Interoperability) performance categories. For details on the release of the feedback reports for the first year of MIPS, we refer readers to section III.I.3.g. of this final rule.

Comment: Several commenters did not support the proposed performance threshold of 30 points, stating their belief that it burdens smaller practices, especially individual clinicians who are unable to afford CEHRT. A few commenters recommended that CMS consider a bonus for solo practitioners.

Response: We acknowledge the concerns of commenters regarding the potential burden on small practices, particularly solo practitioners. We also recognize the unique challenges for solo practitioners who participate in MIPS and have established a set of policies for small practices that apply to solo practitioners as well. The special policies available for small practices include the small practice bonus which is finalized in section III.I.3.i.(1)(b)(viii) of this final rule; the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule; the significant hardship exception for Promoting Interoperability performance category and the associated reweighting policies available for small practices (CY 2018 Quality Payment Program final rule (82 FR 53683)); and special scoring provisions available for the improvement activities performance category (81 FR 77185, 77188; 82 FR 53656. We also note that clinicians in small practices are more likely than clinicians in larger practices to fall below one of the low-volume criteria and would not be required to submit to MIPS; however, if they exceed at least one, but not all, of the low volume criteria, then they would be able to take advantage of the opt-in policy. We refer readers to section III.I.3.c. of this final rule for more details.

Comment: A few commenters recommended a more modest increase to the performance threshold and asked us to consider specialty-specific performance thresholds, or special scoring policies for clinicians in specialty practices, stating this would allow for more fair comparisons among clinicians. One commenter stated concerns with ambulatory surgical center-based clinicians being able to meet a 30-point threshold and requested that CMS consider scoring relief for ambulatory surgical center-based clinicians and groups. One commenter stated concerns for certified registered nurse anesthetists (CRNAs) meeting the performance threshold, citing the lack of anesthesia-related measures, low achievable points due to quality measure benchmarking, the lack of applicable cost measures, and the inability of CRNAs to participate in the Promoting Interoperability performance category that places a significant amount of time, money and resources into achieving performance scores to meet the minimum performance threshold. One commenter did not support the proposed performance threshold and believed that clinicians who are not capable of submitting data for more than one MIPS performance category could not meet the performance threshold.

Response: We appreciate the unique challenges faced by MIPS eligible clinicians that are in specialty practices, including clinicians based in ambulatory surgical centers and CRNAs. However, we believe that different performance criteria for certain types of clinicians would create more confusion and burden than a cohesive set of criteria. We also do not believe the

proposed increase in the performance threshold is overly aggressive or unfair to specialty practices and note that there are multiple pathways for clinicians, including specialty practices, to meet or exceed the performance threshold. We also believe that except for a few circumstances, such as extreme and uncontrollable circumstances, rare cases where there are no quality measures, or clinicians joining an existing practice (existing TIN) during the final 3 months of the calendar year in which the performance period occurs (the performance period year) that is not participating in MIPS as a group, most MIPS eligible clinicians would have sufficient measures and activities available and applicable to them for the quality and improvement activities performance categories and would be scored on these two categories. We also have policies in place, such as data validation process discussed in section III.I.3.i.(1)(b)(vii) of this final rule, to assess if clinicians have fewer than 6 measures available and applicable for the quality performance category. We refer the readers to the discussion of our reweighting policies for extreme and uncontrollable circumstances at section III.I.3.i.(2)(b)(ii) of this final rule.

Comment: A few commenters supported keeping a performance threshold of 15 points to minimize administrative burdens as part of the ''Patients over Paperwork'' initiative and to give clinicians adequate time to adjust their practice to meet the program's requirements.

Response: We are mindful of the efforts and requirements for eligible clinician participation in MIPS and agree that many clinicians need time to become familiar with the program's policies and requirements and gain experience with increased participation under the MIPS program. However, we do not believe that maintaining the performance threshold at 15 points for the 2019 performance period/2021 MIPS payment year appropriately encourages clinicians to actively participate in MIPS and incentivizes clinicians to transition to value-based care with a focus on the delivery of high-value care. Additionally, we do not believe that keeping the performance threshold at 15 points (which was the performance threshold for the 2020 MIPS payment year) would provide the gradual and incremental transition to the performance threshold for the 2024 MIPS payment year that the statute requires. We believe a meaningful increase to a performance threshold of 30 points maintains appropriate flexibility for clinicians to meet or exceed the performance threshold, while requiring increased participation over the level of engagement required to meet or exceed the 15-point threshold for year 2 of MIPS. We also believe the increased participation better prepares clinicians to succeed under MIPS in future years, will encourage a transition to the MIPS program's focus on value-based care, and will improve the overall quality, cost, and care coordination of services to Medicare beneficiaries.

Comment: Several commenters recommended a higher performance threshold believing that the proposed performance threshold punishes eligible clinicians who have invested time and money to achieve high MIPS performance, compromises the ability of high performers to earn the maximum payment adjustment, and dilutes program effectiveness to drive quality improvement and reduce spending growth. A few commenters recommended a performance threshold between 30 points and 60 points. One commenter recommended a performance threshold of 50 points, stating it would better reward clinicians and groups who are engaged with the program and encourage the examination of alternative payment models.

Response: The MIPS statute requires budget neutrality, and clinicians will receive a positive, negative, or neutral payment adjustment factor that is determined by their performance and the distribution of final scores across all MIPS eligible clinicians; accordingly, high performers would likely receive higher payment adjustments if fewer MIPS eligible clinicians meet or exceed the performance threshold. While a higher performance threshold provides a greater financial reward for high performers, we believe the proposal of 30 points is warranted to encourage clinician participation in MIPS and to encourage a movement toward value-based care with a focus on the delivery of high quality care. We also believe that the additional performance threshold for exceptional performance discussed later in section III.I.3.j.(3) of this final rule provides an additional financial incentive and financial reward for high performers and will continue to incentivize their exceptional performance. Moreover, we believe setting the performance threshold higher than 30 points would not provide a gradual and incremental transition to the performance threshold for the 2024 MIPS payment year, as required by the statute, but rather would result in a sharp increase over the performance threshold of 15 points for the 2020 MIPS payment year.

After consideration of the comments, we are finalizing our proposal to set the performance threshold at 30 points for the 2021 MIPS payment year as proposed. We are codifying the performance threshold for the 2021 MIPS payment year and finalizing the regulation text at § 414.1405(b)(6) as proposed.

We also solicited comment on our approach to estimating the performance threshold for the 2024 MIPS payment year, which in the CY 2019 PFS proposed rule we based on the estimated mean final score for the 2019 MIPS payment year (83 FR 35972). We were particularly interested in whether we should use the median, instead of the mean, and whether in the future we should estimate the mean or median based on the final scores for another MIPS payment year. We also solicited comment on whether establishing a path forward to a performance threshold for the 2024 MIPS payment year that provides certainty to clinicians and ensures a gradual and incremental increase from the performance threshold for the 2021 MIPS payment year to the estimated performance threshold for the 2024 MIPS payment year would be beneficial, and whether it would be beneficial for MIPS eligible clinicians to know in advance the performance threshold for the 2022 and 2023 MIPS payment years to encourage and facilitate increased clinician engagement and prepare clinicians for meeting the performance threshold for the 2024 MIPS payment year.

We thank commenters for their input on these topics and will take this input into consideration in future years.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS, an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold for the prior period described in section 1848(q)(6)(D)(i) of the Act.

Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a

final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500,000,000 of funding available for the year under section 1848(q)(6)(F)(iv) of the Act.

As we discussed in the CY 2019 PFS proposed rule (83 FR 35971), we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act, as amended by section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018, to propose a performance threshold of 30 points for the 2021 MIPS payment year. The special rule under section 1848(q)(6)(D)(iii) of the Act also applies for purposes of establishing an additional performance threshold for a year. For the 2021 MIPS payment year, we proposed to again decouple the additional performance threshold from the performance threshold (83 FR 35973 through 35974).

During the time period in which we were drafting the CY 2019 PFS proposed rule, we did not have actual MIPS final scores for a prior performance period. We noted in the CY 2019 PFS proposed rule (83 FR 35973) that if we did not decouple the additional performance threshold from the performance threshold, then we would have to set the additional performance threshold at the 25th percentile of possible final scores above the performance threshold. With a performance threshold set at 30 points, the range of total possible points above the performance threshold is 30.01 to 100 points and the 25th percentile of that range is 47.5, which is less than one-half of the possible 100 points in the MIPS final score. We stated that we do not believe it would be appropriate to lower the additional performance threshold to 47.5 points because we do not believe a final score of 47.5 points demonstrates exceptional performance by a MIPS eligible clinician, as these additional incentives should only be available to those clinicians with very high performance on the MIPS measures and activities. Therefore, we relied on the special rule under section 1848(q)(6)(D)(iii) of the Act and proposed at § 414.1405(d)(5) to set the additional performance threshold at 80 points for the 2021 MIPS payment year, which is higher than the 25th percentile of the range of the possible final scores above the performance threshold (83 FR 35973).

As required by section 1848(q)(6)(D)(iii) of the Act, we took into account the data available and the modeling described in the CY 2019 PFS proposed rule to estimate final scores for the 2021 MIPS payment year (83 FR 35973). We stated that we believed 80 points was appropriate to incentivize clinicians who have made greater strides to meaningfully participate in the MIPS program to perform at even higher levels. An additional performance threshold of 80 points would require a MIPS eligible clinician to perform well on at least two performance categories. We stated that, generally, a MIPS eligible clinician could receive a maximum score of 45 points for the quality performance category, which is below the 80-point additional performance threshold. In addition, 80 points is at a high enough level that MIPS eligible clinicians must submit data for the quality performance category to achieve this target. We noted the additional performance threshold at 80 points could increase the incentive for excellent performance while keeping the focus on quality performance.

We also stated an increase would encourage increased engagement and further incentivize clinicians whose performance meets or exceeds the additional performance threshold, recognizing that a fixed amount is available for a year under section 1848(q)(6)(F)(iv) of the Act to fund the additional MIPS payment adjustments and that the more clinicians who receive an additional MIPS payment adjustment, the lower the average clinician's additional MIPS payment adjustment will be.

For future years, we stated that we may consider additional increases to the additional performance threshold.

We solicited comments on these proposals.

Comment: Many commenters recommended the additional performance threshold remain at 70 points. Several commenters stated it would be more difficult to reach 80 points rather than 70 points because of proposed changes to the Promoting Interoperability performance category, changes to quality measures, more topped out measures, the increased weighting of the cost performance category, the introduction of episode-based cost measures, and the removal of bonus points. One commenter recommended that the additional performance threshold remain at 70 points for at least another year because clinicians are still learning to interpret their feedback reports and make adjustments to their practices accordingly. One commenter stated that clinicians in specialty practices without a significant breadth of reportable measures would be adversely affected while those specialties that do have large numbers of measures with full scoring potential would benefit and that this was unfair and would discourage high performance for those clinicians and groups within specialties. One commenter indicated that the increase may cause more clinicians to report on measures that bring more points rather than the most value to their patients and practice. Another commenter stated the increase seemed arbitrary and that clinicians who earn 70 points should be considered exceptional. One commenter stated that keeping the additional performance threshold at 70 points would allow the payment adjustment to be spread more evenly rather than to only a select few and alleviate some of the lack of positive payment adjustment incentive due to the very low 30-point performance threshold.

A few commenters stated the additional performance threshold should not be increased until information is available and data shared with clinicians from the first 2 years of the program about the number of eligible clinicians who were able to earn the additional payment adjustment, including the number of psychiatrists who exceeded the additional performance threshold during the 2017 MIPS performance period.

Response: We note that many commenters recommended that we maintain 70 points for the additional performance threshold for the 2019 performance period/2021 MIPS payment year. However, we believe for year 3 it is appropriate to raise the bar on what is rewarded as exceptional performance and that increasing the additional performance threshold will encourage clinicians to increase their focus on value-based care and enhance the delivery of high quality care for Medicare beneficiaries. Based on our current data, our belief that raising the additional performance threshold will incentivize continued improved performance, and our concern that policy changes may make it challenging for clinicians to reach an additional performance threshold of 80 points while they are becoming familiar and comfortable with the policy changes, we believe it is important to raise the additional performance threshold, but by less than the original amount proposed. Therefore, for year 3 of the MIPS program, we are finalizing the additional performance threshold at 75 points, which is halfway between our proposal of 80 points and the level recommended by many commenters of 70 points.

We appreciate commenters' concerns about the proposed policy changes for MIPS impacting clinicians' ability to exceed the additional performance threshold. While we recognize that some of the policy changes being

finalized in this rule, including new scoring policies for the Promoting Interoperability performance category, changes to quality measures, the identification of more topped out measures, the increased weighting of the cost performance category, and the introduction of episode-based cost measures, may make it more challenging for clinicians to achieve higher scores while they are becoming more familiar and comfortable with these new policies, we also believe these policy changes help simplify and streamline the MIPS program and reduce overall burden after an initial adjustment period. Thus, we believe it is appropriate to slightly increase the additional performance threshold for year 3 and will consider raising it more in future years.

In addition, despite these changes, we believe that 75 points is achievable for many clinicians. Based on our most current data, we estimated for the 2019 performance period/2021 MIPS payment year a mean final score of 69.53 points and a median final score of 78.72 points as discussed elsewhere in this section and in section VII.F.8.d. of the RIA of this final rule. We also believe a modest increase above the additional performance threshold for the 2018 MIPS performance period/2020 MIPS payment year would result in an additional performance threshold that is attainable and that would allow for multiple pathways for clinicians, including clinicians in specialty practices whose choice of applicable and available measures will likely vary according to specialty, to perform exceptionally well and would encourage higher performance by clinicians for year 3 of the MIPS program.

We acknowledge that the number of quality measures available to clinicians can vary by specialty and practice. We believe our quality performance category scoring validation policy accounts for certain instances where clinicians have less than 6 measure available. We believe these adjustments allow us to develop a fair comparison across different MIPS eligible clinicians and would not preclude clinicians from reaching the final additional performance threshold.

We also note that we have shared performance feedback with clinicians and groups based on their performance in year 1 of MIPS and recognize that clinicians may make adjustments to their clinical practice in response to that feedback, and because we are trying to balance that year 3 is a transition year with the goal of encouraging clinicians to improve their performance and to deliver value-based, high quality care, we believe that a moderate increase to 75 points is appropriate.

Comment: Many commenters supported the proposal to increase the additional performance threshold for exceptional performance to 80 points for the 2021 MIPS payment year and stated it encourages strong performance from clinicians and health systems, supports continuous performance improvement, motivates and holds clinicians accountable to deliver quality care, creates a competitive playing field for high performers, rewards clinicians who have invested time and resources and have demonstrated success under MIPS performance standards, seems reasonable, and is an appropriate increase for year 3 of the program. One commenter supported the proposal because it ensures clinicians are considering both cost and quality. One commenter stated that raising the threshold may help with flattening the overall cost performance score. One commenter supported the proposal because it is high enough to identify exceptional scores, but was uncertain if it would translate into improved patient outcomes or would meet CMS objectives. One commenter supported the proposal should CMS continue its policies that provide bonus points in the MIPS program and allow for claims-based reporting.

Response: We received many comments in support of our proposal for an additional performance threshold of 80 points. We agree with the commenters that raising the performance threshold encourages strong clinician performance, participation in multiple performance categories, and continuous performance improvement; provides an appropriate financial reward for high performers; and promotes a focus on the delivery of high quality, value-based care by clinicians.

We also note that there were many commenters recommending that the additional performance threshold remain at 70 points and other commenters recommending 75 points. We have considered the totality of the comments and are swayed by the comments requesting a more modest increase to the additional performance threshold. We have also considered the updated regulatory impact analysis which incorporates Quality Payment Program year 1 data to estimate performance for the 2019 performance period/2021 MIPS payment year in section VII.F.8.d. of this final rule and found a mean score of 69.53 points and a median final score of 78.72 points. Given these findings, we believe that a small decrease from the proposed additional performance threshold of 80 points that would fall between the mean and the median would help the additional performance threshold remain attainable and would allow for a larger number of clinicians to receive the additional payment adjustment.

We also believe an increase in the additional performance threshold would incentivize clinicians to increase their focus on value-based care with an emphasis on the delivery of high quality care for patients, but that an increase of 10 points is too steep, and thus, are finalizing an additional performance threshold of 75 points that is midway between our original proposal of 80 points and the additional performance threshold for the 2018 MIPS performance period/2020 MIPS payment year of 70 points.

Comment: A few commenters stated an increase to 80 points would disproportionately impact small practices and make it difficult for them to participate successfully in the MIPS program. One commenter recommended CMS should not increase the additional performance threshold until data was available to consider the impact on small practices and then set a fair threshold.

Response: We recognize the unique challenges to eligible clinicians in small practices participating in MIPS and believe the special policies for small practices provide some relief for small practices seeking to perform well. We refer readers to special policies for small practices including: The small practice bonus which is finalized in section III.I.3.i.(1)(b)(viii) of this final rule; the significant hardship exception for the Promoting Interoperability performance category available for small practices (CY 2018 Quality Payment Program final rule 82 FR 53683); the special scoring provisions available for the improvement activities performance category (81 FR 77185, 77188; 82 FR 53656); and the provisions related to the assignment of 3 points for measures that do not meet data completeness criteria which are finalized in section III.I.3.i.(1)(b)(v) of this final rule). We also note that small practices are more likely than larger practices to fall below one or more of the provisions related to the low-volume threshold and would be able to take advantage of the opt-in policy and refer readers to a discussion of the low-volume threshold at section III.I.3.c. of this final rule.

We also analyzed the data referenced in section VII.F.8.d. of the RIA of this final rule, and found that more small practices than larger practices may find it harder to meet or exceed the additional performance threshold. We

agree with commenters referenced here and elsewhere in this section that an additional performance threshold of 80 points is too steep of an increase from 70 points, but we believe that an increase is appropriate for year 3 and that the current policies that provide flexibilities for small practice provide a pathway for a successful transition for clinicians who have made a commitment toward value and the delivery of high quality care in the MIPS program. Based on these competing concerns, as noted above, we are finalizing an additional performance threshold of 75 points.

We also note that the additional performance threshold rewards exceptional performance in the MIPS program and a clinician could successfully participate in MIPS by meeting or exceeding the performance threshold and receive a neutral or positive payment adjustment.

Comment: A few commenters recommended 75 points because it is a more modest, 5-point increase from the previous performance threshold of 70 points. One commenter supported 75 points believing the increase seems fair because the threshold is more attainable for many eligible clinicians who are specialists, such as those practicing interventional pain management, who may have difficulty identifying relevant measures that improve patient quality of care. One commenter supported 75 points should CMS finalize its proposal to remove claims-based reporting and finalize its proposal to remove bonus points for improvement activities completed using CEHRT.

Response: We agree with an additional performance threshold of 75 points. We believe for year 3 it is appropriate to raise the bar on what is rewarded as exceptional performance and that increasing the additional performance threshold will encourage clinicians to increase their focus on value-based care and promote the delivery of high quality care for patients. We also believe that a more modest increase of 5 points, rather than an increase of 10 points, over the additional performance threshold for year 2 is appropriate because year 3 is still a transition year and we want to encourage increased clinician engagement and increased performance in the MIPS program that drives toward the delivery of value-based, high quality care for Medicare beneficiaries. We also note that some commenters stated that the proposed 10-point increase may have unintended consequences especially because of the impact that proposed policy changes could have on final scores as clinicians are becoming familiar with these changes. We want to reward exceptional performance that, given the impact of the policy changes in this final rule, could be less than 80 points. As such, we are swayed by comments that an increase to 75 points is more modest and a reasonable half-way point that still would raise the bar on what is rewarded as exceptional performance for the 2019 MIPS performance period.

We note that a lower additional performance threshold could reduce the maximum additional payment adjustment that a MIPS eligible clinician could potentially receive if the funds available (up to $500 million for the year) are distributed over more clinicians that score above the lower additional performance threshold. For the reasons discussed above, we believe 75 points is appropriate for year 3 and note that the additional performance threshold will be raised in future years.

Comment: A few commenters recommended a higher additional performance threshold for exceptional performers. One commenter recommended an additional performance threshold of 85 points to further efforts to engage clinicians and groups through financial incentives tied to metric performance. One commenter recommended a steeper scale for awarding exceptional performance for scores of 90 points or greater.

Response: We believe that a steeper increase in the additional performance threshold is not appropriate given that MIPS is still in a transition period and because of the MIPS policy changes we are making in this final rule that include scoring changes to the Promoting Interoperability performance category and the addition of episode-based cost measures to the cost performance category, that could impact final scores for year 3 of the MIPS program as eligible clinicians become more familiar and comfortable with these policy changes. We want to reward exceptional performance that, given the impact of our policy changes in this final rule, could include performance below 85 or 90 points, particularly for small practices which may not have sufficient case minimum to achieve maximum quality performance category score. We recognize a higher additional performance threshold will allow for a higher financial reward for high performers, but we want to encourage participation with wider availability of this funding.

Comment: One commenter recommended that CMS increase the thresholds in the CY 2020 performance period and going forward because higher thresholds will result in a wider array of payment adjustments, thereby encouraging more participation and rewarding those that invest in improving their quality of care.

Response: We thank the commenter for the input and will take this comment into consideration in future rule-making.

After consideration of the comments, we are not finalizing our proposal of 80 points for the additional performance threshold and instead are finalizing 75 points for the additional performance threshold for the 2021 MIPS payment year. We are codifying the additional performance threshold for the 2021 MIPS payment year and finalizing the proposed regulation text at § 414.1405(d)(5) with modification to reflect 75 points instead of 80 points.

(4) Application of the MIPS Payment Adjustment Factors

(a) Application to the Medicare Paid Amount for Covered Professional Services

In the CY 2018 Quality Payment Program final rule (82 FR 53795), we finalized the application of the MIPS payment adjustment factor, and if applicable, the additional MIPS payment adjustment factor, to the Medicare paid amount for items and services paid under Part B and furnished by the MIPS eligible clinician during the year. Sections 51003(a)(1)(A)(i) and 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 amended sections 1848(q)(1)(B) and 1848(q)(6)(E) of the Act, respectively, by replacing the references to ''items and services'' with ''covered professional services'' (as defined in section 1848(k)(3)(A) of the Act). Covered professional services as defined in section 1848(k)(3)(A) of the Act are those services for which payment is made under, or is based on, the Medicare PFS and which are furnished by an eligible professional. As a result of these changes, the MIPS payment adjustment factor determined under section 1848(q)(6)(A), and as applicable, the additional MIPS payment adjustment factor determined under section 1848(q)(6)(C) of the Act, will be applied to Part B payments for covered professional services furnished by a MIPS eligible clinician during a year beginning with the 2019 MIPS payment year and not to Part B payments for other items and services.

To conform with these amendments to the statute, we proposed to revise § 414.1405(e) to apply the MIPS payment adjustment factor and, if applicable, the additional MIPS payment adjustment factor, to the

Medicare Part B paid amount for covered professional services furnished by a MIPS eligible clinician during a MIPS payment year (beginning with 2019) (83 FR 35973 through 35974). We also *proposed* to revise § 414.1405(e) to specify the formula for applying these adjustment factors in a manner that more closely tracks the statutory formula under section 1848(q)(6)(E) of the Act (83 FR 35973 through 35974). Specifically, we proposed the following formula: In the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of: The MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100 (83 FR 35974).

We did not receive any comments on this proposal.

We are finalizing our proposed changes to the regulation text at § 414.1405(e) as proposed. We also refer readers to section III.I.3.a. of this final rule where we discuss the covered professional services to which the MIPS payment adjustment could be applied. We also refer readers to section III.I.3.c.(3) of this final rule where we discuss other conforming edits to the regulation text at §§ 414.1310(a), 414.1310(b), and 414.1310(d) that specify the circumstances when the MIPS payment adjustment would not apply to payments for covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) Application for Non-Assigned Claims for Non-Participating Clinicians

In the CY 2018 Quality Payment Program final rule, we did not address the application of the MIPS payment adjustment for non-assigned claims for non-participating clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53795), we responded to a comment requesting guidance on how the MIPS payment adjustment and the calculation of the Medicare limiting charge amount would be applied for non-participating clinicians, and we stated our intention to address these issues in future rulemaking. Beginning with the 2019 MIPS payment year, we proposed that the MIPS payment adjustment does not apply for non-assigned claims for non-participating clinicians (83 FR 35974). This approach is consistent with the policy for application of the value modifier that was finalized in the CY 2015 PFS final rule (79 FR 67950 through 67951). Sections 1848(q)(6)(A) and 1848(q)(6)(C) of the Act require that we specify a MIPS payment adjustment factor, and if applicable, an additional MIPS payment adjustment factor for each MIPS eligible clinician, and section 1848(q)(6)(E) of the Act (as amended by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018) requires that these payment adjustment factor(s) be applied to adjust the amount otherwise paid under Part B for covered professional services furnished by the MIPS eligible clinician during the MIPS payment year. When non-participating clinicians choose not to accept assignment for a claim, Medicare makes payment directly to the beneficiary, and the clinician collects payment from the beneficiary. This is referred to as a non-assigned claim. Application of the MIPS payment adjustment to these non-assigned claims would not affect payment to the MIPS eligible clinician. Rather, it would only affect Medicare payment to the beneficiary. If the MIPS payment adjustment were to be applied to non-assigned services, then the Medicare payment to a beneficiary would be increased when the MIPS payment adjustment is positive and decreased when the MIPS payment adjustment is negative. Although the statute does not directly address this situation, it does suggest that the MIPS payment adjustment is directed toward payment to the MIPS eligible clinician and the covered professional services they furnish. We continue to believe that it is important that beneficiary liability not be affected by the MIPS payment adjustment and that the MIPS payment adjustment should be applied to the amount that Medicare pays to MIPS eligible clinicians.

On that basis, we proposed to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year (83 FR 35974). We do not expect this proposal would be likely to affect a clinician's decision to participate in Medicare or to otherwise accept assignment for a particular claim, but we solicited comment on whether stakeholders and others believe clinician behavior would change as a result of this policy.

We solicited comments on the above proposal.

Comment: A few commenters supported the proposal to apply the adjustment to claims that are billed and paid on an assignment-related basis and not to any non-assigned claims.

Response: We thank the commenters for their support.

Comment: One commenter recommended that this policy be revisited in the next year and evaluated for unintended consequences, including whether there are any adverse effects on Medicare beneficiaries who see a non-participating clinician who does not accept assignment for a claim.

Response: We thank the commenter for the input and will take this comment into consideration in future rulemaking.

After consideration of the comments, we are finalizing our proposal to apply the MIPS payment adjustment to claims that are billed and paid on an assignment-related basis, and not to any non-assigned claims, beginning with the 2019 MIPS payment year.

(c) Waiver of the Requirement To Apply the MIPS Payment Adjustment Factors to Certain Payments in Models Tested Under Section 1115A of the Act

(i) Overview

CMS tests models under section 1115A of the Act that may include model-specific payments made only to model participants under the terms of the model and not to any other providers of services or suppliers. Some of these model-specific payments may be considered payments for covered professional services furnished by a MIPS eligible clinician, meaning that the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) applied under § 414.1405(e) of our regulations would normally apply to those payments.

(ii) Summary of Proposals and Comments Received

Section 1115A(d)(1) of the Act authorizes the Secretary to waive requirements of Title XVIII of the Act (and certain other requirements) as may be necessary solely for the purposes of testing models under section 1115A. We stated in the proposed rule (83 FR 35974 through 35975) that we believe it is necessary to waive the requirement to apply the MIPS payment adjustment factors to a model-specific payment or payments (to the extent such a payment or payments are subject to the requirement to apply the MIPS payment adjustment factors) for purposes of testing a section 1115A model under which such model-specific payment or payments are made in a specified payment amount (for example, $160 per-beneficiary, per-month); or paid according to a methodology for calculating a model-specific payment

that is applied in a consistent manner to all model participants. In both cases, applying the MIPS payment adjustment factors to these model-specific payments would introduce variation in the amounts of model-specific payments paid across model participants, which could compromise the model test and the evaluation thereof.

We proposed to amend § 414.1405 to add a new paragraph (f) to specify that the MIPS payment adjustment factors applied under § 414.1405(e) would not apply to certain model-specific payments as described above for the duration of a section 1115A model's testing beginning in the 2019 MIPS payment year (83 FR 35974 through 35975). We proposed to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e) specifically for these types of payments because the waiver is necessary solely for purposes of testing models that involve such payments (83 FR 35974 through 35975). To illustrate how the proposed waiver would apply, and to provide notice regarding one model-specific payment to which this proposed waiver would apply, we included an example in the proposed rule involving the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM) (83 FR 35975).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported our proposal to waive the application of the MIPS payment adjustment factors to certain model-specific payments. The commenters agreed that these waivers are necessary to test models that would involve these types of model-specific payments, and without such waivers the evaluation of certain models could be compromised.

Response: We appreciate the commenters' support.

Comment: One commenter noted that the proposed amendment at § 414.1405(f) is ambiguous as to whether paragraphs (l), (2), and (3) refer to three different classes of payments, or to one class of payments that meet all three conditions. The commenter suggested that we clarify our intended policy.

Response: We clarify that only payments meeting all three conditions set forth at § 414.1405(f) will qualify for the waiver of the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e). We have amended § 414.1405(f) to specify that payments must meet all three conditions to reduce any potential ambiguity, and made further amendments to § 414.1405(f) for greater clarity and readability and to more closely align with the policy described in the preamble text of the proposed rule, including to clarify that the regulatory text in § 414.1405(f)(3) refers to payments made in a consistent manner to all model participants, including those participants subject to the MIPS payment adjustment factors and participants not subject to the MIPS payment adjustment factors.

After considering public comments, we are finalizing our proposal to use the authority under section 1115A(d)(1) of the Act to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)(6)(E) of the Act and § 414.1405(e) specifically for payments specified at § 414.1405(f) with the clarifying amendments described herein. As discussed in the CY 2019 PFS proposed rule (83 FR 35975), one model-specific payment to which this finalized waiver will apply is the Monthly Enhanced Oncology Services (MEOS) payment in the Oncology Care Model (OCM). The duration of this waiver will begin with the 2019 MIPS payment year and continue for the duration of OCM.

We proposed to provide the public with notice that this proposed new regulation applies to model-specific payments that the Innovation Center elects to test in the future in two ways: first, we would update the Quality Payment Program website (*www.qpp.cms.gov*) when new model-specific payments subject to this proposed waiver are announced; and second, we would provide a notice in the **Federal Register** to update the public on any new model-specific payments to which this waiver would apply (83 FR 35974 through 35975).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter urged CMS to denote which models and model specific payments are subject to this new policy on the Quality Payment Program website and **Federal Register** as soon as possible.

Response: We plan to provide the public with notice as soon as practicable for model-specific payments subject to this waiver via the Quality Payment Program website (*www.qpp.cms.gov*), and separate notice in the **Federal Register**.

After considering public comments, we are finalizing our policy as proposed to provide the public with notice in the following two ways: (1) We will update the Quality Payment Program website (*www.qpp.cms.gov*) when new model-specific payments subject to this waiver are announced; and (2) we will provide a notice in the **Federal Register** to update the public on any new model-specific payments to which this waiver will apply.

(d) CY 2018 Exclusion of MIPS Eligible Clinicians Participating in the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration

(i) Overview

In conjunction with releasing the CY 2019 PFS proposed rule, CMS announced the Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration, established by CMS using our demonstration authority under section 402 of the Social Security Amendments of 1967 (as amended). The MAQI Demonstration is designed to test whether excluding MIPS eligible clinicians who participate to a sufficient degree in certain payment arrangements with Medicare Advantage Organizations (MAOs) from the MIPS reporting requirements and payment adjustments will increase or maintain participation in payment arrangements similar to Advanced APMs with MAOs and change the manner in which clinicians deliver care.

(ii) Summary of Proposals

We proposed to use the authority in section 402(b) of the Social Security Amendments of 1967 (as amended) to waive requirements of section 1848(q)(6)(E) of the Act and the regulations implementing it in order to waive the payment consequences (positive, negative or neutral adjustments) of the MIPS and to waive the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. We noted, relating to our proposal to waive payment consequences, that the Demonstration would have the effect of removing MIPS eligible clinicians from the population across which positive and negative payment adjustments are calculated under MIPS, and because of the requirement to ensure budget neutrality with regard to the MIPS payment adjustments under section 1848(q)(6)(F)(ii) of the Act, the Demonstration may affect the payment

adjustments for other MIPS eligible clinicians.

We proposed that these waivers would be applicable for a MIPS eligible clinician participating in the Demonstration if they meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, and that these thresholds would match the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program. We also proposed to calculate thresholds based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement. For purposes of the Demonstration, we proposed to make determinations about clinicians' Qualifying Payment Arrangements with MAOs, consistent with the criteria used for Other Payer Advanced APMs under the Quality Payment Program and as set forth in § 414.1420. We proposed to begin the MAQI Demonstration in CY 2018, with the 2018 Performance Period, and operate the project for a total of 5 years.

We also noted in the proposed rule that, for eligible clinicians who are excluded from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration, we would waive the provision in section 1848(q)(1)(A)(iii) of the Act requiring that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities. We clarify that, with this waiver, the Demonstration will prohibit voluntary reporting under the MIPS by eligible clinicians who participate in the Demonstration and are not subject to the MIPS reporting requirements and payment adjustment for a given year. This last waiver is intended to prevent potential gaming in the form of an eligible clinician intentionally submitting data showing poor performance for a year for which they are not subject to the MIPS reporting requirements and payment adjustment pursuant to the terms of the Demonstration in order to show improvement in their performance in future years when that improvement could result in higher MIPS scoring.

(iii) Applicable Waivers

Section 402(b) of the Social Security Amendments of 1967 (as amended) authorizes the Secretary to waive requirements of Title XVIII that relate to payment and reimbursement in order to carry out demonstrations under section 402(a). We proposed to use this authority to waive certain requirements of section 1848(q) of the Act and the regulations implementing it, specifically the payment consequences (positive, negative or neutral adjustments) of the MIPS and the associated MIPS reporting requirements in 42 CFR part 414 (adopted to implement the payment consequences), subject to conditions outlined in the Demonstration.

We solicited comment on these proposals.

The following is a summary of the public comments, relating to proposed waivers, received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to use demonstration waiver authority (under section 402 of the Social Security Amendments of 1967 (as amended)) to test the MAQI Demonstration.

Response: We appreciate the commenters' support of the MAQI Demonstration.

Comment: Many commenters urged CMS to use its waiver authority in the MAQI Demonstration to allow another path towards QP status and provide eligible clinicians with the 5 percent incentive payment offered to QPs.

Response: Demonstration projects under the authority of section 402(a)(1)(A) of the Social Security Amendments of 1967 are intended to test whether changes in payment or reimbursement will increase the efficiency or economy of health care services. Our actuarial analyses determined that a demonstration design that would grant QP status, including a 5 percent incentive payment, to eligible clinicians who met the thresholds would have introduced a significant level of new costs to CMS, without adequate evidence for realizing an equal amount of savings from the proposed interventions. Without a basis to believe that the economy or efficiency of health care services would be increased, we do not believe that it is appropriate to design a demonstration with such parameters. Considering that the proposed exclusions from MIPS reporting and payment consequences under the MAQI Demonstration are not anticipated to have a net cost to CMS, we plan to test whether these exclusions will increase or maintain clinician participation in payment arrangements with MAOs that are similar to Advanced APMs and change the manner in which clinicians deliver care. This test is consistent with the standards set forth in section 402(a)(1)(A) of the Social Security Amendments of 1967.

Comment: Some commenters urged CMS to monitor the impact of the Demonstration on MIPS payment adjustments, including one commenter that expressed concern that the MIPS-eligible population pool would be reduced and another commenter that expressed concern about whether the potential benefits being tested under the MAQI Demonstration outweigh any potential impacts on the level of MIPS payment adjustments.

Response: We agree that it will be important to monitor the impact of the Demonstration on payments received by MIPS eligible clinicians to whom the waivers do not apply, but we note that it may be challenging to draw significant conclusions from such monitoring as there are many variables that may impact and influence a clinician's final MIPS payment adjustment. We plan to share information on participation levels in the MAQI Demonstration with the public as soon as this information is available.

Comment: A few commenters commended CMS on starting the MAQI Demonstration in 2018, while a few commenters advised CMS to clarify the timeline associated with a CY 2018 implementation of the Demonstration and when determinations would be made under the Demonstration to identify participating eligible clinicians who are excluded from the MIPS reporting requirements and payment adjustments.

Response: We appreciate certain commenters' support for beginning the Demonstration in CY 2018, and note that by doing so, clinicians that meet threshold levels of participation in Qualifying Payment Arrangements with MAOs in 2018 can be considered for exclusion from the MIPS reporting requirements and payment adjustment under the Demonstration a year before participation in such Qualifying Payment Arrangements could be considered under the All-Payer Combination Option. We anticipate collecting Qualifying Payment Arrangement and threshold information for eligible clinicians participating in the Demonstration starting in late fall of 2018, and making final CMS determinations on whether eligible clinicians meet the criteria to be excluded from the MIPS reporting requirements and payment adjustment, based on this submitted information, by December 2018 or (January 2019 at the latest). We note that eligible clinicians participating in the MAQI Demonstration in 2018 will be evaluated to determine whether they meet the criteria to be excluded from MIPS reporting requirements for the 2018 MIPS performance year, and from the

MIPS payment adjustment for the corresponding 2020 MIPS payment year.

Comment: Some commenters recommended that CMS make changes to the Demonstration criteria relating to clinician eligibility for the exclusion from the MIPS reporting requirements and payment adjustment, such as Qualifying Payment Arrangements and thresholds.

Response: As noted in the proposed rule, we intend to use criteria and requirements that are consistent with the Medicare and Other Payer Advanced APM Options under the Quality Payment Program. Changing the clinician eligibility for exclusion from the MIPS reporting requirements and payment adjustment would not be consistent with this intent.

We also received comments on other provisions associated with the Demonstration.

Comment: Some commenters advised CMS to make changes to the Demonstration application and data collection process.

Response: The application and data collection process are outside the scope of the proposals in the CY 2019 PFS proposed rule; however, we will seek to balance reporting burden with the need to solicit information necessary to ensure that the demonstration is being implemented, tested and evaluated appropriately.

Comment: A few commenters requested additional agency focus in helping physicians and practices better understand their options under Medicare, Medicare Advantage, the Quality Payment Program, the MAQI Demonstration and other value-based payment arrangements.

Response: We are committed to reaching our stakeholders, including clinicians, the technology community, private payers, and beneficiaries, to raise awareness that Medicare is evolving quickly to a value-based system. In addition to raising awareness that change is occurring, we will continue current efforts to engage in a learning process with stakeholders where they may voice opinions and suggestions to help collaboratively drive the goals of the Quality Payment Program. We will continue to set expectations that this will be an iterative process, and, while change will not happen overnight, we are committed to continuing our work to improve how Medicare pays for quality and value, instead of the quantity of services. We will continue to reach out to the clinician community and others to partner in the development of ongoing education, support, and technical assistance materials and activities to help clinicians understand program and model requirements, how to use available tools to enhance their practices, improve quality, reduce expenditures, and progress to participation in Advanced APMs if that is the best choice for their practice.

We are offering support in the form of fact sheets, webinars, online courses, and direct technical assistance to help clinicians successfully participate in the Quality Payment Program, the MIPS or the Advanced APM track. This range of support to help clinician practices actively participate in the Quality Payment Program that can be found at the following website at *https://qpp.cms.gov/*.

We also discussed that the Demonstration would waive the provision in section 1848(q)(1)(A)(iii) of the Act that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities, so that the Demonstration would prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds to be excluded from the MIPS reporting requirements and payment adjustment for a given year. We did not receive any comments on this proposal. We explained that this waiver is necessary to prevent the potential gaming opportunity wherein participating clinicians could intentionally report artificially poor performance under the MIPS for years in which they receive waivers from MIPS payment consequences, then receive artificially inflated quality improvement points under MIPS in later years when they do not receive waivers from MIPS payment consequences. We note here that by prohibiting reporting under MIPS we are also, in effect, disallowing MIPS performance feedback for those clinicians who participate in the Demonstration and meet the criteria to be excluded from the MIPS reporting requirements and payment adjustments. Eligible clinicians who participate in the Demonstration but are not excluded from the MIPS reporting requirements and payment adjustment (whether through participation in the Demonstration or otherwise) would continue to be MIPS eligible clinicians who are subject to the MIPS reporting requirements and payment adjustment as usual.

(iv) Summary of Finalized Policies

After considering public comments, we are finalizing our proposals to implement the MAQI Demonstration in CY 2018 and use the authority in section 402(b) of the Social Security Amendments of 1967 (as amended) to waive certain requirements of section 1848(q)(6)(E) of the Act, specifically the payment consequences (positive, negative or neutral adjustments) of the MIPS and the associated MIPS reporting requirements in 42 CFR part 414 adopted to implement the payment consequences, subject to conditions outlined in the Demonstration. We are also finalizing that we will waive the provision in section 1848(q)(1)(A)(iii) of the Act that the Secretary shall permit any eligible clinician to voluntarily report on applicable measures and activities, so that the Demonstration will prohibit reporting under the MIPS by eligible clinicians who participate in the Demonstration and meet the thresholds that will trigger application of the waivers from the MIPS reporting requirements and payment adjustment for a given year. Related to this waiver of the last sentence of section 1848(q)(1)(A)(iii) of the Act, MAQI Participants who are not subject to the MIPS reporting requirements and payment adjustments will therefore not receive MIPS performance feedback under section 1848(q)(12) of the Act.

In addition, we are also announcing our final policies that, under the waivers identified previously: (1) Eligibility for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration will be determined using thresholds of combined participation in Qualifying Payment Arrangements and Advanced APMs that are the same as the QP thresholds under the Medicare Option of the Quality Payment Program codified at § 414.1430(a); and (2) Qualifying Payment Arrangements under the MAQI Demonstration will be identified using criteria consistent with those used to identify Other Payer Advanced APMs codified at § 414.1420. To qualify for exclusion from the MIPS reporting requirements and payment adjustment under the MAQI Demonstration, a MAQI participating clinician must meet combined thresholds for Medicare payments or patients through Qualifying Payment Arrangements with MAOs and Advanced APMs, using Demonstration thresholds that match the thresholds for participation in Advanced APMs under the Medicare Option of the Quality Payment Program, and based on aggregate participation in Advanced APMs and Qualifying Payment Arrangements with MAOs, without applying a specific minimum threshold to participation in either type of payment arrangement.

(e) Example of Adjustment Factors

In the CY 2019 PFS proposed rule (83 FR 35978 through 35981), we provided a figure and several tables as illustrative examples of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2021 MIPS payment year. We updated the figure and tables based on the policies we are adopting in this final rule, as follows.

Figure 3 provides an example of how various final scores would be converted to a MIPS payment adjustment factor, and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on the policies adopted in this final rule for the 2021 MIPS payment year. In Figure 3, the performance threshold is 30 points. The applicable percentage is 7 percent for the 2021 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 7 percent for the 2021 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First, there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 7.5 points based on the performance threshold of 30 points for the 2021 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 7 percent for the 2021 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 7 percent. If the scaling factor is above 1.0, but less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be higher than 7 percent.

Only those MIPS eligible clinicians with a final score equal to 30 points (which is the performance threshold in this example) would receive a neutral MIPS payment adjustment. Because the performance threshold is 30 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 7 percent.

Figure 3 illustrates an example of the slope of the line for the linear adjustments and has been updated from prior rules, but it could change considerably as new information becomes available. In this example, the scaling factor for the MIPS payment adjustment factor is 0.159. In this example, MIPS eligible clinicians with a final score equal to 100 would have a MIPS payment adjustment factor of 1.11 percent (7 percent $\times$ 0.159). (Note that this is prior to adding the additional payment adjustment for exceptional performance, which is explained below.)

The additional performance threshold is 75 points. An additional MIPS payment adjustment factor of 0.5 percent starts at the additional performance threshold and increases on a linear sliding scale up to 10 percent. This linear sliding scale line is also multiplied by a scaling factor that is greater than zero and less than or equal to 1.0. The scaling factor will be determined so that the estimated aggregate increase in payments associated with the application of the additional MIPS payment adjustment factors is equal to $500,000,000. In Figure 3, the example scaling factor for the additional MIPS payment adjustment factor is 0.358. Therefore, MIPS eligible clinicians with a final score of 100 would have an additional MIPS payment adjustment factor of 3.58 percent (10 percent $\times$ 0.358). The total adjustment for a MIPS eligible clinician with a final score equal to 100 would be 1 + 0.0111 + 0.0358 = 1.0469, for a total positive MIPS payment adjustment of 4.69 percent.

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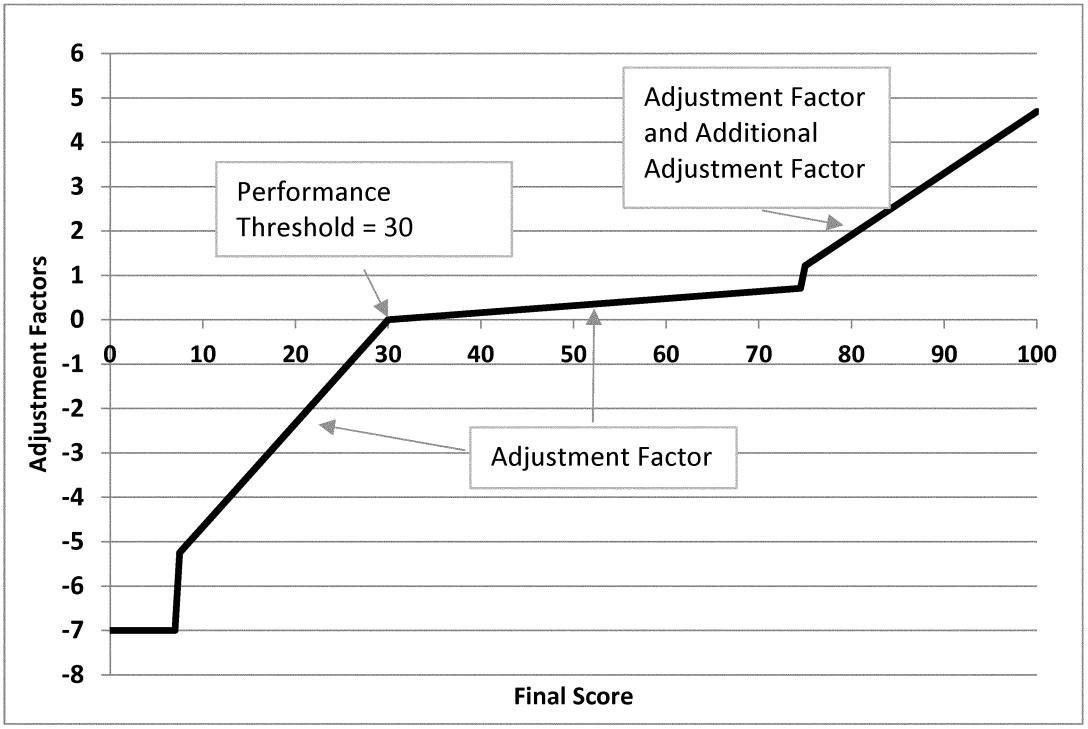
FIGURE 3: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2021 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustrative. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 7 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is intended to ensure budget neutrality, but cannot be higher than 3.0. MIPS clinicians with a final score of at least 75 points would also receive an additional adjustment factor for exceptional performance. The additional adjustment factor is also illustrative. The additional adjustment factor starts at 0.5 percent and cannot exceed 10 percent and is also multiplied by a scaling factor that is greater than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustrative as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

The final MIPS payment adjustments will be determined by the distribution of final scores across MIPS eligible clinicians and the performance threshold. More MIPS eligible clinicians above the performance threshold means the scaling factors would decrease because more MIPS eligible clinicians receive a positive MIPS payment adjustment factor. More MIPS eligible clinicians below the performance threshold means the scaling factors would increase because more MIPS eligible clinicians would receive a negative MIPS payment adjustment factor and relatively fewer MIPS eligible clinicians would receive a positive MIPS payment adjustment factor.

Table 56 illustrates the changes in payment adjustments based on the final policies from the 2019 MIPS payment year and the 2020 MIPS payment year, and on final policies for the 2021 MIPS payment year adopted in this final rule, as well as the statutorily required increase in the applicable percent as required by section 1848(q)(6)(B) of the Act.

TABLE 56: Illustration of Point System and Associated Adjustments Comparison Between the 2019 MIPS payment year, the 2020 MIPS payment year and 2021 MIPS payment year

2019 MIPS payment year		2020 MIPS payment year		2021 MIPS payment year	
Final score points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-0.75	Negative 4%	0.0-3.75	Negative 5%	0.0-7.5	Negative 7%
0.76-2.99	Negative MIPS payment adjustment greater than negative 4% and less than 0% on a linear sliding scale	3.76-14.99	Negative MIPS payment adjustment greater than negative 5% and less than 0% on a linear sliding scale	7.51-29.99	Negative MIPS payment adjustment greater than negative 7% and less than 0% on a linear sliding scale
3.00	0% adjustment	15.0	0% adjustment	30.0	0% adjustment
3.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality.	15.01-69.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	30.01-74.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 4% for scores from 3.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	70.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 5% for scores from 15.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 70.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	75.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 7% for scores from 30.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.

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We note that in this final rule, with the exception of the increase in our small practice bonus in the quality performance category from 3 measure bonus points to 6 measure bonus points, our scoring algorithms have not changed from the CY 2019 PFS proposed rule and that the only policy change from the CY 2019 PFS proposed rule reflected in Figure 3 and Table 56 is that final scores greater than or equal to 75 points qualify for the additional payment adjustment for exceptional performance discussed at section III.I.3.j.(3) of this final rule. Please refer to the CY 2019 PFS proposed rule (83 FR 35979 through 35981) for examples of scenarios in

which MIPS eligible clinicians can achieve a final score at or above the performance threshold of 30 points for the 2021 MIPS payment year.

k. Third Party Intermediaries

We refer readers to § 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390) and the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819) for our previously established policies regarding third party intermediaries.

In the CY 2019 PFS proposed rule (83 FR 35981 through 35986), we proposed to: (1) Define third party intermediary and require third party intermediaries to be based in the U.S.; (2) update certification requirements for data submission; (3) update the definition of Qualified Clinical Data Registry (QCDR); revise the self-nomination period for QCDRs; update of information required for QCDRs at the time of self-nomination; update consideration criteria for approval of QCDR measures; define the topped out timeline for QCDR measures; (4) revise the self-nomination period for qualified registries; (5) define health IT vendor; (6) update the definition, criteria, and requirements for CMS-approved survey vendor; auditing criteria; and (7) revise probation and disqualification criteria. We finalize these proposals in the manner discussed herein.

(1) Third Party Intermediaries Definition

In the CY 2019 PFS proposed rule (83 FR 35981), at § 414.1305, we proposed a new definition to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We also proposed to change the section heading at § 414.1400 from ''Third party data submissions'' to ''Third party intermediaries'' to elucidate the definition and function of a third party intermediary (83 FR 35981).

As discussed in the CY 2019 PFS proposed rule (83 FR 35981), CMS IT systems are required to adhere to multiple agency and federal security standards and policy. CMS policy prohibits non-U.S. citizens from accessing CMS IT systems, and also requires all CMS program data to be retained in accordance with U.S. Federal policy, specifically National Institute of Standards and Technology (NIST) Special Publication (SP) 800–63, which outlines enrollment and identity proofing requirements (levels of assurance) for federal IT system access. Access to the Quality Payment Program would necessitate passing a remote or in-person Federated Identity Proofing process (that is, Equifax or equivalent). A non-U.S. based third party intermediary's potential lack of a SSN, TIN, U.S. based address, and other elements required for identity proofing and identity verification would impact their ability to pass the necessary background checks. An inability to pass identity proofing may limit or fully deny access to the Quality Payment Program if the intent is to interact with the Quality Payment Program outside of the U.S. for the purposes of reporting and storing data.

These requirements are existing federal policies applicable to all HHS/CMS FISMA systems and assets, and the requirements are not specific to the Quality Payment Program. More information on these policies is available at the following websites: HHS Information Security and Privacy Policy (IS2P) (*https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/index.html*); CMS Information Systems Security and Privacy Policy (IS2P2) (*https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/CMS-Information-Systems-Security-and-Privacy-Policy-IS2P2.html*); OMB Memorandum 04–04, E-Authentication Guidance for Federal Agencies (*https://georgewbush-whitehouse.archives.gov/omb/memoranda/fy04/m04-04.pdf*); and NIST SP 800–63 Digital Identity Guidelines (*https://pages.nist.gov/800-63-3/*). Therefore, in the CY 2019 PFS proposed rule (83 FR 35982) we proposed to amend § 414.1400(a)(4) to indicate that a third party intermediary's principle place of business and retention of associated CMS data must be within the U.S.

We would like to note, third party intermediaries that are authorized by us to submit data on behalf of MIPS eligible clinicians, groups, or virtual groups have not otherwise been evaluated for the capabilities, quality, or any other features or its products. The United States Government and CMS do not endorse or recommend any third party intermediary or its products. Prior to selecting or using any third party intermediary or its products, MIPS eligible clinicians, groups or virtual groups should perform their own due diligence on the entity and its products, including contacting the entity directly to learn more about its products.

The following is a summary of the public comments received on the ''Third Party Intermediaries Definition'' proposals and our responses:

Comment: One commenter appeared to advocate that clinicians who must comply with MACRA should be prohibited from using online and/or software-based third party intermediaries that do not use attorneys to advise clinicians on the law. The commenter stated that, in order to protect clinicians from failure to comply with MACRA and to achieve higher MACRA compliance rates, CMS should restrict MIPS participants from using online or software-based third party intermediaries entirely unless the use is through an EMR/EHR dashboard. In addition, the commenter stated that CMS should only allow clinicians to achieve compliance themselves or to achieve compliance through the use of an attorney or an EMR/EHR dashboard.

Response: We do not believe it is appropriate to require third party intermediaries to furnish legal advice to clinicians. If a clinician wishes to receive legal advice regarding compliance with MACRA, or any other law or regulation, the clinician may hire his or her own legal counsel. To the extent the commenter is advocating to eliminate a clinician's ability to report MIPS data through a third party intermediary, the comment is outside the scope of the rulemaking.

Comment: One commenter provided a comment related to the proposed opt-in policy. The commenter encouraged us to allow third-party intermediaries, such as qualified registries, to opt-in on behalf of clinicians and groups as a function of the services they provide and that the clinician opt-in should be at the TIN/NPI level.

Response: The opt-in policy is discussed in section III.I.3.c.(5) in this final rule, where we finalized that a clinician who is eligible to opt-in would be required to make an affirmative election to opt-in to participate in MIPS, elect to be a voluntary reporter, or by not submitting any data the clinician is choosing to not report. We believe that an election to opt-in to MIPS must be made by the clinician or group through a definitive opt-in decision to participate in MIPS regardless of the way in which the data is submitted. We agree that after this decision is confirmed by the clinician or group it should be deliverable through a third party intermediary, if a clinician or group is utilizing a third party intermediary for their data submission. As a result, the third party intermediary

should be able to transmit the clinician's opt-in decision to CMS. Therefore, we are amending § 414.1400(a)(4)(iv) that if the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS. We refer readers to section III.I.3.c.(5) of this final rule for more information regarding low volume threshold exclusion.

After consideration of the public comments received, we are finalizing our proposal, as proposed, at § 414.1305, to define a third party intermediary as an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and Promoting Interoperability performance categories. A QCDR, qualified registry, health IT vendor, or CMS-approved survey vendor are considered third party intermediaries. We are also finalizing our proposal, as proposed, to change the section heading at § 414.1400 from ''Third party data submissions'' to ''Third party intermediaries'' to elucidate the definition and function of a third party intermediary. In addition, we are finalizing our proposal, as proposed, to amend previously finalized policies at § 414.1400(a)(4) to indicate that a third party intermediary's principle place of business and retention of associated CMS data must be within the U.S. Lastly, we are amending § 414.1400(a)(4)(iv) to state that if the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(2) Certification

We previously finalized in the CY 2018 Quality Payment Program final rule (82 FR 53807) at § 414.1400(a)(5), that all data submitted to us by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary to the best of its knowledge as true, accurate, and complete; and that this certification must occur at the time of the submission and accompany the submission. We have discovered it is not operationally feasible to require certification at the time of submission, or to require that the certification accompany the submission, for submission types by third party intermediaries, including data via direct, login and upload, login and attest, CMS Web Interface or Medicare Part B claims. We refer readers to section III.I.3.h.(1)(b) of this final rule for our proposed modifications to the previously established data submission terminology. In order to address these various submission types that are currently available, in the CY 2019 PFS proposed rule (83 FR 35982), we proposed to amend § 414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary must be certified as true, accurate, and complete to the best of its knowledge and that such certification must be made in a form and manner and at such time as specified by CMS.

We did not receive any public comments on our proposed amendments to the certification requirement imposed on third party intermediaries.

We are finalizing our proposal, as proposed, at § 414.1400(a)(5) to state that all data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge, and that such certification must be made in a form and manner and at such time as specified by CMS.

(3) Qualified Clinical Data Registries (QCDRs)

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53807 through 53815) and § 414.1400 for our previously finalized policies regarding QCDRs. In the CY 2019 PFS proposed rule (83 FR 35982 through 35984) we proposed to update the following: The definition of QCDR, the self-nomination period for QCDRs, information required for QCDRs at the time of self-nomination, and consideration of criteria for approval of QCDR measures.

(a) Proposed Update to the Definition of a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) at § 414.1305, we finalized the definition of a QCDR to be a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

As described in the CY 2019 PFS proposed rule (83 FR 35982), we want to ensure that QCDRs that participate in MIPS have access to clinical expertise in quality measurement and are able to provide and demonstrate an understanding of the clinical medicine, evidence-based gaps in care, and opportunities for improvement in the quality of care delivered to patients and priorities that are important to MIPS eligible clinicians. From our experiences with QCDRs to date, we have discovered that certain entities with predominantly technical backgrounds have limited understanding of medical quality metrics or the process for developing quality measures are seeking approval as a QCDR. A large number of entities that do not have the necessary clinical expertise to foster quality improvement have self-nominated or indicated their interest in becoming QCDRs. In reviewing previous QCDR measure submissions during the self-nomination and QCDR measure review and approval cycles in MIPS, we have observed that some entities were developing QCDR measures without a complete understanding of measure constructs (such as what is required of a composite measure or what it means to risk-adjust), and in some instances, QCDRs were developing QCDR measures in clinical areas in which they did not have expertise. We are concerned that QCDR measures submitted by such entities for approval have not undergone the same consensus development, scientific rigor, and clinical assessment that is required for measure development, compared to those QCDR measures that are developed by specialty societies and other entities with clinical expertise.

We recognize the importance of these organizations' expertise within the Quality Payment Program; however, do not believe that these types of entities with the absence of clinical expertise in quality measurement, meet the intent of QCDRs. We believe that with the increasing interest in QCDRs and QCDR measure development, it is important to ensure that QCDRs that participate in MIPS are first and foremost in the business of improving the quality of care clinicians provide to their patients through quality measurement and/or disease tracking and have the clinical expertise to do so.

In the CY 2019 PFS proposed rule (83 FR 35982 through 35983), we proposed beginning with the 2022 MIPS payment year, to amend § 414.1305 to modify the definition of a QCDR to state that the approved entity must have clinical expertise in medicine and quality measure development. Specifically, a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

As described in the CY 2019 PFS proposed rule (83 FR 35983), under § 414.1400(b)(2)(ii), an entity that uses an external organization for purposes of data collection, calculation, or transmission may meet the definition of a QCDR as long as the entity has a signed, written agreement that specifically details the relationship and responsibilities of the entity with the external organization effective as of September 1 the year prior to the year for which the entity seeks to become a QCDR. Thus, we expect entities without clinical expertise in medicine and quality measure development that want to become QCDRs would collaborate or align with entities with such expertise in accordance with § 414.1400(b)(2)(ii).

As a part of the self-nomination process, we will look for entities that have quality improvement, measure development, as well as clinical expertise. We will also follow up with the entity via, for example, email or teleconference, should we question whether or not the entity meets our standards. Alternatively, such entities may seek to qualify as another type of third party intermediary, such as a qualified registry. Becoming a qualified registry does not require the level of measure development expertise that is needed to be a QCDR that develops measures.

The following is a summary of the public comments received on the proposal to update the definition of a QCDR and our responses:

Comment: Many commenters supported the proposal to modify the definition of a QCDR to limit approval to entities that have clinical expertise in medicine and quality measure development. Several commenters recommended CMS provide clarification on how such clinical and quality measure development expertise will be evaluated, with one commenter suggesting the definition of clinical expertise include having a majority-led physician Board of Directors or governing body and that expertise in clinical measure development include demonstrated QCDR measure development processes that take into account the CMS Blueprint for measure development and maintenance activities. A few commenters stated that CMS should establish processes for denying applications and/or measures that appear to not have had any clinical influence rather than requiring the entire entity to have ''expertise'' and provide a definition of what constitutes ''clinical expertise in medicine and quality measure development.''

Response: We appreciate the commenters' support to update the definition of a QCDR, limiting approval to entities that have clinical expertise in medicine and quality measure development. Specifically, we proposed that a QCDR would be defined as an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. We appreciate the commenters' suggestion that CMS provide more clarification on how such clinical and quality measure development expertise will be evaluated. For example, while not exhaustive, some aspects that may be considered during our evaluation are a QCDR's: Previous measure development experience (serving on an NQF TEP, for example); experience with the measure development Blueprint process, which can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-130.pdf;* ability to create and use multi-strata and composite measures where appropriate; ability to risk adjust its own QCDR outcomes measures; technical expertise to run a registry; and ability to reliably collect, retain, aggregate, disseminate, and analyze data from their clinicians. We appreciate the commenter's suggestion to include having a majority-led physician Board of Directors or governing body, but we do not mandate that the QCDR be led by a majority of physicians. We do consider clinical expertise and experience in QCDR measure development and maintenance important, as shown in our updated definition of a QCDR.

Comment: One commenter expressed concern regarding how CMS will allow technical entities to partner with an external organization to gain clinical expertise, citing its opinion that doing so would render the policy ineffective if this enables technical entities to bypass this requirement too easily. Another commenter stated that neither small nor large EHR vendors should be allowed to enter the QCDR space due to the former potentially collecting skewed data related to certain practice arrangements and patient populations and the latter potentially lacking the perspective of care improvement in medical specialties.

Response: We disagree that allowing technical entities to partner with an external organization to gain clinical expertise would render the policy ineffective. The policy is intended to include entities that are able to meet the definition, whether that be by a partnership with a clinical entity, or on their own. In addition, we disagree that neither small nor large EHR vendors should be allowed to collaborate to become a QCDR. As stated in the proposed rule, entities without clinical expertise in medicine and quality measure development, such as small or large EHR vendors, may collaborate or align with entities with such expertise in accordance with § 414.1400(b)(2)(ii). In general, we do not believe that Health IT vendors, including EHR vendors, alone have the necessary clinical expertise. Having the option to collaborate could alleviate the likelihood of skewed data or the absence of perspective regarding care improvement in medical specialties, because a collaboration with a clinical organization would provide knowledge of patient populations, practice arrangements, and care improvement.

Comment: A few commenters disagreed with the proposed update to the definition of a QCDR, citing their beliefs that the updated definition is contrary to the promotion of the benefits of technology; will impose artificial barriers to entry into the market; dictate who can provide services to physicians instead of letting the free market decide; and discriminate against potential vendors because of a perceived advantage at quality measurement based on education, experience, etc. The commenters stated that CMS should only require QCDRs to collaborate with specialty societies in the development of measures to ensure validity, clinical relevance, and proper risk adjustment.

Response: We disagree that the modified definition of QCDR opposes promoting the benefits of technology because there are many options through which MIPS eligible clinicians can utilize different third-party intermediaries to submit data, and this proposed change will not impact the ability for MIPS eligible clinicians to use these mechanisms. We also disagree that the modified definition of QCDR imposes barriers into the market or discriminates against potential vendors because we offer vendors with more of a technical background the opportunity to partner with an organization with greater clinical expertise in order to meet the new QCDR definition. The intent of the modified definition is to promote useful measure development and to emphasize that clinical expertise is critical in gaining useful measures. Furthermore, we believe that updating the definition of a QCDR will help organizations understand the criteria in which we evaluate them against. We want to ensure that the vendors we approve to participate as a QCDR are of

a higher standard and understand the clinical science based off which they develop measures. It is important that QCDRs also understand how to construct measures, the analytics, and are able to ensure the measures are reliable and valid, not doing so may negatively impact the clinician's reporting and final score. Health IT vendors and/or EHR vendors should collaborate with clinical organizations such as specialty societies for their experience not only in measure development but for their clinical expertise as well.

Comment: Some commenters stated that CMS should develop a process by which a clinician who believes they are unsupported by a QCDR can submit information to CMS for further investigation.

Response: If an eligible clinician would like to bring information to CMS' attention regarding a QCDR being unsupportive as it pertains to reporting issues, we suggest the clinician contact the Quality Payment Program Service Center by emailing: *QPP@cms.hhs.gov.*

Comment: One commenter noted that the proposed change may preclude its continued approval by CMS as a QCDR because it does not dictate the timeline in which specialty societies perform measure development and without this approval, it would not be able to assist them in measure development when necessary.

Response: Our updated definition of a QCDR would be effective beginning with the 2022 MIPS payment year; and to clarify, we will not be ''grandfathering'' in existing QCDRs who do not meet the updated QCDR definition for the 2020 performance period. In coordination with the finalization of the new QCDR definition and the publication of the CY 2019 PFS final rule, we intend to notify existing QCDRs as to whether they would meet the new QCDR definition or not based on information submitted for a previous MIPS payment year.

Comment: A few commenters stated that CMS should finalize its proposal for the 2019 performance year instead of the 2020 performance year because removing non-clinician led vendors from the list of QCDRs will not pose a significant burden on eligible clinicians or group practices in 2019.

Response: While we appreciate commenters' support, we would like to keep the effective timeframe of this policy (that is, the 2020 performance year) as proposed to provide existing QCDRs that would not meet the updated QCDR definition with an appropriate amount of time to comply or take other paths.

Comment: Many commenters who supported the proposal to update the definition of a QCDR also provided recommendations including: Development of a separate definition for QCDRs put forth by technology companies to differentiate them from QCDRs managed by specialty societies; requiring third-party entities that are not specialty societies that would like to become QCDRs to collaborate with specialty society QCDRs; and expansion of the definition of a QCDR to align with the 21st Century Cures Act (especially with regard to entities being clinician-led) or at minimum, revision of the definition to include clinical expertise in medicine, quality improvement, and quality measure/guideline development, as well as providing methods to ensure data quality, routine metric reporting, and quality improvement consultation.

Response: We do not agree that separate definitions are necessary to differentiate between QCDRs, as the definition includes criteria set for all QCDRs; or that the definition requires criteria as prescriptive as entities being clinician-led. There are flexibilities in place, such as collaboration with other entities such as large healthcare systems, regional collaboratives, or specialty societies, in order for vendors to meet the criteria in the definition. We believe we cover the areas of clinical expertise, measure development, and quality improvement work through this new definition. We believe that experience with data quality and routine metric reporting is related to their measure development experience and their registry experience, which is covered by the new QCDR definition and the criteria of requiring that the vendor must exist by January 1 of the performance period and have 25 participants submitting data to the QCDR (not necessarily for purposes of MIPS).

After consideration of the public comments received, we are finalizing our proposal to update the definition of a QCDR at § 414.1305 beginning with the 2022 MIPS payment year, as proposed, to state that a QCDR is an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(b) Establishment of an Entity Seeking To Qualify as a QCDR

In the CY 2017 Quality Payment Program final rule (81 FR 77364), we require at § 414.1400(c)(2) that the QCDR must have at least 25 participants by January 1 of the performance period. These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement. We realize that a QCDR's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a QCDR to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, we proposed to redesignate § 414.1400(c)(2) as § 414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the performance period (83 FR 35983). These participants do not need to use the QCDR to report MIPS data to us; rather, they need to submit data to the QCDR for quality improvement.

The following is a summary of the public comments received on the ''Establishment of an Entity Seeking To Qualify as a QCDR'' proposals and our responses:

Comment: Many commenters disagreed with the proposal to require QCDRs to have 25 participants by January 1 of the year prior to performance period. Commenters noted it would place an undue burden on QCDRs serving small specialties and inhibit the ability of new registries to qualify as QCDRs, thus discouraging the use of QCDRs to report MIPS data. One commenter suggested CMS work with stakeholders to develop a timeline that is feasible and leads to properly functioning QCDRs that can meet the goals of the MIPS program and the requirements of the MACRA law. Another commenter stated that the existing requirement is sufficient to ensure QCDR preparedness, while another commenter stated that the threshold should be lowered or removed completely, at least for those QCDRs that have already been in operation and have lost participants when the low volume threshold increased significantly.

Response: We disagree with commenters that this proposed policy would cause undue burden or the ability of new entities to qualify as QCDRs. To clarify, this requirement would demonstrate that the entity has prior registry experience and the capability to accept, aggregate, calculate, provide feedback to their participants on, retain, and submit the data to CMS on the behalf of MIPS eligible clinicians. We have previously experienced during

the past two performance periods that there have been instances of new QCDRs that are not ready to accept data from eligible clinicians from the start of the performance period due to operational issues within the QCDR, including instances of QCDRs withdrawing during the performance period because of reporting inexperience. We proposed this requirement to ensure that organizations have this experience prior to self-nomination. We continue to provide educational materials for QCDRs on what is necessary to meet program criteria and requirements. We clarify that the requirement to have at least 25 participants by January 1 of the year prior to performance period does not require that the entity's prior registry experience be under MIPS or any other CMS program or that the participants be MIPS eligible clinicians. With increasing stakeholder interest in the use of third-party intermediaries to report for MIPS, we believe the threshold of 25 participants is a reasonable thresholds for QCDRs to attain.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to redesignate § 414.1400(c)(2) as § 414.1400(b)(2)(i) to state that beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(c) Self-Nomination Process

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813) for our previously established policies regarding the simplified self-nomination process for existing QCDRs in MIPS that are in good standing and web-based submission of self-nomination forms. We did not propose any changes to those policies in this final rule; however, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update: (1) The self-nomination period; and (2) information required at the time of self-nomination.

(i) Self-Nomination Period

Under § 414.1400(b), QCDRs must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. As indicated in the CY 2017 Quality Payment Program final rule (81 FR 77366), our goal has been to publish the list of approved QCDRs along with their approved QCDR measures prior to the beginning of the applicable performance period.

We have received feedback from entities that have self-nominated to be a QCDR about the need for additional time to respond to requests for information during the review process, particularly with respect to QCDR measures that the entity intends to submit to us for the applicable performance period. In addition, based on our observations of the previous two self-nomination cycles, we anticipate an increase in the number of QCDR measure submissions for our review and consideration. For the transition year of MIPS, we received over 1,000 QCDR measure submissions for review, and for the CY 2018 performance period, we received over 1,400 QCDR measure submissions. In order for us to process, review, and approve the QCDR measure submissions and provide QCDRs with sufficient time to respond to requests for information during the review process, while still meeting our goal to publish the list of approved QCDRs along with their approved QCDR measures prior to the start of the applicable performance period, we believe that an earlier self-nomination period is needed.

Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we also proposed to amend § 414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.I.3.g. of this final rule. Therefore for the CY 2020 performance period, the self-nomination period would begin on July 1st, 2019 and end on September 1st, 2019, and we will make QCDRs aware of this through our normal communication channels. We believe that updating the self-nomination period would allow for additional review time and measure discussions with QCDRs.

We refer readers to section III.I.3.k.(3)(c)(ii) of this final rule for a summary of the public comments received on these proposals and our responses.

(ii) Information Required at the Time of Self-Nomination

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53814), where we finalized that as a part of the self-nomination review and approval process for the CY 2018 performance period and future years, we will assign QCDR measure IDs to approved QCDR measures, and the same measure ID must be used by any other QCDRs that have received permission to also report the measure. We have received some questions from stakeholders as to whether the QCDR measure ID must be utilized or whether it is optional. As stated in the CY 2018 Quality Payment Program final rule, QCDRs, including any other QCDRs that have received permission to also report the measure, must use the CMS-assigned QDCR measure ID. It is important that the CMS-assigned QCDR measure ID is posted and used accordingly, because without this ID we are not able to accurately identify and calculate the QCDR measures according to their specifications. Therefore, in the CY 2019 PFS proposed rule (83 FR 35983), we proposed to update § 414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

The following is a summary of the public comments received on the ''Self-Nomination Process'' proposals and our responses:

Comment: Several commenters noted they would support the proposed change to the self-nomination timeline if CMS would adopt multi-year approval of QCDRs as they noted doing so would reduce burden, alleviate a shortened nomination timeline, potentially strengthen the measure development process in future years, encourage uptake of new measures, allow for uninterrupted data collection, and allow for more consistent and robust data collection and benchmarking.

Response: In the CY 2018 Quality Payment Program final rule (82 FR 53808), we discussed our concerns with multi-year approval and sought comment from stakeholders as to how to mitigate our concerns. Moreover, a multi-year approval process would not take into consideration potential changes in criteria or requirements of participation for QCDRs that may occur

as the MIPS program develops through future program years. We did not receive any suggestions or responses from stakeholders that would alleviate our concerns with adopting this policy. Therefore, we continue to believe multi-year approval of QCDRs is inappropriate at this time.

Comment: One commenter stated that in order to encourage QCDRs to continue seeking QCDR status, CMS should work with specialty-led QCDR stewards to further improve the self-nomination process and ensure a viable and private sector-run reporting option to alleviate burden and increase evidence-based decisions.

Response: We value stakeholder input and conduct process improvement on an ongoing basis. We will continue to seek opportunities to receive input throughout the year.

Comment: Many commenters disagreed with the proposal to change the QCDR self-nomination period, citing their beliefs that maintaining the September 1 through November 1 self-nomination period without change is necessary to minimize additional burden and constraints on QCDRs; provide QCDRs the time to prepare data to support measures in the application process; provide QCDRs an opportunity to gain insight into recent policy changes; and negate potentially adverse impacts to the life cycle of QCDRs, the maintenance process for existing QCDR measures, and/or development of new measures. One commenter stated that due to additional data being required as part of the self-nomination process, the revised self-nomination period would be more difficult. Another commenter suggested the change should not be implemented until the CY 2021 performance period and noted QCDR approval will need to expand beyond 12 months to avoid a scenario where a QCDR is only approved for a few months before they must go through the self-nomination process again. Finally, another commenter suggested the self-nomination period be extended to 90 days due to its belief that the 60-day period is excessively challenging and burdensome in terms of the information required and additional requests to which QCDRs must be respond.

Response: As described in the CY 2019 PFS proposed rule (83 FR 35983), we have heard from QCDRs that they need additional time to respond to our requests for additional information during the QCDR measure review process, as well as requests for feedback or measure harmonization across QCDRs in a more extensive manner that would not be feasible with the current timeline. We believe with sufficient notice, providing stakeholders with educational material, and the implementation of the simplified self-nomination process we are minimalizing additional burden on QCDRs. Through the publication of self-nomination reference material prior to the self-nomination period, as we have done for the 2019 self-nomination period, we intend on giving QCDRs the utmost resources and support as they prepare to self-nominate prior to the closing of the self-nomination period. We plan to post self-nomination material prior to the start of the self-nomination period in July, thereby giving stakeholders' time to prepare the necessary materials needed, inclusive of the additional information requested as a part of the self-nomination process. As we develop QCDR and qualified registry related policies for future rulemaking, we will factor in how the proposals impact an entity's ability to self-nominate and participate in the program prior to deciding what year to implement the policies for. We do not believe that delaying the finalization of this proposal until the 2021 performance period of MIPS would benefit the QCDRs, as we have previously explained, QCDR self-nomination must occur on an annual basis to take into consideration policy, participation requirement, and considerations to a QCDR or registry's standing (if they are on probation or have been precluded).

We believe the benefits of moving up the self-nomination period to allow for additional time and discussion of QCDR measures is beneficial for both QCDRs and CMS. We disagree that the self-nomination period needs to be extended to a 90-day period, we believe with the resource materials provided, as well as us offering to meet with QCDRs prior to self-nomination to discuss their QCDR measures and receive preliminary feedback, QCDRs have the ability to better prepare for the self-nomination period.

Comment: A few commenters supported the proposal to update the QCDR self-nomination timeline. One commenter stated that CMS should use the updated nomination period to facilitate additional discussion with QCDRs regarding measure development. Another commenter stated that CMS should change its expectations for providing data for measures accordingly and allow a transition year to lessen the impact on the measure development life cycle and maintenance of existing measures.

Response: We agree that this change in the self-nomination period will allow for additional conversations on measure development and QCDR measure feedback. We disagree with the implementation of a transition year, considering that on annual basis we must review performance data to evaluate whether the measure demonstrates a gap in performance or whether the measure demonstrates topped out performance where no meaningful measurement can be obtained. As previously mentioned, QCDR measures do not have to go through the NQF's Measures Application Partnership (MAP) committee prior to implementing them in MIPS. If a QCDR is unable to provide performance data reflecting a gap, the QCDR may provide for our consideration citations to recent studies or clinical journals that demonstrate a need for measurement.

Comment: One commenter suggested CMS provide a definition of ''minimal changes'' regarding the QCDR self-nomination process as well as specifications around data requests to support QCDR measures.

Response: In the CY 2018 Quality Payment Program final rule (82 FR 53811), we stated that minimal changes include, but are not limited to: Limited changes to performance categories, adding or removing MIPS quality measures, and adding or updating existing services and/or cost information. Additional educational resources are available in the QPP resource library at *https://qpp.cms.gov/.*

Comment: One commenter recommended changes to the QCDR self-nomination process, including updating QCDR self-nomination application and materials to outline all of the information needed to determine QCDR status to avoid delays and misunderstandings and providing at least a 60-day notice of any changes to the QCDR vetting process, including review of measures and a minimum of 30 days to appeal changes. The commenter further stated that changes to the 2019 QCDR application requirements should not be made until after the final rule is released due to the current QCDR application timeline closing on November 1 coinciding with publication of the final rule and that since the majority of specialty QCDRs stewards are currently submitting QCDR applications, CMS should allow these QCDRs to fully comment on these new proposed standards to which they are being held and which they may not support. Alternatively, the commenter suggested CMS allow for a nimble 2019 QCDR application process, including changes to the licensing standards given

the significant changes CMS proposes for 2019.

Response: To clarify, we proposed that the self-nomination period be moved for the 2020 performance period, not the 2019 performance period as indicated by the commenter, to allow for sufficient time and notice of the changes. We will continue to provide educational materials that will outline all of the information needed to evaluate a QCDR's ability to meet participation standards and QCDR measure evaluation criteria prior to the start of the self-nomination period. With the publication of this final rule, we intend on communicating any changes to the review process. For the 2019 performance period, it is not feasible to allow for a minimum of 30 days to appeal changes due to our goal of approving and publicizing the QCDRs by the start of the performance period. By moving up the self-nomination period, we will be able to allow QCDRs to have more time to consider our QCDR measure feedback. Additionally, moving the timeline to earlier in the year will allow CMS to review the measures fully and provide feedback to the QCDR who submitted the measures. The earlier self-nomination will also allow QCDRs who submit clinically similar measures to another QCDR and whose measure(s) are rejected to reach out to the QCDR whose measures are approved to attempt to enter into a licensing use agreement with the QCDR with the approved measures if desired. It is the goal of CMS to post the most comprehensive list of approved QCDRs and their measures before the start of the performance period so that eligible clinicians intending to use a QCDR can review these materials and select the QCDR that best meets their needs. In this way, the eligible clinician may begin submitting data to the QCDR at the start of the performance period. By doing so, the clinician will be more likely to receive timely feedback from the QCDR regarding his/her performance (earlier in the year) which will allow for quality improvement to occur during the performance period instead of receiving this data later in the year or after the conclusion of the performance period.

The CY 2019 performance period self-nomination form reflects the proposed MIPS quality measures, Promoting Interoperability measures, and Improvement Activities as proposed in the CY 2019 PFS proposed rule. We include disclaimer language that indicates that measures and activity availability are subject to change, pending upon what is finalized in the final rule. We continuously take into consideration stakeholder feedback as we look into process improvements and policy development for future program years. We appreciate the commenters' suggestions, and ask that they provide more detail as to the changes to the licensing standards that they recommend we implement for future consideration.

After consideration of the public comments received, we are finalizing our proposal to amend § 414.1400(b)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as QCDRs must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. In addition, we are finalizing our proposal to update § 414.1400(b)(3)(iii) to state that QCDRs must include their CMS-assigned QCDR measure ID number when posting their approved QCDR measure specifications, and also when submitting data on the QCDR measures to us.

(d) QCDR Measure Requirements

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) for where we previously finalized standards and criteria used for selecting and approving QCDR measures. We finalized that QCDR measures must: Provide specifications for each measure, activity, or objective the QCDR intends to submit to CMS; and provide CMS descriptions and narrative specifications for each measure, activity, or objective no later than November 1 of the applicable performance period for which the QCDR wishes to submit quality measures or other performance category (improvement activities and Promoting Interoperability) data starting with the 2018 performance period and in future program years. In the CY 2019 PFS proposed rule (83 FR 35983), we proposed to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at § 414.1400(e) and (f) at § 414.1400(b)(3). We also proposed to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year (83 FR 35983).

In the CY 2018 Quality Payment Program final rule (82 FR 53814), we noted our interest in elevating the standards for which QCDR measures are selected and approved for use and sought comment on whether the standards and criteria used for selecting and approving QCDR measures should be more closely aligned with those used for the Call for Quality Measures process described in the CY 2017 Quality Payment Program final rule (81 FR 77151). Some commenters expressed concern with this alignment, stating that the Call for Measures process is cumbersome, and would increase burden. Other commenters expressed the belief that the Call for Measures process does not recognize the uniqueness of QCDRs, and is not agile. We would like to clarify that our intention with any future alignment is to work towards consistent standards and evaluation criteria that would be applicable to all MIPS quality measures, including QCDR measures. We understand that some of the criteria under the Call for Measures process may be difficult for QCDRs to meet prior to submitting a particular measure for approval; however, we believe that the criteria under the Call for Measures process helps ensure that any new measures are reliable and valid for use in the program. Having a greater alignment in measure standards helps ensure that MIPS eligible clinicians and groups are able to select from an array of measures that are considered to be higher quality and provide meaningful measurement. As such, we believe that as we gain additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years.

Therefore, in addition to the QCDR measure criteria previously finalized at § 414.1400(f), we proposed in the CY 2019 PFS proposed rule (83 FR 35984) to apply select criteria used under the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule (82 FR 53636). Specifically, in addition to the QCDR measure criteria at proposed § 414.1400(b)(3), we proposed in the CY 2019 PFS proposed rule (83 FR 35984) to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.

• Measures that address the domain for patient and caregiver experience.
• Measures that address efficiency, cost and resource use.
• Measures that address significant variation in performance.

We believe that as we gain additional experience with QCDRs in MIPS, it would be appropriate to further align these criteria for QCDR measures with those of MIPS quality measures in future program years. Specifically, we are considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking.

In addition, we refer readers to the CMS Quality Measure Development Plan at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf* for more information regarding the measure development process.

The following is a summary of the public comments received on the ''QCDR Measure Requirements'' proposals and our responses:

Comment: A few commenters stated that CMS should offer multi-year approval of QCDR measures to maximize stability and predictability while minimizing redundancy. The commenters further stated that QCDRs should be allowed to make minor modifications to measures under this multi-year approval process based on updated guidelines, evidence, or measure methodologies and if QCDR measures were approved for 2 to 3 years, the earlier self-nomination deadline would not be as problematic for registry vendors and would streamline CMS' process.

Response: We disagree that offering multi-year approval of QCDR measures would minimize redundancy, as this may actually lead to duplicative measures which is counter intuitive to our meaningful measures initiative. Multi-year approvals of QCDR measures does not account for the possibility of there being more robust QCDR measures of similar concepts being submitted for CMS consideration. We may consider a similar process for future years, which is used with MIPS quality measures, where we'd continue to evaluate all the measures on an annual basis and compare them to those submitted during the measure consideration period (self-nomination period) to determine what QCDR measures would be best to include for the upcoming performance period. QCDRs making changes to their measures would have to self-nominate those changes for CMS' approval, and if we receive measures of similar concept that are more robust they may be considered to replace the existing approved QCDR measures.

Comment: One commenter supported the proposal to include the CMS-assigned QCDR measure ID number when posting the approved QCDR measure specifications, and also when submitting data on the QCDR measures to CMS.

Response: We appreciate the commenter's support.

Comment: One commenter stated that CMS should not approve highly duplicative measure concepts submitted at a later time as doing so increases confusion among physicians and competition among QCDRs while disregarding the time, resources, and intellectual property rights of the measure owners. Some commenters noted that measures are misaligned, overlapping and duplicative across QCDR and MIPS measures.

Response: We agree that duplicative measures are counterintuitive to the Meaningful Measures initiative that promotes more focused quality measure development towards outcomes that are meaningful to patients, families and their providers. It is our intent to move toward measure harmonization, which supports our efforts to increase measure alignment and eliminate redundancy both within the MIPS measure set and across CMS programs.

Comment: A few commenters supported the proposal to update QCDR measure criteria and encouraged CMS to have dialogue with QCDRs regarding the submission of measures. One commenter stated that CMS should expand the policy toward having a common national framework for endorsement of measures by a national consensus body (which currently is the National Quality Forum) and set expectations when accepting QCDR measures that measure stewards would be expected to get endorsement after a certain defined time period.

Response: We will continue dialogue with QCDRs during our scheduled calls. As far as expanding our policy toward having a common national framework for endorsement of measures by a national consensus body, we agree this would be valuable and encourage QCDRs to have their measures NQF endorsed. However, it is not a necessary requirement at this time because of its potential increase in burden and potential unintended impacts on the ability of QCDRs to adapt their measures.

Comment: A few commenters stated that CMS should work with both specialty societies and vendors in facilitating the time and effort needed to successfully encourage reporting of specialty-specific process and outcome measures while ensuring proper review and that appropriate data can be collected and shared. One commenter suggested CMS develop a review process where CMS and its contractor consult with appropriate physician experts and QCDR stewards to ensure sufficient clinical expert review on the importance and relevancy of a measure.

Response: We hold QCDR measure preview calls to provide a forum to work with both specialty societies and vendors wishing to self-nominate QCDR measures. New entities wishing to review QCDR measure concepts with CMS, may request a meeting with CMS by contacting the Quality Payment Program Service Center at *QPP@cms.hhs.gov*. Existing QCDRs may contact our contractor support team to set up a QCDR measure preview call. We have several measure experts as part of our review process, many of which have specialty specific expertise. Furthermore, we hold calls prior to self-nomination to allow experts to discuss their QCDR measure concepts, and will also continue to schedule calls with QCDRs after the self-nomination period closes to provide feedback, which provides time for QCDRs to invite their clinical experts to provide additional information and explanation that would provide us with clarifications that may lead to a QCDR measure reexamination.

Comment: Many commenters did not support the proposal to align QCDR measure requirements with the criteria used under the Call for Quality Measures Process due to their beliefs that applying this criteria to QCDR measures fails to recognize the unique role of QCDRs who fill critical gaps in traditional quality measure sets as they support different specialties, and that doing so would limit the number of measures available for QCDR participants, would create more stringent standards for QCDR measures resulting in additional burden, and be counterproductive toward the goal of encouraging the use of QCDRs. Commenters stated that rather than require these criteria, the criteria should be made optional, but strongly preferred, as there are existing evidence-based process measures that are still valuable to improving patient care and should still be considered for inclusion in the QCDR program; and that since some outcome measures which evaluate degenerative or rare incidences, conditions that are terminal with limited treatment options, or conditions which result in increased co-morbidities require measurement over the course of multiple years to have sufficient

statistical power, CMS should continue the use of certain process measures until they can be easily converted to meaningful outcome measures.

Response: We believe that our process seeks to ensure reliable measures and expect all measures in the program, including QCDRs, to be held to that standard. We believe that it is imperative to raise the bar with QCDR measures in order to ensure that we move away from standard of care, low-bar, process, and/or duplicative measures. Specifically, we are considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking. In the CY 2018 Quality Payment Program final rule (82 FR 53814), we state that as the MIPS program progresses in its implementation, we are interested in elevating the standards for which QCDR measures are selected and approved for use. As a part of our QCDR measure review process, we do consider the complexity of what is being measured, while being mindful that measures with high performance do not provide value with regards to the quality performance category in MIPS. There are process measures in MIPS that are considered high priority, we believe it is important to retain those so long as they demonstrate room for improvement and lead to meaningful outcomes.

Comment: One commenter suggested CMS clarify the process by which a measure would be assigned within the domains provided under the proposed alignment with the Call for Quality Measures process and offer greater transparency in the rationale for this assignment or outcome status. In addition, the commenter recommended that CMS defer to the rationale and status identified by the QCDR, in particular for clinician-led registries.

Response: During the self-nomination process, we ask the QCDR to assign their QCDR measure a NQS domain, Meaningful Measure Area, whether or not their measure is high priority and/or an outcome measure. As a part of the vetting process, we review those selections and will reach out to the QCDR should we not agree with their assignment.

Comment: One commenter stated that due to the announcement of approved measures continuing to occur on a fixed schedule shortly before the start of each MIPS performance period despite the rolling submission process for new MIPS measures through the Call for Quality Measures Process, CMS should transition to a rolling review and approval process for QCDR measures to allow stakeholders more time to implement new measures prior to the MIPS performance period. This commenter also stated that if CMS is unwilling to move to a rolling review and approval process, the quality category performance period should be reduced. The commenter noted that the rolling submission process has not benefited measure owners, QCDRs, registries, and EHR vendors, all of which have very little time to modify their systems to include new measures post-approval and prior to the start of the next MIPS performance period.

Response: We note that a rolling review basis would adversely impact our ability to limit the number of duplicative measures that are similar in concept, which is inconsistent with the meaningful measure initiative. We believe that the change in the self-nomination period would allow for increased time in the measure review process, as well as provide additional time for QCDRs to respond to feedback provided by CMS. We do not believe a rolling review and approval process is appropriate, as it is not a process that is used for MIPS quality measures. We do not agree that the quality performance period should be reduced dependent on whether or not a rolling review and approval process is implemented as there is no correlation between the two processes.

Comment: One commenter suggested CMS should require measure developers to include a section in each measure that specifies how eligible clinicians and TINs should be attributed for that measure to assist in preventing different interpretations for measure attribution which could lead to TIN/NPI mismatches and resulting determinations by CMS that submitted data is inaccurate.

Response: We agree that attribution should be clearly stated in the QCDR measure specifications and appreciate the commenter's feedback. We will take this suggestion into consideration as we review QCDR measure concepts, and will share this feedback with the QCDRs for their consideration.

After consideration of the public comments received, we are finalizing our proposal to consolidate our previously finalized standards and criteria used for selecting and approving QCDR measures at § 414.1400(e) and (f) at § 414.1400(b)(3) and to apply certain criteria used under the Call for Quality Measures Process when considering QCDR measures for possible inclusion in MIPS beginning with the MIPS 2021 payment year. We are also finalizing our proposal to apply select criteria used under the Call for Measures Process, as described in the CY 2018 Quality Payment Program final rule (82 FR 53636) in addition to the QCDR measure criteria previously finalized at § 414.1400(f). Specifically, in addition to the QCDR measure criteria that we are finalizing at § 414.1400(b)(3), we are also finalizing our proposal to apply the following criteria beginning with the 2021 MIPS payment year when considering QCDR measures for possible inclusion in MIPS:

- Measures that are beyond the measure concept phase of development.
- Preference given to measures that are outcome-based rather than clinical process measures.
- Measures that address patient safety and adverse events.
- Measures that identify appropriate use of diagnosis and therapeutics.
- Measures that address the domain for care coordination.
- Measures that address the domain for patient and caregiver experience.
- Measures that address efficiency, cost and resource use.
- Measures that address significant variation in performance.

(e) QCDRs Seeking Permission From Another QCDR To Use an Existing, Approved QCDR Measure

In the CY 2018 Quality Payment Program final rule (82 FR 53813), we finalized that beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. We intended for this policy to help reduce the number of QCDR measures that are similar in concept or clinical topic, or duplicative of other QCDR measures that are being approved. Furthermore, having multiple QCDRs report on the same QCDR measure allows for a larger cohort of clinicians to report on the measure, which helps establish more reliable benchmarks and may give some eligible clinicians or group a better chance of obtaining a higher score on a particular measure. However, we have experienced that this policy has created unintended financial burden for QCDRs requesting permission from other QCDRs who own QCDR measures, as some QCDRs charge a fee for the use of their QCDR measures. MIPS quality measures, while stewarded by specific specialty societies or organizations, are generally available for third party intermediaries, MIPS eligible clinicians, and groups to report on for purposes of MIPS without a fee for use. Similarly, we believe, that once a QCDR measure is approved for reporting in MIPS, it should be generally available for other

QCDRs to report on for purposes of MIPS without a fee for use. In the CY 2019 PFS proposed rule (83 FR 35984), we proposed at § 414.1400(b)(3)(ii)(C) that beginning with the 2021 MIPS payment year, as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. In the CY 2019 PFS proposed rule (83 FR 35984) we also proposed at § 414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID. If a QCDR refuses to enter into such a license agreement, the QCDR measure would be rejected and another QCDR measure of similar clinical concept or topic may be approved in its place.

The following is a summary of the public comments received on the ''QCDRs Seeking Permission from another QCDR to Use an Existing, Approved QCDR Measure'' proposals and our responses:

Comment: Many commenters disagreed with CMS' proposal to require QCDRs to enter into a measure licensing agreement with CMS beginning with the 2021 MIPS payment year, stating that QCDRs would be required to attest to these measures before knowledge that this proposal would be finalized and that they, therefore, did not know that they would be required to enter into mandatory licensing agreements for these measures at the time of attestation. Commenters specifically stated that this timeline would violate the Administrative Procedure Act. Other commenters stated that should the proposal be finalized, it would be unreasonable for QCDR measure stewards to implement the policy by January 1 of the 2019 performance period given that the self-nomination period closes prior to publication of the CY 2019 PFS final rule. Commenters stated that the proposal, if it is finalized, should be delayed at least 1 year to give QCDRs an opportunity to decide whether to continue participating in the program. One commenter stated that some specialty societies may delay their QCDR application until this issue has been addressed by CMS.

Response: Based on the feedback and concerns raised by stakeholders, in the interim, we are not finalizing this proposal. Rather, while we believe our proposal is consistent with the Administrative Procedure Act, we are persuaded by the other concerns raised by stakeholders on the implementation of this policy and are therefore retaining our existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813).

Comment: Many commenters disagreed with the proposal to require QCDR measure owners to allow other QCDRs to submit data on the QCDR measure as a condition of measure approval. Reasons cited for disagreeing with the proposal include beliefs that it does not acknowledge the cost in developing complex measures; would unfairly reduce costs for QCDRs that do not develop their own measures while increasing costs for QCDRs that do; would compromise the intellectual property of measure stewards as CMS would have a mandatory, exclusive, and unfettered right to sublicense their QCDR measures for MIPS purposes as a condition of measure approval; would undermine the smooth operation of the QCDR measure market; is an arbitrary and capricious reversal of existing policy; violates intellectual property law, judicial precedent, executive order, and copyrights; nullifies the rights of copyright owners to collect reasonable royalties, maintain measure integrity, and limit inappropriate use; might remove the right of QCDR developers to have input into how CMS uses their measures; may result in a developer having to seek CMS's approval prior to working with another payer entity for reporting of its measures; and ignores the time and resources spent in developing and maintaining measures.

Response: As noted above we are not finalizing this proposal. We note that we do not believe this proposal would have violated intellectual property rights or law, as QCDRs would not have been required to submit QCDR measures for approval, and if a QCDR had refused to enter into such a license agreement, the QCDR measure would have been rejected and another QCDR measure of similar clinical concept or topic may have been approved in its place. We will take the many concerns raised by commenters into consideration as we work with stakeholders to address this issue in the future.

Comment: Many commenters disagreed with the proposal to require QCDR measure owners to allow other QCDRs to submit data on the QCDR measure as a condition of measure approval believing it contradicts the intent of the Meaningful Measure Initiative by eliminating the incentive to develop innovative quality measures that focus on meaningful outcomes; will disincentivize societies from investing in the development of new and improved measures; may increase the incidence of inappropriate use of measures by QCDRs lacking the necessary clinical breadth of exposure/experience resulting in lower quality data being collected, decreased reliability and validity of results, and potential misclassification of providers; would negatively impact the quality of available measures and physician community support for the Quality Payment Program in general; would disincentivize QCDRs from remaining in business, resulting in loss of significant private sector knowledge and experience, as well as increasing the financial burden on the government to hire more federal contractors to replace lost innovation and creativity; and disregards the original intent of QCDRs to submit data on non-MIPS measures focused on disease, condition, procedure, or therapy-specific patient populations.

Response: We do not believe this proposed policy contradicts the Meaningful Measure Initiative, which seeks to reduce the number of duplicative measures in quality performance programs, thereby reducing clinician burden and complexity. However, as noted above we are not finalizing this proposal. We also note that with the finalization of the updated QCDR definition, we believe we will be able to negate any concerns of inappropriate use of QCDR measures by QCDRs who do not have the clinical expertise needed to understand the measure at hand. We have observed increasing interest in stakeholders becoming QCDRs, and believe that they will continue to drive innovation and competition within the market.

Comment: A few commenters suggested alternatives to the proposal to require QCDRs to license their measures to CMS. These alternatives include encourage licensing agreements between QCDRs and reinforcing the ability of QCDRs to develop their own measures should they elect not to license them from other QCDRs. One commenter suggested that CMS should create a ''measure complexity score'' with a corresponding, volume-based, licensing fee payable to the QCDR holding the original measure in conjunction with an annual consolidation of measures to support harmonization requiring stakeholders to collaborate on a ''shared'' measure creation (with licensing fees split evenly) or lose the opportunity for future licensing fee payments. Another commenter recommended CMS propose including a cost-based algorithm that would be used to determine a specific QCDR measure fee which would protect organizations

that could not afford the development of a quality measure or that were not able to develop a measure because a similar measure exists, as well as preventing QCDR measure developers from assigning unreasonable fees to their measures. One commenter recommended CMS establish a pilot program that would encourage collaboration across QCDRs and require users of QCDR measures to agree to adhere to certain requirements of the measure steward, as well as share measure performance information to implement and test measure changes, progressing all concepts to patient-centered outcome measures through measure retirement. Another commenter recommended that CMS follow NQF's example that anyone can report the measure scores and there has to be public/free access for the measures to be used in clinical care, but the measure steward should be permitted to require licensing and fees for anyone who wants to use the measures for more sophisticated purposes, such as programming into software that will result in sales/profit. Other commenters cited their opinions that should the proposal be finalized, it should be done with modification to require a standard data dictionary be used for all QCDR measures and include risk adjustment as well as the same standard methodology used by the measure developer.

Response: We note that the suggestion to encourage licensing agreements between QCDRs was implemented in the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814); however, we have decided not to finalize the measure licensure policy at this time. Our goal in enacting such a policy was to promote measure harmonization and decrease the number of duplicative QCDR measures in the program. We appreciate the suggestion of a ''measure complexity score'' but envision such an approach would be difficult to implement. We would need additional information from stakeholders prior to implementing such a policy, such as how would CMS know how to correlate the volume and complexity to a specific score? What would that entail if on an annual basis the number of QCDRs who submit a similar measure concept increases, and what would they have to do in order to be a part of the harmonization effort? We request clarification on how a cost-based algorithm can be developed, and would also like to clarify that CMS does not regulate the minimum or maximum amounts that a QCDR may charge as a licensing fee.

We thank the commenter for their suggestion of implementing a pilot program where QCDRs would need to share measure performance information, test and implement measure changes, and work towards patient-centered outcome measures. We agree that the sharing of performance data, testing results, and moving towards outcome based measures are all important, but will need to look into the feasibility and operations of implementing such requirements. With regards to the development of a standard data dictionary, as described in the CY 2018 Quality Payment Program final rule (82 FR 53813), we encourage QCDR measure developer to utilize the current Measure Development Plan available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/2018-MDP-annual-report.PDF.* Furthermore, as explained through posted sub-regulatory documents for the 2019 self-nomination period, the current Blueprint for the CMS Measures Management System available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/BlueprintVer14.pdf.* Both resources provide information on standardized terminology, measure concepts and constructs.

Comment: Many commenters requested CMS work with them to adopt a market-based solution to create safeguards to protect the proper implementation of QCDR measures and enforce the intellectual property rights of developers of QCDR measures, while also ensuring that the measures are readily available to other QCDRs with clinical expertise and experience in quality measure development.

Response: We will look to provide listening sessions to better understand and explore the feasibility of this approach.

Comment: Many commenters expressed concern with CMS' requests for harmonization of similar MIPS measures due to their belief that some vendors may be misusing measures and diminishing the integrity of the data, the quality of feedback to physicians, and ability to compare performance. The commenters further cited their belief that such harmonization can lead to inconsistencies in implementation, yielding incomparable results and inaccurate benchmarking due to lack of accountability and standardization across registries which may be employing different methods for obtaining, risk adjusting, and aggregating data, thereby creating variations in how clinicians are measured and how their care is classified.

Response: To clarify, in the CY 2019 PFS proposed rule (83 FR 35984), we indicated that the QCDRs would be required to use the QCDR measure without any modification, and would have to report on the measure utilizing the CMS assigned measure ID. We encourage QCDRs to work together through measure harmonization, and to reach out to QCDR measure owners when they believe a revision to the measure specification is appropriate, for the QCDR measure owner to consider.

Comment: A few commenters suggested the proposal to require QCDRs to license measures to CMS should include allowing qualified registries and other non-QCDR submitter types to also report QCDR measures; only counting measures developed by a QCDR to count toward the 30 measure threshold; and requiring QCDR measure owners to provide detailed specifications including ICD–10–CM codes, CPT codes, required clinical data elements, et cetera, so that all QCDR registries administer the specification uniformly, and developing a system to properly record and track ownership rights, including making ownership information CMS collects available to QCDRs to better facilitate sharing of QCDR measures between QCDR stewards. Commenters also suggested that CMS reserve the right of the measure owner to review interim performance results of other QCDRs utilizing their measures with full cooperation of the other QCDRs to ensure performance results do not vary significantly between QCDRs, thereby ensuring alignment on execution of the measure specification between QCDRs before performance is scored and future benchmarks are impacted.

Response: To clarify, we are only allowing other QCDRs to report on the QCDR measures. Other submitter types would not have the QCDR measures available for reporting. As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53811), QCDRs have the capability to develop and submit for consideration up to 30 QCDR measures per performance period. However, there is no limit as to the number of MIPS quality measures they intend on supporting for a given performance period. We disagree that QCDR measures should be available for reporting by non-QCDR submitter types. As we provide QCDRs with feedback on harmonizing or using QCDR measures owned by other QCDRs, we encourage them to reach out to the QCDRs specifically for the detailed specification inclusive of ICD–10 and CPT codes, as each measure owner is responsible for tracking ownership

rights. The MIPS quality measures provide a detailed measure specification to allow consistency in implementation, but data abstraction may include multiple methods. We would require QCDRs to follow a similar approach, where QCDRs would need to provide a detailed specification to the QCDRs approved to submit the QCDR measure. This would include any applicable ICD–10–CM codes, CPT codes, required clinical data elements, et cetera, to allow implementation with minimal variance. We would like to hear from QCDRs on whether or not they would find this useful; and if this effort will increase burden on their end regarding measure specification development. We will take the suggestion that CMS reserve the right of the measure owner to review interim performance results of other QCDRs utilizing their measures into consideration for future rulemaking.

Comment: A few commenters stated that the proposal blurs the line between QCDR measures and Quality Payment Program measures and would eliminate the ability for a QCDR to ''test'' a measure in the sandbox of their own QCDR before submitting it to CMS to become a Quality Payment Program measure under the Measures Under Consideration (MUC) process. Finally, one commenter suggested that if a measure owner was ready to make a measure available for reporting by all of the Quality Payment Program, they should submit it to CMS under the MUC process.

Response: The QCDR measure approval process is not intended to act as a test bed for measure concepts, we expect QCDRs to have measures that are analytically sound, are reliable, and feasible. Furthermore, we certainly encourage that if a measure owner is ready to make a measure available for reporting by all of the Quality Payment Program, they should submit it to CMS under the MUC process as discussed in section III.I.3.h.(2)(b)(i) of the CY 2019 PFS proposed rule (83 FR 35898 through 35899).

Comment: One commenter stated its belief that the proposal does not align with the intended purpose of the MACRA grant for measure development, which they further noted demonstrates the federal government's recognition of measure development expense. A second commenter stated that the proposal lacks provisions on how to determine whether a specific measure is intended for another population and that the absence of such provisions can lead to inappropriate implementations in patient populations with the inability of the measure owner to review data collected on their measures and maintain the measures appropriately.

Response: We do not believe this policy would not align with the MACRA grant for measure development, since generally across all quality programs we are looking to reduce the number of duplicative measures available for reporting and to transition to more outcomes based measures. We believe that QCDRs exist to address measurement gaps as identified by the specialists and that QCDRs are intended to address gaps in measurement that would better reflect a clinician's scope of practice. Based on the updates to the QCDR definition we have finalized in this final rule (in the above section) for the 2020 performance period of MIPS, we believe we will be able to further vet QCDR applications to ensure that approved QCDRs would have the clinical expertise and measure development experience. We are also streamlining the number of measures available to clinicians in order to align with our Meaningful Measures initiative. We note that our review and approval of the QCDR measures will follow our existing process utilizing the QCDR measure evaluation criteria as detailed through sub-regulatory guidance in the 2019 QCDR Measure Development Handbook, located in the 2019 Self-Nomination Toolkit on the Quality Payment Program Resource Library web page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html*. Once the QCDR measures have been finalized for the performance period, and the specification has been finalized, we intend to post the list of QCDR measure specifications for QCDRs to review and consider prior to deciding whether or not they wish to support additional QCDR measures. As a part of this consideration, we encourage QCDRs to review the measure specifications to determine the populations addressed.

Comment: A few commenters supported the proposal to require QCDRs to enter into licensing agreements with CMS as a condition of approval. Reasons cited include their beliefs that the proposal allows different vendors to have the ability to address different specialty needs appropriately thereby providing greater choice to eligible clinicians, increases the effectiveness of quality measurement, and increases the relevance and usefulness of measures in evaluating the quality of care provided to patients nationally by increasing the number of providers reporting data.

Response: We thank the commenters for their support but as noted previously we are not finalizing this policy at this time.

Comment: A few commenters stated that CMS should adopt a model where one measure is supported by one entity that represents a single clinical domain or subspecialty as they noted doing so will enhance consistency and validity across measurements; allow for a single method for data aggregation, analytics, and reporting; reduce benchmarking issues; decrease the risk of clinicians being misclassified in the quality of care they provide; and remedy CMS' lack of ability to co-aggregate data from multiple data sources and properly risk-adjust measures. The commenters noted that the approved registry should be required to meet standards for data which include rigor in explicitly defining data elements used in the measurement, serve as a single source of data aggregation and data normalization to secure data integrity, apply approved and consistent statistical standards for analytics, respond to clinical and methodological questions, and be responsible for reporting requirements as defined by CMS. One commenter further noted that CMS policy should require QCDRs to always refer eligible clinician questions on specific measures back to the measure steward, prohibit vendors and other QCDRs from specifying CQMs into eCQMs without permission, require QCDRs to use current measure specifications, and require CMS to publicly post complete measure specifications, where appropriate, to the CMS Quality Payment Program resources website to ensure all registries are implementing the most updated measure specifications.

Response: We are not looking to set limitations, such as, one clinical domain being assigned to one entity. We have multiple instances where there are a few QCDRs covering similar areas (that is, surgery, anesthesia, rheumatology). We would appreciate thoughts on how we can reduce benchmarking issues to thereby incentivize QCDR measure reporting. QCDRs are required to meet CMS data aggregation and reporting requirements and agree that it is important that QCDRs are able to meet data integrity standards in using data elements for purposes of measurement. We believe there are circumstances out of CMS' control where the clinician will reach out to the QPP service center for assistance with a measure related question or to the QCDR they are specifically working with. It would not be feasible to set such a requirement when we could not monitor that it would be followed. We encourage clinicians who have questions on the

QCDR measure specifications to reach out directly to the QCDR measure owner in order to gain clarity on their questions. We agree, however, that the QCDR must use the measure in its original state. QCDRs have to use the measure in its ''as is'' state; meaning, how it was approved for the given performance period. We post QCDR measure specifications, inclusive of: The measure's specialty; QCDR name; measure title; measure description; denominator; numerator; denominator exclusions; denominator exceptions; numerator exclusions; data source used; NQF number (if applicable); NQS domain; whether the measure is high priority, outcome; measure type; whether the measure is inverse, proportional, continuous variable, ratio; the range of scores if the measure is continuous variable or ratio measures; number of performance rates submitted; overall performance rate; whether the measure is risk-adjusted; if risk-adjusted, and which score is risk-adjusted within the QPP resource library. The systems are programmed on an annual basis to only accept those QCDR measures and correlated specifications as approved for the upcoming performance period.

Based on the feedback and concerns raised by stakeholders, in the interim, we are not finalizing at § 414.1400(b)(3)(ii)(C) that as a condition of a QCDR measure's approval for purposes of MIPS, the QCDR measure owner would be required to agree to enter into a license agreement with CMS, permitting any approved QCDR to submit data on the QCDR measure (without modification) for purposes of MIPS and each applicable MIPS payment year. Rather we are retaining our existing policy that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813). We remain very concerned about duplicative measures and their impact to our meaningful measures initiative. We are eager to work with the stakeholder community to determine solutions for this issue and will continue to look for policy resolutions to address this issue.

We are finalizing our proposal at § 414.1400(b)(3)(iii) that other QCDRs would be required to use the same CMS-assigned QCDR measure ID.

(4) Qualified Registries

We refer readers to § 414.1400 and the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818) for our previously finalized policies regarding qualified registries. In the CY 2019 PFS proposed rule (83 FR 35984), we proposed to update: Information required for qualified registries at the time of self-nomination and the self-nomination period for qualified registries.

(a) Establishment of an Entity Seeking To Qualify as a Qualified Registry

In the CY 2017 Quality Payment Program final rule (81 FR 77383), we state at § 414.1400(h)(2) that the qualified registry must have at least 25 participants by January 1 of the performance period. These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement. We realize that a qualified registry's lack of preparedness to accept data from MIPS eligible clinicians and groups beginning on January 1 of the performance period may negatively impact a clinician's ability to use a Qualified Registry to report, monitor the quality of care they provide to their patients (and act on these results) and may inadvertently increase clinician burden. For these reasons, in the CY 2019 PFS proposed rule (83 FR 35984), we proposed to redesignate § 414.1400(h)(2) as § 414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period. These participants do not need to use the qualified registry to report MIPS data to us; rather, they need to submit data to the qualified registry for quality improvement.

We did not receive any comments on the ''Establishment of an Entity Seeking To Qualify as a Qualified Registry.'' We are finalizing our proposal to redesignate § 414.1400(h)(2) as § 414.1400(c)(2) to state that beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(b) Self-Nomination Process

We refer readers to § 414.1400(g), the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77383 and 82 FR 53815, respectively) for our previously established policies regarding the self-nomination process for qualified registries. We did not propose any changes to this policy.

(c) Self-Nomination Period

Under the previously finalized policy at § 414.1400(g), qualified registries must self-nominate from September 1 of the year prior to the applicable performance period until November 1 of the same year and must, among other things, provide all information requested by us at the time of self-nomination. To maintain alignment with the timelines proposed for QCDR self-nomination, as discussed in section III.I.3.k.(3)(c) of this final rule, we also proposed in the CY 2019 PFS proposed rule (83 FR 35985) to update the self-nomination period from September 1 of the year prior to the applicable performance period until November 1 to July 1 of the calendar year prior to the applicable performance period until September 1. Specifically, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) at § 414.1400(c)(1) that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process. For example, for the 2022 MIPS payment year, the applicable performance period would be CY 2020, as discussed in section III.I.3.g. of this final rule. Therefore, the self-nomination period for qualified registries would begin on July 1, 2019 and end on September 1, 2019.

We did not receive any comments on the ''Self-nomination Period'' for Qualified Registries. We are finalizing our proposal to amend § 414.1400(c)(1) to provide that, beginning with the 2022 MIPS payment year, entities seeking to qualify as qualified registries must self-nominate during a 60-day period beginning on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year; must provide all information required by us at the time of self-nomination; and must provide any additional information requested by us during the review process.

(5) Health IT Vendors or Other Authorized Third Parties That Obtain Data From MIPS Eligible Clinicians' Certified EHR Technology (CEHRT)

We refer readers to § 414.1400 and the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382) for our previously finalized policies regarding health IT vendors or other authorized third parties that obtain data from MIPS eligible clinicians. We finalized that health IT vendors that obtain data from a MIPS eligible clinician, like other third party intermediaries, would have to meet all criteria designated by us as a condition

of their qualification or approval to participate in MIPS as a third party intermediary. This includes submitting data in the form and manner specified by us. In the CY 2019 PFS proposed rule (83 FR 35985), we proposed to codify these policies at § 414.1400(d). Although we specified criteria for a health IT vendor in the CY 2017 Quality Payment Program final rule, we failed to codify the definition of a health IT vendor. Therefore, in the CY 2019 PFS proposed rule (83 FR 35985), we proposed to define at § 414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

As indicated in footnote 1 of the CY 2017 Quality Payment Program final rule (81 FR 77014 through 77015), the term ''health IT vendor'' encompasses many types of entities that support the health IT requirements on behalf of a MIPS eligible clinician. A ''health IT vendor'' may or may not also be a ''health IT developer'' for the purposes of the ONC Health IT Certification Program (Program), and, in some cases, the developer and the vendor of a single product may be different entities. Under the Program, a health IT developer constitutes a vendor, self-developer, or other entity that presents health IT for certification or has health IT certified under the Program. Other health IT vendors may maintain a range of data transmission, aggregation, and calculation services or functions, such as organizations which facilitate health information exchange.

We did not receive any comments on the ''Health IT Vendors or Other Authorized Third Parties That Obtain Data From MIPS Eligible Clinicians' Certified EHR Technology (CEHRT).'' Therefore, we are finalizing our proposal to codify our previously established policies at § 414.1400(d). We are also finalizing our proposal to define at § 414.1305, that health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

(6) CMS-Approved Survey Vendors

In the CY 2017 Quality Payment Program final rule (81 FR 77386), we finalized the criteria, required forms, and vendor business requirements needed to participate in MIPS as a CMS-approved survey vendor. In the CY 2019 PFS proposed rule (83 FR 35985), we proposed at § 414.1400(e) to codify these previously finalized criteria and requirements. Accordingly, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) at § 414.1400(e) that an entity seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. We also proposed to require that the application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. In addition, we proposed that a CMS-approved survey vendor must meet several criteria. First, we proposed to require that an entity have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;
- At least 3 years of experience administering CAHPS surveys within the past 5 years;
- Experience administering surveys in English and one of the following languages: Cantonese; Korean; Mandarin; Russian; or Vietnamese;
- Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
- Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

Furthermore, we proposed in the CY 2019 PFS proposed rule (83 FR 35985) that to be a CMS-approved survey vendor, the entity must also meet the following criteria:

- It must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data;
- The entity must have successfully completed, and required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors;
- The entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts;
- The entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and
- The entity must have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

We also refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53818 through 53819) for our previously established policies regarding the updated survey vendor application deadline.

The following is a summary of the public comments received on the ''CMS-Approved Survey Vendors'' proposals and our responses:

Comment: A few commenters commended CMS for making the CAHPS for Physician Quality Reporting System (PQRS) survey available in Cantonese, Korean, Mandarin, Russian, Spanish, and Vietnamese and for making the Medicare Accountable Care Organization CAHPS survey available in Cantonese, Korean, Mandarin, Portuguese, Russian, Spanish, and Vietnamese. These commenters encouraged CMS to work with stakeholders to develop validated translations of all CAHPS surveys used in MIPS and APMs in at least the top ten primary languages among Medicare beneficiaries.

Response: We appreciate the commenters' feedback. We have made the CAHPS for MIPS survey available in Spanish and we will continue to work with stakeholders to develop additional translations of the surveys. In addition, because the CAHPS for MIPS survey is available in Spanish and may become available in other languages in the future, we believe it is appropriate to modify our proposed requirement at § 414.1400(e)(1)(iv) to more broadly state that an entity must have experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available. These languages currently consist of Cantonese, Korean, Mandarin, Russian, Spanish, and Vietnamese.

After consideration of the public comments received, we are finalizing our proposal at § 414.1400(e) to state that entities seeking to be a CMS-approved survey vendor for any MIPS

performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data; and that the application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. We are also finalizing our proposal at § 414.1400(e) that a CMS-approved survey vendor must meet several criteria that consists of the following:

An entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

- At least 3 years of experience administering mixed-mode surveys (surveys that employ multiple modes to collect data) that include mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);
- At least 3 years of experience administering surveys to a Medicare population;
- At least 3 years of experience administering CAHPS surveys within the past 5 years;
- Experience administering CAHPS surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available. These languages currently consist of Cantonese, Korean, Mandarin, Russian, Spanish or Vietnamese;
- Use of equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and
- Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

In addition, we are finalizing without change our proposal that an entity must have certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data; the entity must have successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors; the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts; the entity must have agreed to participate and cooperate, and have required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors; and the entity must have sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(7) Auditing of Third Party Intermediaries Submitting MIPS Data

In the CY 2018 Quality Payment Program final rule (82 FR 53819), we established at § 414.1400(j) policies regarding auditing of third party intermediaries submitting MIPS data. In the CY 2019 PFS proposed rule (83 FR 35985), we did not propose any changes to these policies. In this final rule, the provision that currently appears at § 414.1400(j) is redesignated as § 414.1400(g) and contains no substantive changes.

(8) Remedial Action and Termination of Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule (81 FR 77548), we finalized the criteria for probation and disqualification for third party intermediaries at § 414.1400(k). In the CY 2019 PFS proposed rule (83 FR 35986), we proposed to revise the numbering of this section and the title to more accurately describe the policies in this section. Specifically, we proposed to renumber this section as § 414.1400(f) and to rename it as ''remedial action and termination of third party intermediaries.'' Additionally, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) changes to § 414.1400(f) to amend, clarify, and streamline our policies related to remedial action and termination.

Our intent with these policies is to identify and remedy noncompliance with the applicable third party intermediary criteria, as well as identify issues that may impact the accuracy of or our ability to use the data submitted by third party intermediaries. Accordingly, in the CY 2019 PFS proposed rule (83 FR 35986), we proposed to amend § 414.1400(f)(1) to state that we may take remedial action for noncompliance with applicable third party intermediary criteria for approval (a deficiency) or for the submission of inaccurate, unusable, or otherwise compromised data. In the CY 2017 Quality Payment Program final rule, we finalized our policy regarding data inaccuracies at § 414.1400(k)(4). In the CY 2019 PFS proposed rule (83 FR 35986), we proposed at § 414.1400(f)(3) to expand data inaccuracies to include a determination by us that data is inaccurate, unusable, or otherwise compromised. However, we did not propose to change the factors we may consider to make such a determination. In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed to move the notification requirement at § 414.1400(k)(6) to § 414.1400(f)(1) and to apply the requirement to all deficiencies and data errors.

Based on our early experience with third party intermediaries under MIPS and the challenges for both third party intermediaries and us in regards to timing and trying to resolve deficiencies and data errors within the various reporting and performance periods, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to amend the timeframes by which a third party intermediary must submit a Corrective Action Plan (CAP) to us or come into compliance. Specifically, we proposed § 414.1400(f)(2), which requires third party intermediaries to submit a CAP or correct the deficiencies or data errors by the date specified by us (83 FR 35986).

Additionally, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to consolidate at § 414.1400(f)(1) the grounds for remedial action against a third party intermediary currently specified at § 414.1400(k)(1) and (4) and to consolidate at § 414.1400(f)(2) the grounds for terminating a third party intermediary currently found at § 414.1400(k)(3), (5) and (7). Therefore, we proposed at § 414.1400(f)(1) that if at any time we determine that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may take certain remedial actions (for example, request a CAP) (83 FR 35986). In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed at § 414.1400(f)(2) that we may terminate, immediately or with advance notice, the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons: We have grounds to impose remedial action, we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us.

Additionally, in the CY 2019 PFS proposed rule (83 FR 35986), we proposed to consolidate at § 414.1400(f)(1) the actions we may take

if we identify a deficiency or data error that are set forth at § 414.1400(k)(3) and (7). Thus, we proposed at § 414.1400(f)(1) in the CY 2019 PFS proposed rule (83 FR 35986) that if we determine a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, we may require the third party intermediary to submit a CAP to us to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. We proposed to require that the CAP be submitted to CMS by a date specified by CMS.

In the CY 2019 PFS proposed rule (83 FR 35986), we also proposed that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data: (1) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and (2) affects more than 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary. In addition, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) that if the third party intermediary has a data error rate of 3 percent or more, we will publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

We clarify in this final rule that CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary. In the CY 2017 Quality Payment Program final rule (81 FR 77387 through 77388), we explained that if a third party intermediary has data inaccuracies including (but not limited to) TIN/NPI mismatches, formatting issues, calculation errors, data audit discrepancies affecting in excess of 3 percent (but less than 5 percent) of the total number of MIPS eligible clinicians or groups submitted by the third party intermediary, we would annotate on the CMS qualified posting that the third party intermediary furnished data of poor quality and would place the entity on probation for the subsequent MIPS performance period. If a third party intermediary does not reduce their data error rate below 3 percent for the subsequent performance period, the third party intermediary would continue to be on probation and have their listing on the CMS website continue to note the poor quality of the data they are submitting for MIPS for one additional performance year. After 2 years on probation, the third party intermediary would be disqualified for the subsequent performance year. We also explained that data errors affecting in excess of 5 percent of MIPS eligible clinicians or group submitted by the third party intermediary may lead to the disqualification of the third party intermediary from participation for the following performance period (that is, without first placing the third party intermediary on probation).

Accordingly, it was always our intent that data errors affecting in excess of 3 percent of the MIPS eligible clinicians or group submitted by a third party intermediary would result in remedial action or disqualification (termination) of the third party intermediary. In this final rule, we are correcting an obvious error in the regulation text we proposed at § 414.1400(f)(3)(ii) to clarify that if submitted data is inaccurate, unusable, or otherwise compromised if errors in the submitted data affect more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

Finally, we proposed to remove our probation policy. Therefore, we proposed in the CY 2019 PFS proposed rule (83 FR 35986) to remove the definition of probation at § 414.1400(k)(2) and references to probation in § 414.1400(k)(1), (3) and (5).

The following is a summary of the public comments received on the ''Remedial Action and Termination of Third Party Intermediaries'' proposals and our responses:

Comment: One commenter stated that CMS should put in place a safe harbor policy in order to minimize the impact on clinicians when a data issue outside of a clinician's or group's control occurs due to a third party intermediary. The commenter indicated that, under those circumstances, CMS should automatically consider the clinician or group to have satisfied the quality performance category. The commenter cited concerns with the transition and upgrade to 2015 CEHRT and references data issues under 2016 PQRS related to the 2014 CEHRT upgrade.

Response: We do not agree that we should create a safe harbor policy to address the circumstances described by the commenter. Instead, we believe it would be appropriate to address data issues on a case-by-case basis. As we discussed in the CY 2018 Quality Payment Program final rule (82 FR 53807), we expect third party intermediaries to develop processes to ensure that the data and information they submit to CMS on behalf of MIPS eligible clinicians, groups, and virtual groups are true, accurate, and complete; we also rely on the third party intermediaries to address these issues in its arrangements and agreements with other entities, including MIPS eligible clinicians, groups, and virtual groups.

Comment: One commenter agreed with the proposal to remove the probation policy.

Response: We appreciate the commenter's support.

Comment: A few commenters disagreed with our proposal at § 414.1400(f)(2) because it would allow us to immediately or with advance notice terminate a third party intermediary's ability to submit MIPS data without first placing the third party intermediary on probation. The commenters believe that termination should occur only with advance notice through a clearly defined process that reflects the current procedure set forth at § 414.1400(f). Commenters suggested that CMS' termination procedure include formal consideration of a CAP.

Response: We appreciate the commenters' concerns, and therefore, we expect that in most circumstances, we would take remedial action, including imposition of a CAP, prior to terminating the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group. Before deciding whether to terminate a third party intermediary's ability to submit MIPS data, we would take into account a third party intermediary's actions, the severity of the non-compliance or errors at issue, and the potential for undue hardship or negative impact on affected eligible clinicians. In addition, we would expect to provide advance notice of most terminations; we would likely impose immediate termination on a third party intermediary's ability to submit MIPS data only in circumstances where egregious non-compliance or data errors have occurred. However, if we have not received a CAP within the specified time period or the CAP is not accepted by us, or the third party intermediary fails to correct the deficiencies or data errors by the date specified by us, we may terminate the third party intermediary, immediately or with advance notice.

Comment: A few commenters stated that the proposed termination policy could result in undue hardship on or negatively impact affected eligible clinicians should termination occur during a performance period.

Response: We recognize that termination of a third party intermediary's ability to submit MIPS data during a performance period may result in undue hardship on eligible clinicians who are supported by the third party intermediary. Therefore, we would consider whether a third party intermediary is supporting eligible clinicians in deciding when to terminate the ability of the third party intermediary to submit MIPS data. In addition, we will consider for future rulemaking whether a third party intermediary should be required to submit to CMS a transition plan that addresses how submission of data would be handled in the event that termination occurs during a performance period.

Comment: A few commenters representing QCDRs and qualified registries stated that CMS should clearly define, and provide examples of, a ''data error'' for purposes of determining a third party intermediary's data error rate, which may be disclosed publicly by CMS if it exceeds 3 percent. In addition, the commenters stated that CMS should set forth how the data error rate is calculated and develop a report that describes and differentiates data errors and other ''issues'' that should be brought to a third party intermediary's attention.

Response: The ''data error rate'' measures the amount of data submitted by a third party intermediary that was ''inaccurate, unusable, or otherwise compromised.'' Additional material regarding data inaccuracies and error rates is available in the ''2019 Qualified Clinical Data Registry (QCDR) Fact Sheet'' and the ''2019 Qualified Registry Fact Sheet'' in the 2019 Self-Nomination Toolkit for QCDRs & Registries, located in the Quality Payment Program Resource Library at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html*. We appreciate the suggestion of creating a report that describes data errors and ''other issues,'' however, we believe that our existing material addresses the commenters' concern.

After consideration of the public comments received, we are finalizing our proposal to revise the numbering of § 414.1400(k) as § 414.1400(f) and to rename it as ''remedial action and termination of third party intermediaries.'' We are also finalizing our proposal to amend, clarify, and streamline our policies related to remedial action and termination as follows:

- We are finalizing § 414.1400(f)(1) to state that CMS may take one or more of the following remedial actions if we determine that a third party intermediary has ceased to meet one or more of the applicable third party intermediary criteria for approval or has submitted data that is inaccurate, unusable, or otherwise compromised: We will require the third party intermediary to submit by a deadline specified by CMS a CAP that addressed the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring; or we will publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.
- We are finalizing § 414.1400(f)(2) to state that CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician group, or virtual group for one or more of the following reasons: CMS has grounds to impose remedial action; CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; or, the third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.
- We are finalizing § 414.1400(f)(3) to state that, for purposes of paragraph (f), CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if it: Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

l. Public Reporting on Physician Compare

This section contains our approach for public reporting on Physician Compare for year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and future years, including MIPS, APMs, and other information as required by the MACRA and building on our previously finalized public reporting policies (see 82 FR 53819 through 53832).

Physician Compare (*http://www.medicare.gov/physiciancompare*) draws its operating authority from section 10331(a)(1) of the Affordable Care Act. Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare initiated a phased approach to publicly reporting performance scores that provide comparable information on quality and patient experience measures. A complete history of public reporting on Physician Compare is detailed in the CY 2016 PFS final rule (80 FR 71117 through 71122). More information about Physician Compare, including the history of public reporting and regular updates about what information is currently available, can also be accessed on the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53820), Physician Compare has continued to pursue a phased approach to public reporting under the MACRA in accordance with section 1848(q)(9) of the Act. Generally, all data available for public reporting on Physician Compare must meet our established public reporting standards under § 414.1395(b). In addition, for each program year, CMS provides a 30-day preview period for any clinician or group with Quality Payment Program data before the data are publicly reported on Physician Compare under § 414.1395(d). All data available for public reporting—measure rates, scores, and attestations, objectives, etc.—are available for review and correction during the targeted review process. See the CY 2018 Quality Payment Program final rule for details on this process (82 FR 53820).

Lastly, section 104(e) of the MACRA requires the Secretary to make publicly available, on an annual basis, in an easily understandable format, information for physicians and, as appropriate, other eligible clinicians related to items and services furnished to Medicare beneficiaries under Title XVIII of the Act. In accordance with section 104(e) of the MACRA, we finalized a policy in the CY 2016 PFS final rule (80 FR 71131) to add utilization data to the Physician Compare downloadable database.

We believe section 10331 of the Affordable Care Act supports the overarching goals of the MACRA by providing the public with performance information that will help them make informed decisions about their health care, while encouraging clinicians to improve the quality of care they provide to their patients. In accordance with section 10331 of the Affordable Care Act, section 1848(q)(9) of the Act, and section 104(e) of the MACRA, we plan to continue to publicly report performance information on Physician Compare. As such, the following sections discuss the information previously finalized for inclusion on Physician Compare for all program years, as well as our finalized policies for public reporting on Physician Compare for year 3 of the Quality

Payment Program (2019 data available for public reporting in late 2020) and future years.

We received several miscellaneous comments, but since these were not applicable to specific proposals made, these comments are outside the scope of this section and the proposed rule.

(1) Final Score, Performance Categories, and Aggregate Information

In the CY 2018 Quality Payment Program final rule (82 FR 53823), we finalized a policy to publicly report on Physician Compare, either on profile pages or in the downloadable database, the final score for each MIPS eligible clinician and the performance of each MIPS eligible clinician for each performance category, and to periodically post aggregate information on the MIPS, including the range of final scores for all MIPS eligible clinicians and the range of performance of all the MIPS eligible clinicians for each performance category, as technically feasible, for all future years. We will use statistical testing and user testing, as well as consultation with the Physician Compare Technical Expert Panel convened by our contractor, to determine how and where these data are best reported on Physician Compare.

A summary of the previously finalized policies related to each performance category of MIPS data, as well as finalized policies for year 3 and future years, follows. It is important to note just because performance information is available for public reporting, it does not mean all data under all performance categories will be included on either public-facing profile pages or the downloadable database. These data must meet the public reporting standards, first. And, second, we are careful to ensure that we do not include too much information on public-facing profile pages in an effort not to overwhelm website users. Although all information submitted under MIPS is technically available for public reporting, we will continue our phased approach to making this information public.

(2) Quality

In the CY 2018 Quality Payment Program final rule (82 FR 53824), we finalized a policy to make all measures under the MIPS quality performance category available for public reporting on Physician Compare, either on profile pages or in the downloadable database, as technically feasible. This includes all available measures across all collection types for both MIPS eligible clinicians and groups, for all future years. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We will not publicly report first year quality measures, meaning any measure in its first year of use in the quality performance category, under § 414.1395(c). We will also include the total number of patients reported on for each measure included in the downloadable database (82 FR 53824).

We proposed to modify § 414.1395(b) to reference ''collection types'' instead of ''submission mechanisms'' to accurately update the terminology (83 FR 35987), consistent with the proposal to add this term and its definition under § 414.1305. We also proposed to revise § 414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category (83 FR 35987). We proposed this change to encourage clinicians and groups to report new measures, get feedback on those measures, and learn from the early years of reporting measures before measure are made public. We requested comment on these proposals.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Most commenters supported not publicly reporting first year data on quality measures for the first 2 years to encourage adoption of new measures and allow clinicians and groups to get experience with and feedback on these measures before they are publicly reported. One commenter noted concern with delaying the public reporting of first year quality measures for the first 2 years they are in use, stating it would slow the progress toward full Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures. A few commenters suggested that 3 years is a more appropriate length of time for delaying publicly reporting first year measures, stating this timeframe would allow CMS to adequately evaluate meaningful trends over time and provide clinicians with an adequate period to fix data collection issues and give clinicians more time to respond to performance feedback. A few commenters requested that public reporting on Physician Compare be delayed until the transition years to full Quality Payment Program implementation end and there is more predictability, continuity, consistency, and decreased complexity in the program. In addition, several commenters submitted suggestions regarding transparency of publicly reported performance data. One commenter requested that Physician Compare note for publicly reported measures if a change to clinical guidelines occurred during the performance year, so that the data provided is not misleading to the public.

Response: We agree that not publicly reporting first year data on quality measures for the first 2 years they are in use is sufficient time to gain experience with them before they are considered for public reporting and believe 2 years also meets the goal of providing more timely and transparent information to the public on clinician performance for making their healthcare decisions. We believe that waiting 3 years to publicly report first year measures unnecessarily hinders the ability to provide the public with transparent performance information after clinicians have already received such feedback and also reduces the non-financial incentive for clinicians to improve their performance. Additionally, we do not believe that delaying the public reporting of first year quality measures for the first 2 years they are in use delays Quality Payment Program implementation or evaluation of more clinicians reporting a consistent set of measures, since, at this time, eligible clinicians and groups have the flexibility to select from a broad list of measures and do not all need to report the exact same measures. Regarding the comment suggesting public reporting be delayed until the Quality Payment Program is fully implemented, we note that we are required under section 1848(q)(9)(A) and (D) of the Act to publicly report certain MIPS eligible clinician and group performance information on Physician Compare. However, we do recognize that we are in early stages of MIPS, which is why we are continuing to publicly report this information under a phased approach. In response to the suggestion to indicate, on Physician Compare, when a measure specification has changed, we note that if there are significant changes to a clinical guideline during the performance year and the measure specifications do not reflect the current standard of care, the measure is suppressed from MIPS scoring. Refer to III.I.3.i.(1)(b)(vii) of this final rule for more information on the scoring policy. Only data that meet our established public reporting standards under § 414.1395(b) will be publically reported on Physician Compare.

Regarding the comments supporting data transparency, we agree that for public reporting to be meaningful to all stakeholders, transparency is key. Each year we strive to actively share information, via the Physician Compare

initiative page and other channels, on our public reporting efforts as testing is completed and measures to be publicly reported are finalized. Last year in response to similar comments, we produced additional educational materials about the 5-star rating methodology and cut-offs, for example. We will continue our educational efforts as public reporting on Physician Compare evolves. We also reiterate our belief in the importance of clinicians reviewing their data for accuracy prior to it being publicly reported. All performance data publicly reported on Physician Compare will reflect the scores eligible clinicians and groups receive in their MIPS performance feedback, which are available for review and correction during the targeted review process.

After consideration of the comments, we are finalizing our proposal to revise § 414.1395(c) to indicate that we will not publicly report first year quality measures for the first 2 years a measure is in use in the quality performance category. We did not receive any comments on changing ''submission mechanism'' to ''collection type'' for the purposes of public reporting, and as a result are finalizing our proposal to modify § 414.1395(b) to reference ''collection types'' instead of ''submission mechanisms''.

(3) Cost

In the CY 2018 Quality Payment Program final rule (82 FR 53825), we finalized a policy to include on Physician Compare a subset of cost measures that meet the public reporting standards at § 414.1395(b), either on profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available cost measures, and applies to both MIPS eligible clinicians and groups. We will use statistical testing and website user testing to determine how and where measures are reported on Physician Compare. We previously finalized that we will not publicly report first year cost measures, meaning any measure in its first year of use in the cost performance category, under § 414.1395(c).

Consistent with our proposal for first year quality measures, we proposed to revise § 414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use in the cost performance category (83 FR 35987). We proposed this change to help clinicians and groups get feedback on these measures and learn from the early years of these new measures being calculated before measure are made public (83 FR 35987). We requested comment on this proposal.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Most commenters supported not publicly reporting first year data on cost measures for the first 2 years to encourage adoption of new measures and allow clinicians and groups to get experience with and feedback on these measures before they are publicly reported. One commenter expressed concern that delaying the public reporting of first year cost measures for the first 2 years they are in use, stating it would slow the progress toward full Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures. Another commenter recommended, separately from the other cost measures, that we consider extending the timeframe for which the new episode-based cost measures are publicly reported, so that there is time to gain experience with collecting and analyzing these measures.

Response: We agree that not publicly reporting first-year data on cost measures for the first 2 years they are in use is sufficient time to gain experience with them, including for the new episode-based cost measures, before they are considered for public reporting and believe 2 years also meets the goal of providing more timely and transparent information to the public on clinician performance for making their healthcare decisions. We believe that waiting 3 years to publicly report first year measures hinders the ability to provide the public with transparent information after clinicians will have already received such feedback and also reduces the non-financial incentive for clinicians to improve their performance. Additionally, we do not believe that delaying the public reporting of first year quality measures for the first 2 years they are in use delays Quality Payment Program implementation and in fostering evaluation of more clinicians reporting a consistent set of measures, as the cost performance category's full implementation is already delayed. We also do not believe there is a need or benefit to set a different timeframe for episode-based measures than there is for other cost measures that will also have 2 years of usage prior to being considered for public reporting.

After consideration of the comments, we are finalizing our proposal to revise § 414.1395(c) to indicate that we will not publicly report first year cost measures for the first 2 years a measure is in use.

(4) Improvement Activities

In the CY 2018 Quality Payment Program final rule (82 FR 53826), we finalized a policy to include a subset of improvement activities information on Physician Compare, either on the profile pages or in the downloadable database, if technically feasible, for all future years. This includes all available activities reported via all available collection types, and applies to both MIPS eligible clinicians and groups. For those eligible clinicians and groups that successfully meet the improvement activities performance category requirements, this information will be posted on Physician Compare as an indicator. We also finalized for all future years to publicly report first year activities if all other public reporting criteria are satisfied.

(5) Promoting Interoperability (PI)

In the CY 2018 Quality Payment Program final rule (82 FR 53827), we finalized a policy to include an indicator on Physician Compare for any eligible clinician or group who successfully meets the Promoting Interoperability performance category, as technically feasible, for all future years. ''Successful'' performance is defined as obtaining the base score of 50 percent (82 FR 53826). We also finalized a policy to include on Physician Compare, either on the profile pages or in the downloadable database, as technically feasible, additional information, including, but not limited to, objectives, activities, or measures specified in the CY 2018 Quality Payment Program final rule (82 FR 53827; see 82 FR 53663 through 53688). This includes all available objectives, activities, or measures reported via all available collection types, and applies to both MIPS eligible clinicians and groups (82 FR 53827). We will use statistical testing and website user testing to determine how and where objectives, activities, and measures are reported on Physician Compare. We also finalized for all future years to publicly report first year Promoting Interoperability objectives, activities, and measures if all other public reporting criteria are satisfied.

In addition, we finalized that we will indicate ''high'' performance, as technically feasible and appropriate, in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019). ''High'' performance is defined as obtaining a score of 100 percent (82 FR 53826 through 53827).

As the Quality Payment Program progresses into year 3, and consistent with our work to simplify the requirements under the Promoting Interoperability performance category of MIPS, we proposed not to include the indicator of ''high'' performance and to maintain only an indicator for ''successful'' performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019) (83 FR 35988). Not including the ''high'' performance indicator while maintaining the ''successful'' performance indicator continues to provide useful information to patients and caregivers without burdening website users with the additional complexity of accurately differentiating between ''successful'' and ''high'' performance, as this proved difficult for users in testing. User testing to date shows that website users value this information overall, however, as they appreciate knowing clinicians and groups are effectively using EHR technology to improve care quality (83 FR 35988).

We requested comment on our proposal not to include the indicator for ''high'' performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019) (83 FR 35988).

The following is a summary of the comments we received on our proposal and our responses.

Comment: The majority of commenters supported the proposal to move to a designation of ''successful'' only and to remove the ''high'' designation in the Promoting Interoperability performance category, as it offers a clear indication that clinicians are effectively using EHRs and would make the user experience more straightforward than delineating between multiple indicators. One commenter opposed the proposal to only include a ''successful'' indicator, since in future years it would be difficult to be ''successful,'' as defined, when the base scores, performance scores, and bonus scores are changed or removed. Another commenter requested clarification on how ''successful'' would be defined when the Promoting Interoperability performance category no longer includes a base score.

Response: We agree that moving from having both a ''successful'' and ''high'' indicator of an eligible clinician or group's Promoting Interoperability performance to having a single indicator of ''successful'' not only shows that clinicians are effectively using EHRs, but also is easier for patients to understand. Additionally, it is more technically feasible to designate a single ''successful'' indicator than both a ''successful'' and ''high'' indicator as the Promoting Interoperability performance category scoring methodology evolves and as we evaluate operational facets of the data. We wish to also clarify that having only a ''successful'' indicator will apply to individuals and groups who have a Promoting Interoperability performance category score above zero.

After consideration of the public comments received, we are finalizing our proposal to not include the indicator of ''high'' performance and to maintain only an indicator for ''successful'' performance in the Promoting Interoperability performance category beginning with year 2 of the Quality Payment Program. We note that in the CY 2017 Quality Payment Program final rule (81 FR 77397), we finalized a policy to include, as technically feasible, additional indicators, including but not limited to indicators such as, identifying if the eligible clinician or group scores high performance in patient access, care coordination and patient engagement, or health information exchange. We have since determined that it is not technically feasible to include an indicator of ''high'' performance that meets our public reporting standards as defined at § 414.1395(b) for year 1 of the Quality Payment Program. The reason we are not reporting this indicator, is because based upon conducting analysis against our public reporting standards, the scoring variability in the Promoting Interoperability performance category of the Quality Payment Program (year 1 to year 3) creates challenges that we are still uncovering for making the data useful to Physician Compare's primary patient and caregiver audience. Additionally, in reviewing the year 1 data (which was not available at the time the CY 2019 proposed rule was released) we have learned through user testing that patients and caregivers find clinician and group usage of EHR technology to generally be a meaningful indicator of quality, regardless of whether ''successful'' or ''high'' was noted. That is, including the word ''high'' did not result in patients and caregivers believing the clinician or group to be of higher quality than those that had the word ''successful'' next to their Promoting Interoperability performance category indicator. Therefore, the high performing indicator will not be reported in year 1, 2, 3 or future years of the Quality Payment Program on Physician Compare.

As noted above, we previously defined ''successful'' performance as obtaining the base score of 50 percent (82 FR 53826). As discussed in section III.I.3.h.(5) of this final rule, the Promoting Interoperability performance category will no longer have a base score beginning with year 3. To account for this change, we are finalizing a modified definition of ''successful'' performance to mean a Promoting Interoperability performance category score above zero beginning with year 3. We will include the modified indicator (above zero) for years 1, 2, and 3 to avoid confusion and preserve year-to-year comparability, and the previously finalized indicator (base score) for years 1 and 2 for transparency and consistency with our previously finalized policy, as technically feasible.

We also solicited comment on the type of EHR utilization performance information stakeholders would like CMS to consider adding to Physician Compare. This information may be considered for possible future inclusion on the website. We did not receive any comments.

(6) Achievable Benchmark of Care (ABC™)

Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark allows website users to more easily evaluate the information published by providing a point of comparison between groups and between clinicians. In the CY 2018 Quality Payment Program final rule (82 FR 53829), we finalized a policy to use the Achievable Benchmark of Care (ABC™) methodology to determine a benchmark for the quality, cost, improvement activities, and Promoting Interoperability data, as feasible and appropriate, by measure and collection type for each year of the Quality Payment Program based on the most recently available data each year. We also finalized a policy to use this benchmark as the basis of a 5-star rating for each available measure, as feasible and appropriate. For a detailed discussion of the ABC™ methodology, and more information about how this benchmark together with the equal ranges method is currently used to determine the 5-star rating system for Physician Compare, see the CY 2018 Quality Payment Program final rule (82 FR 53827 through 53829). Additional information, including the Benchmark and Star Rating Fact Sheet, is available on the Physician Compare Initiative website at *https://www.cms.gov/*

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/index.html. We appreciate comments received for this section, but since no proposals were made, these comments are outside the scope of this section and the proposed rule.

(a) Historical Data-Based Benchmarks

Benchmarks, and the resulting star rating, are valuable tools for patients and caregivers to use to best understand the performance information included on Physician Compare. Benchmarks can also help the clinicians and groups reporting performance information understand their performance relative to their peers, and therefore, help foster continuous quality improvement. In the initial years of the Quality Payment Program, we anticipated year-to-year changes in the measures available. As noted, we previously finalized a policy to determine the benchmark using the most recently available data (82 FR 53829). This ensured that a benchmark could be calculated despite potential year-to-year measure changes, but it also meant that the benchmark was not known to clinicians and groups prior to the performance period.

By year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020), we expect enough year-to-year stability in the measures available for reporting across all MIPS performance categories to use historical data to produce a reliable and statistically sound benchmark for most measures, by measure and collection type (83 FR 35988). Therefore, we proposed to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) (83 FR 35988). Specifically, benchmarks would be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period would be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks would be published prior to the start of the performance period, as technically feasible. For example, for the CY 2019 performance period, the benchmark developed using the ABC™ methodology would be calculated using CY 2017 performance period data and would be published by the start of CY 2019, as feasible and appropriate. If historical data is not available for a particular measure, we would indicate that and calculate the benchmark using performance data from the performance period. In this example, we would use CY 2019 performance period data to calculate the benchmark for CY 2019 performance period measures, as needed. This approach of utilizing historical data would be consistent with how the MIPS benchmarks are calculated for purposes of scoring the quality performance category. But, most importantly, this approach would provide eligible clinicians and groups with valuable information about the benchmark to meet to receive a 5-star rating on Physician Compare before data collection starts for the performance period (83 FR 35988). We requested comment on this proposal.

The following is a summary of the comments we received regarding our proposal to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020) and our responses.

Comment: Two commenters supported using benchmarks based on performance from a prior period so that clinicians are able to understand how their measure scores will translate into a 5-star rating. One commenter cautioned that historical benchmarks may penalize those clinicians who successfully managed costs at the onset of the benchmark while inadvertently incentivizing high spenders. Another commenter questioned whether there was enough stability year-to-year in MIPS to create valid and reliable benchmarks. Another commenter noted concern that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the Physician Quality Reporting System (PQRS). Another commenter cautioned that CMS needs to consider certain clinicians' ability to affect quality and cost when treating patients. One commenter recommended we postpone using benchmarks for measures with no historical data, for example, a new MIPS measure with no performance data from a prior performance year.

Response: Regarding the concern that historical benchmarks would be based on data from a small number of clinicians from various legacy programs such as the PQRS, we wish to clarify that only historical MIPS data will be used to create benchmarks; for example, year 3, which is 2019 data available for public reporting in late 2020, would use year 1 (CY 2017) MIPS data. Additionally, since these benchmarks will be based on the MIPS performance information that eligible clinicians choose to report, we assume that these measures, upon which the benchmarks will be based, reflect the areas in which eligible clinicians and groups believe they can most affect quality of care furnished. Since we are finalizing that we will not publicly report first year measures for the first 2 years they are in the program, new measures, which have no prior MIPS performance data, would not be available for public reporting until the third year they are in use, at which point there should be historical data upon which to set a historical benchmark if eligible clinicians and groups reported them. If, however, a measure does not meet our public reporting standards, for example due to lack of performance data available or insufficient sample size, then the measure would not be available for public reporting, and would not need a benchmark. Regarding the concern about stability of data, we do believe that if a measure is in use for multiple years of MIPS that the performance should stabilize. We do not expect that clinicians and groups who manage costs effectively in 2017 should suffer a penalty by comparing their 2019 data to 2017 benchmarks. We appreciate the comment about high spenders and will plan to analyze impact. That said, we appreciate the concerns raised and will continuously evaluate the data against our public reporting standards for year-to-year stability. We will also monitor whether the historical benchmarking approach inadvertently creates negative incentives, though early testing has not shown this to be the case. Regarding the suggestion to postpone using benchmarks for measures without historical data, we disagree and believe it is important for website users to understand clinician performance in a meaningful way. Our testing and experience to date has shown that the next best way to create benchmarks for information reported on Physician Compare, in the absence of historical data, is by using information from the most recent performance period.

After consideration of the comments, we are finalizing our proposal to modify our existing policy to use the ABC™ methodology to determine benchmarks for the quality, cost, improvement activities, and Promoting Interoperability performance categories

based on historical data, as feasible and appropriate, by measure and collection type beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). Specifically, benchmarks will be based on performance data from a baseline period or, if such data is not available, performance data from the performance period. The baseline period will be the 12-month calendar year that is 2 years prior to the applicable performance period. The benchmarks will be published prior to the start of the performance period, as technically feasible.

(b) QCDR Measure Benchmarks

Currently, only MIPS measures are star rated on Physician Compare. QCDR measures, as that term is used in § 414.1400(e), are publicly reported as percent performance rates. As more QCDR measure data is available for public reporting, and appreciating the value of star rating the measures presented to website users, we believe star rating the QCDR measures will greatly benefit patients and caregivers as they work to make informed health care decisions. Particularly in the quality performance category, we believe that reporting all measure data in the same way will ease the burden of interpretation placed on site users and make the data more useful to them. Therefore, we proposed (83 FR 35988 through 35989) to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed § 414.1400(b)(3), as feasible and appropriate, using current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020). We requested comment on this proposal.

The following is a summary of the comments we received to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures and our responses.

Comment: One commenter supported using the ABC™ methodology to create a benchmark for MIPS and QCDR measures, as well as creating a 5-star rating for QCDR measures, beginning with year 3 of the Quality Payment Program. Several commenters expressed concern about QCDR benchmarks, noting that measure scores could be misinterpreted on Physician Compare, particularly if the ABC™ methodology is used, since it may differ from the QCDR's own rating methodology and further confuse patients. One commenter also noted that use of the ABC™ methodology for QCDR measures would cause clinician confusion and potentially misrepresent clinicians in the public domain if it results in benchmarks that are also different from the ones used in the MIPS scoring methodology. Another commenter noted the sample size for some QCDR measures will be too small for public reporting and encouraged CMS to work with QCDR measure owners in establishing benchmarks for QCDR measures.

Response: We reiterate our belief that star rating the QCDR measures will greatly benefit patients and caregivers. Because the QCDRs do not uniformly measure performance and each uses their own methodology, as commenters pointed out, in our experience it makes it more difficult for patients to use this information to make informed healthcare decisions. Regarding the concern about differences in MIPS scoring benchmarks and public reporting benchmarks, we note that we will continue to evaluate approaches to alignment, but reiterate that it is not always necessary or ideal to use the same methodology for scoring and public reporting given the unique goals of each. QCDR measures will undergo the same statistical testing as other measures do to ensure they meet our public reporting standards before they are publicly reported, and this testing does account for sample size concerns.

After consideration of the comments, we are finalizing our proposal to further modify our existing policy to extend the use of the ABC™ methodology and equal ranges method to determine, by measure and collection type, a benchmark and 5-star rating for QCDR measures, as that term is used in proposed § 414.1400(b)(3), as feasible and appropriate. This benchmark will use current performance period data in year 2 of the Quality Payment Program (2018 data available for public reporting in late 2019), and using historical benchmark data when possible as proposed above, beginning with year 3 of the Quality Payment Program (2019 data available for public reporting in late 2020).

(7) Voluntary Reporting

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to make available for public reporting all data submitted voluntarily across all MIPS performance categories, regardless of collection type, by eligible clinicians and groups that are not subject to the MIPS payment adjustments, as technically feasible, for all future years. If an eligible clinician or group that is not subject to the MIPS payment adjustment chooses to submit data on quality, cost (if applicable), improvement activities, or Promoting Interoperability, these data are available for public reporting. We also finalized that during the 30-day preview period, these eligible clinicians and groups may opt out of having their data publicly reported on Physician Compare (82 FR 53830). If these eligible clinicians and groups do not opt out during the 30-day preview period, their data will be available for inclusion on Physician Compare if the data meet all public reporting standards at § 414.1395(b).

(8) APM Data

In the CY 2018 Quality Payment Program final rule (82 FR 53830), we finalized a policy to publicly report the names of eligible clinicians in Advanced APMs and the names and performance of Advanced APMs and APMs that are not considered Advanced APMs related to the Quality Payment Program, such as Track 1 Shared Savings Program Accountable Care Organizations (ACOs), as technically feasible, for all future years. We also finalized a policy to link clinicians and groups and the APMs they participate in on Physician Compare, as technically feasible.

4. Overview of the APM Incentive

a. Overview

Section 1833(z) of the Act requires that an incentive payment be made (or, in years after 2025, a different PFS update) to QPs for achieving threshold levels of participation in Advanced APMs. In the CY 2017 Quality Payment Program final rule (81 FR 77399 through 77491), we finalized the following policies:

- Beginning in payment year 2019, if an eligible clinician participated sufficiently in an Advanced APM during the QP Performance Period, that eligible clinician may become a QP for the year. Eligible clinicians who are QPs are excluded from the MIPS reporting requirements for the performance year and payment adjustment for the payment year.
- For payment years from 2019 through 2024, QPs receive a lump sum incentive payment equal to 5 percent of their prior year's estimated aggregate payments for Part B covered

professional services. Beginning in payment year 2026, QPs receive a higher update under the PFS for the year than non-QPs.

- For payment years 2019 and 2020, eligible clinicians may become QPs only through participation in Advanced APMs.
- For payment years 2021 and later, eligible clinicians may become QPs through a combination of participation in Advanced APMs and Other Payer Advanced APMs (which we refer to as the All-Payer Combination Option).

In the CY 2018 Quality Payment Program final rule (82 FR 53832 through 53895), we finalized clarifications, modifications, and additional details pertaining to Advanced APMs, Qualifying APM Participant (QP) and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, Calculation of All-Payer Combination Option Threshold Scores and QP Determinations, and Physician-Focused Payment Models (PFPMs). In the CY 2019 PFS proposed rule (83 FR 35989 through 36006), we proposed clarifications and modifications to policies that we previously finalized pertaining to Advanced APMs, QP and Partial QP determinations, Other Payer Advanced APMs, Determination of Other Payer Advanced APMs, and the Calculation of All-Payer Combination Option Threshold Scores and QP Determinations. In this CY 2019 PFS final rule, we respond to public comments on those proposals and announce our final policies.

The following is a summary of the general public comments received on Advanced APMs and our responses:

Comment: Many commenters encouraged us to accelerate our efforts to develop more Advanced APM opportunities for clinicians. These commenters noted that Advanced APMs have great potential to incentivize high-quality and coordinated care while driving down overall costs, and encouraged us to continue developing Advanced APMs to offer clinicians more opportunity to participate in value-based payment and care delivery. Some commenters noted concern that no progress has been made in creating more opportunities for specialists and non-physician professionals to participate in Advanced APMs. The commenters encouraged CMS to develop Advanced APMs that provide opportunities for specialists and non-physician professionals, and to create additional pathways for specialists and non-physician professionals to meaningfully participate in existing Advanced APMs.

Response: We agree that APMs represent an important step forward in our efforts to move our healthcare system from volume-based to value-based care. We note that in 2018 a number of additional Advanced APM opportunities were made available, including the introduction of the Medicare ACO Track 1+ Model, and the introduction of new participants into some existing Advanced APMs, such as the Next Generation ACO Model and Comprehensive Primary Care Plus (CPC+) Model. In 2019, there will be even more available Advanced APM opportunities including the Bundled Payments for Care Improvement Advanced Model, which began in October 2018, and the Maryland Total Cost of Care (which includes the Care Redesign Program and the Maryland Primary Care Program). Additionally, we are in the process of developing several new APMs and Advanced APMs, and continue to work with stakeholders on new model concepts.

Comment: Some commenters suggested CMS establish a clear pathway for clinicians to transition from MIPS to MIPS APMs and then to Advanced APMs. The commenters noted that MIPS APMs represent a stepping stone between MIPS and Advanced APMs providing clinicians a necessary glide path into risk-based contracts.

Response: The Quality Payment Program represents a significant opportunity to collaborate with the clinical community to advance policy that pays for what works—both for clinicians and patients—to create a simpler, sustainable Medicare program. We believe that the Quality Payment Program provides new opportunities to improve care delivery by supporting and rewarding clinicians as they find new ways to engage patients, families, and caregivers and to improve care coordination and population health management. In addition, we believe that by developing a program that is flexible instead of one-size-fits-all, clinicians will be able to choose to participate in a way that is best for them, their practice, and their patients. For clinicians interested in APMs, including MIPS APMs and Advanced APMs, we believe that by setting ambitious yet achievable goals, eligible clinicians will move with greater certainty toward these new approaches that incentivize the delivery of high-value care.

We will continue to reach out to the clinician community and others to partner in the development of ongoing education, support, and technical assistance materials and activities to help clinicians understand Quality Payment Program requirements, how to use available tools to enhance their practices, improve quality, reduce cost, and progress to participation in APMs and Advanced APMs if that is the best choice for their practice.

Comment: Many commenters requested that we implement and test new models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The commenters noted that the stakeholder community is also well aware the Department has not selected any PTAC recommended models for testing. Specifically, the commenters noted that the PTAC had received 27 proposals for new physician-focused payment models, 15 of which have been reviewed by the PTAC with comments and recommendations sent to the Secretary. Of those, the commenters stated that 10 proposals were recommended favorably with six recommended for limited scale testing and four recommended for implementation, but the agency has taken no action to test or implement any of the recommended models.

Some commenters suggested we provide more direct, regular feedback to the PTAC and stakeholders to ensure they can address concerns and shortcomings earlier in the development process, so that the PTAC comment and recommendation process can yield physician-led APMs that will be tested and implemented. The commenters also requested that we provide technical assistance to stakeholders working to develop proposals for the PTAC, and specifically that we make claims data available to allow for more detailed financial modeling to be part of the development process.

Many commenters requested that we establish a clear process and timeline for responding to PTAC proposals in the future. The commenters suggested that a 60-day window from the date that the Secretary receives a recommendation from the PTAC would be appropriate.

Response: We believe that PTAC can help us make the shift from a healthcare system that pays for volume to one that pays for value. The commitment to health care payment innovation by the PTAC and the broader stakeholder community is evident in the number and types of specialties represented in the proposals being submitted to PTAC. CMS' Center for Medicare and Medicaid Innovation (CMS Innovation Center) staff have met with stakeholders about proposed models, including some stakeholders that have submitted proposed physician-focused payment models to the PTAC.

We note that while it seems unlikely that all of the features of any PTAC-reviewed proposed model will be tested exactly as presented in the proposal, certain features of proposed models may be incorporated into new or existing models. As the CMS Innovation Center launches new value-based payment and service delivery models, the PTAC's critical review of proposals will be a valuable resource. Additionally, the CMS Innovation Center will further engage with stakeholders that have submitted proposals related to new or existing models to leverage their experiences in the field.

While we will not provide technical assistance to individual stakeholders before they submit proposals, we encourage potential submitters to review the detailed responses from the Secretary to past comments and recommenations from the PTAC to guide development of their proposals. We also encourage stakeholders designing proposals to review the data resources available on the Office of the Assistance Secretary for Planning and Evaluation (ASPE) website at *https://aspe.hhs.gov/resources-public-comment-physician-focused-payment-model-technical-advisory-committee*. Lastly, available from the CMS Innovation Center website is a toolkit for Alternative Payment Model Design (APM Toolkit) to serve as a resource for any entities or individuals interested in developing ideas for APMs (*https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Alternative-Payment-Model-APM-Design-Toolkit.pdf* provides a detailed and comprehensive set of resources to help design an APM).

We note that PTAC meets on a periodic basis to review proposals for physician-focused payment models submitted by individuals and stakeholder entities. The PTAC prepares comments and recommendations on proposals that are received, determining whether such models meet the criteria established by the Secretary for physician-focused payment models in the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008, 77496–77499) and codified at § 414.1465. The PTAC's comments and recommendations generally must be discussed during their public meetings and must be submitted to the Secretary. Subsequently, the Secretary reviews the comments and recommendations submitted by PTAC and posts a detailed response to these recommendations on the CMS Innovation Center website at *https://innovation.cms.gov/initiatives/pfpms/*. Given this standard timeline, we do not believe it would be realistic to set a strict 60-day timeframe for responding to physician-focused payment models recommended by the PTAC. As discussed in the CY 2018 Quality Payment Program final rule, the variation in the number and nature of proposals makes it difficult to establish such a deadline. However, HHS will continue to make every effort to respond expeditiously to the PTAC's comments and recommendations.

b. Terms and Definitions

In the CY 2019 PFS proposed rule, we explained that as we continue to develop the Quality Payment Program, we have identified the need to propose changes to some of the previously finalized definitions. A complete list of the original definitions is available in the CY 2017 Quality Payment Program final rule (81 FR 77537 through 77540).

In the CY 2018 Quality Payment Program final rule, to consolidate our regulations and avoid unnecessarily defining a term, we finalized removal of the defined term for ''Advanced APM Entity'' in § 414.1305 and replaced instances of that term throughout the regulation with ''APM Entity.'' Similarly, we finalized replacing ''Advanced APM Entity group'' with ''APM Entity group'' where it appears throughout our regulations (82 FR 53833). We noted that these changes were technical and had no substantive effect on our policies.

In the CY 2019 PFS proposed rule, to further consolidate our regulations and to clarify any potential ambiguity, we proposed to revise the definition of Qualifying APM Participant (QP) at § 414.1305 to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM. The current definition of QP is based on an eligible clinician's participation in an Advanced APM Entity, which no longer is a defined term. Simply replacing the term ''Advanced APM Entity'' with the term ''APM Entity,'' as we had in the CY 2018 Quality Payment Program final rule, does not fully convey the definition of QP because, as noted at the time, an APM Entity can participate in an APM that is, or is not, an Advanced APM; and QP status is attainable only through participation in an Advanced APM (82 FR 53833). Again we note that this proposed change is technical and will not have a substantive effect on our policies.

We solicited comments on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise the definition of Qualifying APM Participant (QP) at § 414.1305 to provide that a QP is an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold for the year based on participation in or with an APM Entity that is participating in an Advanced APM.

c. Advanced APMs

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that:

- Requires its participants to use certified EHR technology (CEHRT) (81 FR 77409 through 77414);
- Provides for payment for covered professional services based on quality measures comparable to measures under the quality performance category under MIPS (81 FR 77414 through 77418); and
- Either requires its participating APM Entities to bear financial risk for monetary losses that are in excess of a nominal amount, or is a Medical Home Model expanded under section 1115A(c) of the Act (81 FR 77418 through 77431). We refer to this criterion as the financial risk criterion.

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 35989–35992), we included the following proposals, each of which is discussed in further detail below:

Use of CEHRT

- We proposed to revise § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures

- We proposed to revise § 414.1415(b)(2) to clarify, effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.
- We also proposed to revise § 414.1415(b)(3), effective January 1, 2020, to provide that at least one

outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses

- We proposed to revise § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

(3) Use of CEHRT

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that an Advanced APM must require at least 50 percent of eligible clinicians in each APM Entity to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals. Further, we proposed but did not finalize an increase to the requirement wherein Advanced APMs must require 75 percent CEHRT use in the subsequent year. Instead we maintained the 50 percent CEHRT use requirement for the second performance year and beyond and indicated that we would consider making any potential changes through future rulemaking (81 FR 77412).

(b) Increasing the CEHRT Use Criterion for Advanced APMs

In the CY 2019 PFS proposed rule, we proposed that, beginning for CY 2019, to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

According to data collected by the Office of the National Coordinator for Health Information Technology (ONC), over 3 in 4 office-based physicians adopted a certified EHR in CY 2015,[32] and approximately 9 in 10 clinicians have 2015 Edition certified technology available from their EHR developer.[33] Additionally, in response to the CY 2017 Quality Payment Program proposed rule, commenters encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. We further believe that most existing Advanced APMs already include provisions that would require participants to adhere to the level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent in 2019. Some commenters noted that the use of CEHRT is a fundamental component of any Advanced APM and that such APMs are more likely to be successful if physicians are able to receive information on their patients in a seamless manner, as well as document and communicate clinical care with patients and other health care professionals.

Response: We appreciate the commenters' support of our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent beginning in 2019.

Comment: Many commenters requested that CMS not finalize the proposed increase in the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent beginning in 2019. Some commenters stated that such an increase could be too burdensome for some APM participants, especially in light of the regulatory requirement to upgrade from 2014 Edition CEHRT to 2015 Edition CEHRT in CY 2019. Other commenters noted the proposed increase could create a barrier to entry into Advanced APMs or create additional obstacles in designing APMs targeted for small or rural practices.

Response: We do not believe that the proposed increase in the Advanced APM minimum CEHRT use threshold from 50 to 75 percent will be burdensome for APM participants. As noted above, approximately 9 in 10 clinicians have 2015 Edition certified technology available from their most recently reported EHR developer, and we believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. Also, in the CY 2017 Quality Payment Program final rule, we acknowledged that eligible clinicians would be expected to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2018, and that some eligible clinicians who had not yet adopted CEHRT may wish to delay acquiring CEHRT products until a 2015 Edition certified product is available. We also note that the requirement to use 2015 Edition CEHRT was delayed in the CY 2018 Quality Payment Program final rule (82 FR 53671–53672), to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. Further, we note that most current Advanced APMs already include provisions that would require participants to adhere to this new level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs. Moving forward, though, we will consider the applicability of the CEHRT requirement for any potential models designed specifically for small or rural practices.

Comment: Many commenters requested that we consider delaying our proposal to increase the Advanced APM minimum CEHRT use threshold from 50 percent to 75 percent until CY 2020. Commenters stated there already is a regulatory requirement to upgrade to 2015 edition CEHRT in CY 2019 and that clinicians participating in Advanced APMs should not be subject to additional health information technology requirements in a single year. Commenters also noted that maintaining the current Advanced APM minimum CEHRT use threshold for an additional year will allow time for organizations and clinicians to implement the upgrade to 2015 edition CEHRT and not discourage smaller practices that are in the process of upgrading their systems from participating in Advanced APMs.

Response: We appreciate commenters' concerns, but as noted previously in this final rule, the requirement to use 2015 Edition CEHRT was delayed in the CY 2018 Quality Payment Program final rule (82 FR 53671 through 53672), to provide eligible clinicians an additional year to upgrade from technology

[32] Office of the National Coordinator for Health Information Technology. 'Office-based Physician Electronic Health Record Adoption,' Health IT Quick-Stat #50. *dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php*. December 2016.

[33] Office of the National Coordinator for Health Information Technology. '2015 Edition Market Readiness for Hospitals and Clinicians,' Health IT Quick-Stat #55. *dashboard.healthit.gov/quickstats/pages/2015-edition-market-readiness-hospitals-clinicians.php*. October 2018.

certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. We believe organizations and clinicians had sufficient time to implement upgrades and that it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019. Thus, we believe a delay in implementation of the increase in the Advanced APM minimum CEHRT use threshold increase is unnecessary.

Comment: Many commenters requested that CMS phase in the increase in the Advanced APM minimum CEHRT use threshold over time, or develop a glide path more reflective of the multi-year contracting cycles of APMs given that current contracts with Advanced APMs, were signed with the current Advanced APM minimum CEHRT use threshold in place. Some commenters also suggested that CMS could retain the current 50 percent Advanced APM minimum CEHRT use threshold, but allow APM Entities to attest that an additional percentage of eligible clinicians are either using CEHRT or other health information technology that augments or is an extension of CEHRT to achieve the specific goals of the APM.

Response: We reiterate that in the CY 2017 Quality Payment Program final rule, we stated that setting the threshold at 50 percent of eligible clinicians would allow APMs sufficient room to meet this requirement even if the APM includes some participants who do not have internet access, lack face-to-face interactions with patients, or are hospital-based. At that time, we recognized commenters' concerns that raising the threshold to 75 percent in 2018 risked creating an overly rigorous standard for Advanced APMs and that it would be prudent to wait until we have more information on how the threshold would impact specific APMs, such as specialty APMs, before increasing the threshold. As noted previously in this final rule, we now understand that certified EHR adoption has been more widespread, and therefore do not believe that it is necessary to phase in the increase in the Advanced APM minimum CEHRT use threshold over time any more so than we already have by maintaining the threshold at 50 percent for the 2017 and 2018 QP performance periods. We also note that most current Advanced APMs already include provisions that require participants to adhere to this new level of CEHRT use specified in our regulations, and therefore this increase will not negatively impact the Advanced APM status of those APMs.

Comment: One commenter suggested that CMS provide flexibility for APM Entities participating in Advanced APMs by allowing them to include eligible clinicians in the 75 percent threshold calculation who are actively working with their EMR vendors to transition to the 2015 Edition CEHRT. The commenter noted that there may be instances where EMR vendors are finalizing their certification process during the 2019 performance year, and that may prevent an APM Entity from fully complying with the 75 percent threshold.

Response: We reiterate that the Advanced APM CEHRT use criterion applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs. This means that once an APM has been determined to be an Advanced APM (by requiring the specified percentage of eligible clinicians in each of its participating APM Entities to use CEHRT), the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM and may not involve a threshold calculation. We acknowledge there may be instances where EMR vendors are finalizing their certification process, but as noted previously, the requirement to use 2015 Edition CEHRT was delayed to provide eligible clinicians an additional year to upgrade from technology certified to the 2014 Edition to technology certified to the 2015 Edition for use in 2019. Therefore, we believe it is appropriate to require the use of 2015 Edition CEHRT beginning in CY 2019.

Comment: Many commenters noted that the proposed increase in the Advanced APM minimum CEHRT use threshold could limit the ability of non-physician professionals, such as physical therapists, occupational therapists, audiologists, and speech-language pathologists, to meaningfully participate in APMs. The commenters noted that current CEHRT requirements are designed for prescribing professionals and do not capture tasks performed by non-physician professionals using different types of EHRs. Specifically, the commenters stated that the EHRs non-physician professionals often use have not been taken into account by ONC in developing the CEHRT standards and certification criteria, and therefore, they would not be able to meet the definition of CEHRT required for purposes of the Advanced APM minimum CEHRT use threshold. The commenters suggested that CMS establish a dedicated CEHRT program for non-physician and non-prescribing professionals and that CMS offer assistance in the form of funding and technical support to help these types of clinicians participate in Advanced APMs.

Response: We reiterate that the Advanced APM minimum CEHRT use threshold applies to APMs and the requirements they impose on participating APM Entities, not to the individual APM Entities participating in APMs. We also note that the Advanced APM minimum CEHRT use threshold does not mean that all eligible clinicians in each participating APM Entity are required to use CEHRT, and that the methods used in the Advanced APM to ascertain whether the required percentage of CEHRT use is met may be unique to each APM. This means there can be a percentage of eligible clinicians participating in an APM Entity who are not using CEHRT and the APM Entity will still be in compliance with the APM's terms and conditions. Understanding this may have a greater effect on non-physician or non-prescribing eligible clinicians, moving forward, we will monitor this issue for new APMs and will consider possible solutions to facilitate participation in Advanced APMs by non-physician or non-prescribing eligible clinicians that may not use CEHRT due to lack of certified systems for that specific specialty.

After considering public comments, we are finalizing our proposal that, for QP Performance Periods beginning in 2019, to be an Advanced APM, the APM must require at least 75 percent of eligible clinicians in each APM Entity (or, for APMs in which hospitals are the APM Entities, each hospital, as specified in our current regulation) to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals. We are amending § 414.1414(a)(1) to reflect this change.

(4) MIPS-Comparable Quality Measures

(a) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for an APM to be an Advanced APM is that it must provide for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(A) of the Act, which is the MIPS quality performance category. We generally refer to these measures in the remainder of this discussion as ''MIPS-comparable quality measures.'' We also explained that we interpret this criterion to require the APM to incorporate quality measure results as a factor when determining

payment to participants under the terms of the APM (81 FR 77414).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Advanced APM, an APM must base payment on quality measures that are evidence-based, reliable, and valid; and that at least one measure must be an outcome measure unless there is not an applicable outcome measure on the MIPS quality list at the time the APM is developed. The required outcome measure does not have to be one of those on the MIPS quality measure list. We did not specify that the outcome measure is required to be evidence-based, reliable, and valid. (81 FR 28302). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified at § 414.1415(b).

(b) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at § 414.1415(b)(2) that at least one of the quality measures upon which an Advanced APM bases the payment must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria: Used in the MIPS quality performance category as described in § 414.1330; endorsed by a consensus-based entity; developed under section 1848(s) of the Act; submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that some have interpreted § 414.1415(b)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS-comparable quality measures, even if they are not evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding will automatically qualify as MIPS-comparable even if the measure was never endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. Although we believe such measures may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of § 414.1415(b)(2) without independent verification by a consensus-based entity, or based on our own assessment and determination, that they are evidence-based, reliable, and valid. We further believe the same principle applies to Qualified Clinical Data Registry (QCDR) measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable quality measures for purposes of § 414.1415(b)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable quality measures (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution to avoid any adverse impact on APM entities, eligible clinicians, or other commenters, we have used the more permissive interpretation of the regulation text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period until our new proposal described, in this final rule, is effective on January 1, 2020. Recognizing that APMs and other payer payment arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we proposed to amend § 414.1415(b)(2) to be effective as of January 1, 2020. Specifically, we proposed that at least one of the quality measures upon which an Advanced APM bases payment must be finalized on the MIPS final list of measures, as described in § 414.1330; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, to be considered MIPS-comparable quality measures.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported the proposal. Some commenters suggested that Advanced APMs should be required to include more than one MIPS-comparable quality measure.

Response: We appreciate the commenters' support of our proposal. We reiterate that the quality measures criterion stipulates that to be an Advanced APM an APM must require at least one of the quality measures upon which an Advanced APM bases payment to be MIPS-comparable. This does not preclude an Advanced APM from including more than one MIPS-comparable quality measure. However, we also note that under the statute, not all quality measures under which an APM is assessed are required to be MIPS-comparable and not all payments under the APM must be based on MIPS-comparable quality measures. As such, we believe that by requiring only one quality measures upon which an Advanced APM bases payment to be MIPS-comparable, APMs have the latitude to base payment on quality measures that meet the goals of the APM and assess the quality of care provided to the population of patients that the APM participants are serving.

Comment: One commenter suggested that CMS consider Core Quality Measure Collaborative (CQMC) endorsement as meeting the criterion for a measure being endorsed by a consensus-based entity. The commenter noted that as more health care providers move toward the adoption of the CQMC Core Measure Sets, using the CQMC multi-stakeholder, consensus-based process in determining MIPS-comparable measures would further CMS's goal of alignment between its programs and the CQMC Core Measure Sets.

Response: We note that, under MIPS, we currently try to align with the CQMC measures as much as possible. However, for a measure to meet the criterion of MIPS-comparable, only measures on the list of consensus-endorsed measures maintained by the NQF will currently meet the criterion as being endorsed by a consensus-based entity because NQF is the consensus-based entity that endorses standardized healthcare performance measures for CMS as defined under 1890(b)(2) and (3) of the Act. Therefore, CQMC endorsement does not currently meet the criterion for a measure being endorsed by a consensus-based entity.

We also note, that we believe the revised criteria for the MIPS-comparable measures used in Advanced APMs do not prevent an APM from using a core measure set or using measures developed and included in other CMS programs, but instead provides the criteria for what constitutes a MIPS-comparable measure to meet the Advanced APM requirement (81 FR 77417). Not all quality measures upon

which an APM bases payment are required to be MIPS-comparable, and not all payments under the APM must be based on MIPS-comparable measures. However, at least some payments must be tied to MIPS-comparable measures.

Comment: Some commenters expressed concern that designating measures determined to be evidenced-based, reliable, and valid by CMS as MIPS-comparable amounts to bypassing the standard vetting process of consensus-based entities; publishing in applicable specialty-appropriate, peer-reviewed journals; notice-and-comment rulemaking or separate publication in the **Federal Register**. The commenters suggested that all MIPS-comparable quality measures for the Advanced APM pathway should go through a fair and standard vetting process open to the medical profession rather than being independently determined and approved by CMS.

Response: As finalized in the CY 2017 Quality Payment Program final rule, we established an Innovation Center quality measure review process for those measures that are not NQF-endorsed or included on the final MIPS measure list. The sole purpose of this process is to assess for purposes of the Advanced APM MIPS-comparable measure criterion whether these measures have an evidence-based focus, and are reliable and valid (81 FR 77418). In most instances, the Innovation Center internal committee responsible for this review process will make this determination for measures that were tested for use in Innovation Center models using internal analyses and other experts to demonstrate that the measure meets these criteria, and thus can be used as a MIPS-comparable measure before it is considered for inclusion in MIPS or submitted to the consensus based entity for endorsement consideration. The Innovation Center committee is not a substitute for those existing processes but allows the Innovation Center to innovate by using new measures that meet the same standards as MIPS measures. Therefore, we appreciate the commenters' concerns but do not believe that the Innovation Center quality measure review process bypasses the currently established vetting process for quality measures.

After considering public comments, we are finalizing our proposal to revise § 414.1415(b)(2) to clarify, effective January 1, 2020, to clarify that at least one of the quality measures upon which an Advanced APM bases payment must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

(c) Outcome Measures: Evidence-Based, Reliable, and Valid

In § 414.1415(b)(3), we generally require that the measures upon which an Advanced APM bases payment must include at least one outcome measure, but specify that this requirement does not apply if CMS determines that there are no available or applicable outcome measures in the MIPS quality measure lists for the Advanced APM's first QP Performance Period. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid. Although it was our general expectation when developing the CY 2017 Quality Payment Program final rule that outcome measures will meet this standard, we did not explicitly include this requirement.

In the CY 2019 PFS proposed rule, we proposed to modify § 414.1415(b)(3) to explicitly require that an outcome measure must be evidence-based, reliable, and valid (unless, as specified in the current regulation, there is no available or applicable outcome measure), so that at least one outcome measure used for purposes of § 414.1415(b)(1) must also be:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

We proposed that this change would have an effective date of January 1, 2020, and would specifically require that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM must also be a MIPS-comparable quality measure. This is intended to align with our parallel proposal for the Other Payer Advanced APM criteria that we discuss in section III.I.4.e.(3)(d)(iii) of this final rule.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Commenters supported the proposal to explicitly require that an outcome measure must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid. One commenter noted that this proposal is reasonable given the general growth in the use of outcome measures.

Response: We appreciate the commenters' support, but note that our proposal does not eliminate the exception for models where there are no available or applicable outcome measures at the performance start date of the model.

Comment: One commenter expressed concerns with the proposal to explicitly require that an outcome measure must be finalized on the MIPS final list of measures; be endorsed by a consensus-based entity; or otherwise determined by CMS to be evidenced-based, reliable, and valid. The commenter noted that there is little variation in outcomes for many surgical procedures as judged by existing outcome measures, and that outcome measures alone are not sufficient to verify that the highest quality care is made available to patients. The commenter suggested CMS implement a framework that could provide a much clearer picture of the quality of care provided to the patient and includes elements such as: Standards-based facility-level verification programs; patient reported experience and outcomes measures; and traditional quality measures including registry and claims-based measures.

Response: We acknowledge the commenter's concerns regarding this use of outcomes measures and appreciate the commenter's suggestions. The Advanced APM requirement for inclusion of one MIPS-comparable measure that is also an outcome measure does not represent a quality measure strategy for Advanced APMs. Rather, the statute identifies outcome measures as a priority measure type, and we wanted to encourage the use of outcome measures for quality performance assessment in APMs. The quality strategy for most Advanced APMs typically includes quality and/or utilization measures that correspond with the key payment and practice transformation activities being tested in the APM. This is why the majority of APMs include more than just one quality measure and many different types of quality performance measures (for example, process, clinical outcome, patient experience of care or patient reported outcome measures) to assess the clinical care provided by eligible clinicians under the APM. Our goal in developing APMs is to ensure that all patients realize better care, improved clinical outcomes and more efficient cost-effective care. We believe our requirement that at least one outcome measure for which measure results are included as a factor when determining payment to participants under the terms of the APM must also be a MIPS-

comparable quality measure further reinforces these goals.

Comment: One commenter expressed concern that CMS is placing too much emphasis on outcome measures. Specifically, the commenter suggested that CMS continue to support the use of process measures until meaningful outcome measures are available in more specialty areas.

Response: We note that we require only one of the quality measures to be an outcome measure, and have established an exception for models where there is no available or applicable outcome measure at the performance start date of the model. As such, we do not agree that we are emphasizing outcome measures over process measures.

After considering public comments, we are finalizing our proposal to revise § 414.1415(b)(3), effective January 1, 2020, to require that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM, must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid. As specified in the current regulation, this requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the Advanced APM's first QP Performance Period.

(5) Bearing Financial Risk for Monetary Losses

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized the amount of the generally applicable revenue-based nominal amount standard at 8 percent for the first two QP Performance Periods only, and we sought comment on what the revenue-based nominal amount standard should be for the third and subsequent QP Performance Periods. Specifically, we sought comment on: (1) Setting the revenue-based standard for 2019 and later at up to 15 percent of revenue; or (2) setting the revenue-based standard at 10 percent so long as risk is at least equal to 1.5 percent of expected expenditures for which an APM Entity is responsible under an APM (81 FR 77427).

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to maintain the generally applicable revenue-based nominal amount standard at 8 percent for the 2019 and 2020 QP Performance Periods at § 414.1415(c)(3)(i)(A). We also specified that the standard is based on the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities. We stated that we will address the nominal amount standard for QP Performance Periods after 2020 in future rulemaking (82 FR 53838).

(b) Generally Applicable Nominal Amount Standard

We proposed to amend § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported our proposal to maintain the 8 percent generally applicable revenue-based standard for QP performance periods 2021–2024. Commenters noted that maintaining the 8 percent revenue-based standard through the 2024 QP performance period will promote consistency for participants across performance periods and further support CMS' efforts to transition clinicians into Advanced APMs.

Response: We appreciate the commenters' support of our proposal to maintain the 8 percent generally applicable revenue-based standard for QP performance periods 2021–2024.

Comment: Two commenters suggested that we limit the generally applicable revenue-based nominal amount standard to only include the average estimated total Part B revenue of participating providers and suppliers in APM Entities, rather than the average estimated total Part A and Part B revenues of providers and suppliers in APM Entities. The commenters stated that by including Part A revenue, CMS significantly disadvantages APM Entities, such as ACOs, that have hospital participants. The commenters noted that the APM Incentive Payment is based on payments for Part B covered professional services under the Medicare PFS, and as such, recommends that we revise the generally applicable revenue-based nominal amount standard to only consider Part B revenue under the Medicare PFS.

Response: We note that we did not propose to make changes to the types of revenue that are included in the generally applicable revenue-based nominal amount standard. However, we note that we disagree that the generally applicable revenue-based nominal amount standard should only include Part B revenues, as many APM Entities participating in Advanced APMs often include hospitals and other types of institutional providers or suppliers that may receive both Part A and B revenues. Additionally, the generally applicable revenue-based nominal amount standard is inclusive only of the Medicare Part A and B revenues of providers and suppliers in participating APM Entities; therefore, if the providers and suppliers in a given APM Entity have only Medicare Part B revenues, only such revenues will be considered.

Comment: Some commenters suggested we reconsider establishing a separate, lower nominal amount standard for small and rural practices. The commenters stated that a lower revenue-based nominal amount standard is necessary to ensure that the challenging operational risks and expenses, which put such practices at greater financial risk when compared to larger practices, do not prevent participation in Advanced APMs. The commenters suggested establishing a nominal amount standard for small and rural practices that would be aligned with the Medical Home Model nominal amount standard or set equal to the percentage of the APM incentive payment that an eligible clinician might attain based on their participation in an Advanced APM. The commenters noted that a lower revenue-base nominal amount standard may encourage greater participation in APMs by small and rural practices.

Response: We will continue to monitor the impact of the generally applicable revenue-based nominal amount standard and Medical Home Model nominal amount standard on small practices and those in rural areas. We did not include any proposals in the CY 2019 PFS proposed rule regarding a separate standard for small or rural practices, but may consider revisiting establishing a lower revenue-based nominal amount standard for small practices and those in rural areas in future rulemaking.

Comment: Some commenters requested CMS consider the financial and administrative risk that non-physician practitioners face when joining Advanced APMs. Specifically, the commenters suggested that CMS should adopt a more inclusive interpretation of financial risk for monetary losses by including any losses incurred in the operation of the APM

Entity rather than limiting financial risk only to losses or increased spending in the Medicare program. The commenters stated that the magnitude of risk CMS currently requires for participation in an Advanced APM may prevent many eligible clinicians from considering participation in the limited Advanced APMs available.

Response: As we stated in the CY 2018 Quality Payment Program final rule, we recognize the substantial investments that many APM Entities make to become successful APM participants, and also the financial and administrative burden that eligible clinicians of all types face when deciding to join an APM Entity. Nonetheless, as we discussed in the CY 2017 Quality Payment Program final rule, we continue to believe that there would be significant complexity involved in creating an objective and enforceable standard for determining whether an entity's business risk exceeds a nominal amount. We also reiterate that business risk is generally a cost that is unrelated to performance-based payment under an APM. No matter how well or poorly an APM Entity performs when assessed for purposes of the APM, costs associated with business risk are not reduced or increased correspondingly. Therefore, we maintain our view that business risk is not analogous to performance risk in the APM context because the costs of those activities and investments are not incorporated into the performance-based financial calculations of an APM, and are therefore not appropriate for consideration for purposes of the Advanced APM financial risk criterion (81 FR 77420).

After considering public comments, we are finalizing our proposal to revise § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024. We continue to believe that 8 percent of Medicare Parts A and B revenues of all providers and suppliers in participating APM Entities generally represents an appropriate standard for more than a nominal amount of financial risk at this time. We also believe that maintaining a consistent standard for several more years will help APM Entities to plan for multi-year Advanced APM participation. We further believe that maintaining a consistent standard will allow us to evaluate how APM Entities succeed within these parameters over the applicable timeframe.

We also sought comment on whether, as APM entities and participating eligible clinicians grow more comfortable with assuming risk, we should consider increasing the nominal amount standard. Specifically, we requested comments on whether we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later.

Several comments stated we should consider raising the revenue-based nominal amount standard to 10 percent, and the expenditure-based nominal amount standard to 4 percent starting for QP Performance Periods in 2025 and later. We thank commenters for their feedback and will take this input into consideration for future years.

(6) Summary of Final Policies

Use of CEHRT

- We are finalizing revisions to § 414.1415(a)(i) to specify that an Advanced APM must require at least 75 percent of eligible clinicians in each APM Entity, or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT as defined at § 414.1305 to document and communicate clinical care with patients and other health care professionals.

MIPS-Comparable Quality Measures

- We are finalizing revisions to clarify at § 414.1415(b)(2), effective January 1, 2020, that at least one of the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.
- We are finalizing revisions at § 414.1415(b)(3), effective January 1, 2020, to provide that at least one outcome measure, for which measure results are included as a factor when determining payment to participants under the terms of the APM must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity; or determined by CMS to be evidence-based, reliable, and valid.

Bearing Financial Risk for Monetary Losses

- We are finalizing revisions at § 414.1415(c)(3)(i)(A) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

We finalized policies relating to QP and Partial QP determinations in the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450).

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 3599 through 35994), we included the following proposals, each of which is discussed in further detail below:

QP Performance Period

- We proposed that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

Partial QP Election To Report to MIPS

- We proposed that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS will result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

(3) QP Performance Period

In the CY 2017 Quality Payment Program final rule, we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year (81 FR 77446–77447). During that QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three

separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

We also finalized that for each of the three QP determinations, we will allow for claims run-out for 3 months, or 90 days, before calculating the Threshold Scores so that QP determinations will be completed approximately 4 months after each snapshot date. As a result, the last of these three QP determinations is complete on or around January 1 of the subsequent calendar year, which is the year immediately prior to the MIPS payment year. For most MIPS data submission types, January 1 of the subsequent calendar year is also the beginning of the MIPS data submission period. This way, eligible clinicians know of their QP status prior to or near the beginning of the MIPS data submission period and know whether they should report any performance period data to MIPS for the applicable MIPS payment year.

Upon further consideration and based on our experience implementing the program to date, we believe providing eligible clinicians notification of their QP status more quickly after each of the three QP determination snapshot dates, and prior to the beginning of the MIPS data submission period after the last determination, will potentially reduce burden for eligible clinicians and APM Entities while improving their overall experience participating in the program.

We proposed that beginning in 2019 for each of the three QP determination dates, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations will be completed approximately 3 months after the end of that determination time period. We note that this proposal does not affect the QP Performance Period per se, but rather the date by which claims for services furnished during the QP Performance Period will need to be processed for those services to be included in calculating the Threshold Scores. To the extent that claims are used for calculating the Threshold Scores, such claims will have to be processed by no later than 60 days after each of the three QP determination dates, for information on the claims to be included in our calculations.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters supported the proposal to allow for claims run-out of 60 days (approximately 2 months), before calculating the QP threshold scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period. Commenters noted the importance for APM Entities to have information about their QP status as soon as possible after each snapshot to determine if they will need to take any additional action to report to MIPS or seek a QP determination under the All-Payer Combination Option should they fall short of the QP thresholds under the Medicare Option.

Response: We appreciate the commenters' support of our proposal to allow for a claims run-out of 60 days before calculating the QP threshold scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

After considering public comments, we are finalizing our proposal that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

(4) Partial QP Election To Report to MIPS

(a) Overview

Section 1848(q)(1)(C)(ii)(II) of the Act excludes from the definition of MIPS eligible clinician an eligible clinician who is a Partial QP for a year and who does not report on applicable measures and activities as required under MIPS for the year. However, under section 1848(q)(1)(C)(vii) of the Act, an eligible clinician who is a Partial QP for a year and reports on applicable measures and activities as required under the MIPS is considered to be a MIPS eligible clinician for the year.

In the CY 2017 Quality Payment Program final rule, we finalized that following a determination that eligible clinicians in an APM Entity group in an Advanced APM are Partial QPs for a year, the APM Entity will make an election whether to report on applicable measures and activities as required under MIPS. If the APM Entity elects to report to MIPS, all eligible clinicians in the APM Entity will be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the APM Entity elects not to report, all eligible clinicians in the APM Entity group will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year (81 FR 77449).

We also finalized that in cases where the Partial QP determination is made at the individual eligible clinician level, if the individual eligible clinician is determined to be a Partial QP, the eligible clinician will make the election whether to report on applicable measures and activities as required under MIPS and, as a result, be subject to the MIPS reporting requirements and payment adjustment (81 FR 77449). If the individual eligible clinician elects to report to MIPS, he or she will be subject to the MIPS reporting requirements and payment adjustments for the relevant year. If the individual eligible elects not to report to MIPS, he or she will be excluded from the MIPS reporting requirements and payment adjustments for the relevant year. We note that QP determinations are made at the individual eligible clinician level when the clinician is identified as participating in an Advanced APM on an Affiliated Practitioner List rather than a Participation List, or when an eligible clinician is in more than one APM Entity group in one or more Advanced APMs, and does not achieve QP status as part of any single APM Entity group (see § 414.1425(b)(2) and (c)(4) our regulations).

We also clarified how we consider the absence of an explicit election to report to MIPS or to be excluded from MIPS. We finalized that for situations in which the APM Entity is responsible for making the decision on behalf of all eligible clinicians in the APM Entity group, the group of Partial QPs will not be considered MIPS eligible clinicians unless the APM Entity opts the group into MIPS participation, so that no actions other than the APM Entity's election for the group to participate in MIPS will result in MIPS participation (81 FR 77449).

For eligible clinicians who are determined to be Partial QPs individually, we finalized that we will use the eligible clinician's actual MIPS reporting activity to determine whether to exclude the Partial QP from MIPS in the absence of an explicit election. Therefore, if an eligible clinician who is individually determined to be a Partial QP submits information to MIPS (not including information automatically populated or calculated by CMS on the Partial QP's behalf), we will consider the Partial QP to have reported, and thus to be participating in MIPS. Likewise, if such an individual does not take any action to submit information to MIPS, we will consider the Partial QP to have elected to be excluded from MIPS (81 FR 77449).

(b) Alignment of Partial QP Election Policies

We proposed that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to MIPS reporting requirements and payment adjustments. If the eligible clinician elects to not report to MIPS, they will not be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We note that this proposed policy change would affect only situations where the Partial QP makes no election to either report to MIPS or to be excluded from the MIPS reporting requirements and payment adjustment. Under our proposed policy, all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment; whereas, if the Partial QP does not make any election, they will not be subject to the MIPS reporting requirements and payment adjustment.

We solicited comment on this proposal.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Some commenters supported our proposal. Specifically, the commenters supported our proposal to exclude eligible clinicians determined to be a Partial QP for a year at the individual eligible clinician level from the MIPS reporting requirements and payment adjustment, in the absence of an explicit election to report to MIPS. Commenters noted this proposal will help to avoid confusion and prevent inadvertently subjecting eligible clinicians to MIPS reporting requirements and payment adjustments when information has been reported on their behalf.

Response: We appreciate the commenters' support of our proposal to align the Partial QP election policy for eligible clinicians who are determined to be Partial QPs individually and for eligible clinicians who are determined to be Partial QPs at the APM Entity level.

Comment: One commenter expressed concern that our proposal may create additional confusion for eligible clinicians. Specifically, the commenter noted that many eligible clinicians may not be aware that they attained Partial QP status, and that an affirmative election is required to participate in MIPS. The commenter also noted that such clinicians may assume that their MIPS data is being reported on their behalf by their practice or TIN, and as a result may inadvertently forego a potential positive MIPS payment adjustment.

The commenter suggested an alternative approach where CMS would apply the policy which yields the most advantageous MIPS final score and subsequently the most advantageous MIPS payment adjustment. The commenter noted that this alternative approach would work in such a manner that in cases where data is submitted by a Partial QP, or on their behalf, that would earn the Partial QP a MIPS final score resulting in a positive MIPS payment adjustment, CMS would use that data to provide them a MIPS final score, regardless of whether they made an election to participate in MIPS. In cases where data is submitted by a Partial QP, or on their behalf, that would earn the Partial QP a MIPS final score resulting in a negative MIPS payment adjustment, CMS would not use that data to provide them a MIPS final score, and they would be exempt from MIPS based on the Partial QP status.

The commenter noted this alternative approach would eliminate all potential unintended consequences and would be consistent with other CMS policies to use data that yields the most advantageous result. The commenter also noted the alternative approach may further incentivize participation in APMs and reduce burden on both eligible clinicians and CMS because eligible clinicians would no longer have to make an election to affirmatively opt-in or opt-out of MIPS.

Response: We acknowledge that our proposal could, in certain limited instances, create additional confusion for eligible clinicians, particularly eligible clinicians who may not be aware that they attained Partial QP status and an affirmative election is required for them to participate in MIPS. However, we note that clinicians' QP status, including Partial QP status, is accessible via the QPP Participation Status Tool via the Quality Payment Program website at *https://qpp.cms.gov/participation-lookup*. We also continue to believe our proposed approach will allow for greater operational simplicity while minimizing the possibility of unexpected participation in MIPS. We reiterate that all Partial QPs retain the full right to affirmatively decide through the election process whether or not to be subject to the MIPS reporting requirements and payment adjustment.

After considering public comments, we are finalizing our proposal that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

(5) Summary of Final Policies

In this section, we are finalizing the following policies:

QP Performance Period

- We are finalizing our proposal that for each of the three QP determinations, we will allow for claims run-out for 60 days (approximately 2 months), before calculating the Threshold Scores so that the three QP determinations can be completed approximately 3 months after the end of that determination time period.

Partial QP Election To Report to MIPS

- We are finalizing our proposal that when an eligible clinician is determined to be a Partial QP for a year at the individual eligible clinician level, the individual eligible clinician will make an election whether to report to MIPS. If the eligible clinician elects to report to MIPS, they will be subject to the MIPS reporting requirements and payment adjustment. If the eligible clinician elects not to report, they will be excluded from the MIPS reporting requirements and payment adjustment. In the absence of an explicit election to report to MIPS, the eligible clinician will be excluded from the MIPS reporting requirements and payment adjustment. This means that no actions other than the eligible clinician's affirmative election to participate in MIPS would result in that eligible clinician becoming subject to the MIPS reporting requirements and payment adjustment.

e. All-Payer Combination Option

(1) Overview

Section 1833(z)(2)(B)(ii) of the Act requires that beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the Combination All-Payer and Medicare Payment Threshold Option, which we refer to as the All-Payer Combination Option. In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77459). The Medicare Option focuses on participation in Advanced APMs, and we make QP determinations under this option based on Medicare Part B covered professional services attributable to services furnished through an APM Entity. The All-Payer Combination Option does not replace or supersede the Medicare Option; instead, it will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs. We finalized that beginning in payment year 2021, we will conduct QP determinations sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77438). The All-Payer Combination Option encourages eligible clinicians to participate in payment arrangements that satisfy the Other Payer Advanced APM criteria with payers other than Medicare. It also encourages sustained participation in Advanced APMs across multiple payers.

We finalized that the QP determinations under the All-Payer Combination Option are based on payment amounts or patient counts as illustrated in Tables 36 and 37, and Figures 1 and 2 of the CY 2017 Quality Payment Program final rule (81 FR 77460 through 77461). We also finalized that, in making QP determinations with respect to an eligible clinician, we will use the Threshold Score that is most advantageous to the eligible clinician toward achieving QP status, or if QP status is not achieved, Partial QP status, for the year (81 FR 77475).

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TABLE 57: QP Payment Amount Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	25%	25%	25%
Total			50%	50%	75%
Partial QP Payment Amount Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			40%	40%	50%

TABLE 58: QP Patient Count Thresholds – All-Payer Combination Option

Payment Year	2019	2020	2021	2022	2023 and later
QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	20%	20%	20%
Total			35%	35%	50%
Partial QP Patient Count Threshold					
Medicare Minimum	N/A	N/A	10%	10%	10%
Total			25%	25%	35%

FIGURE 4: QP Determination Tree, Payment Years 2021-2022

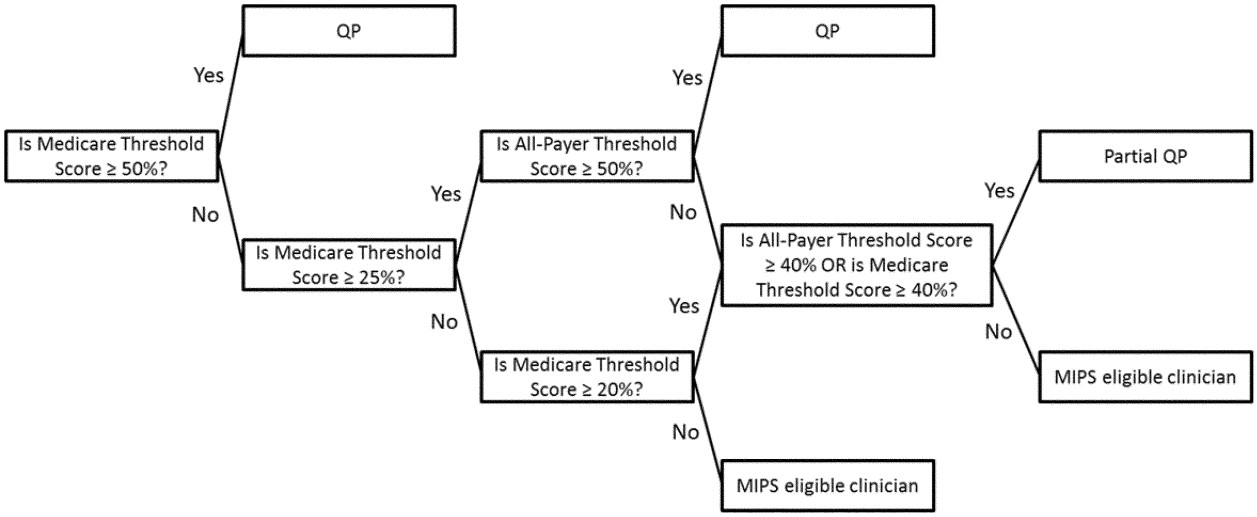
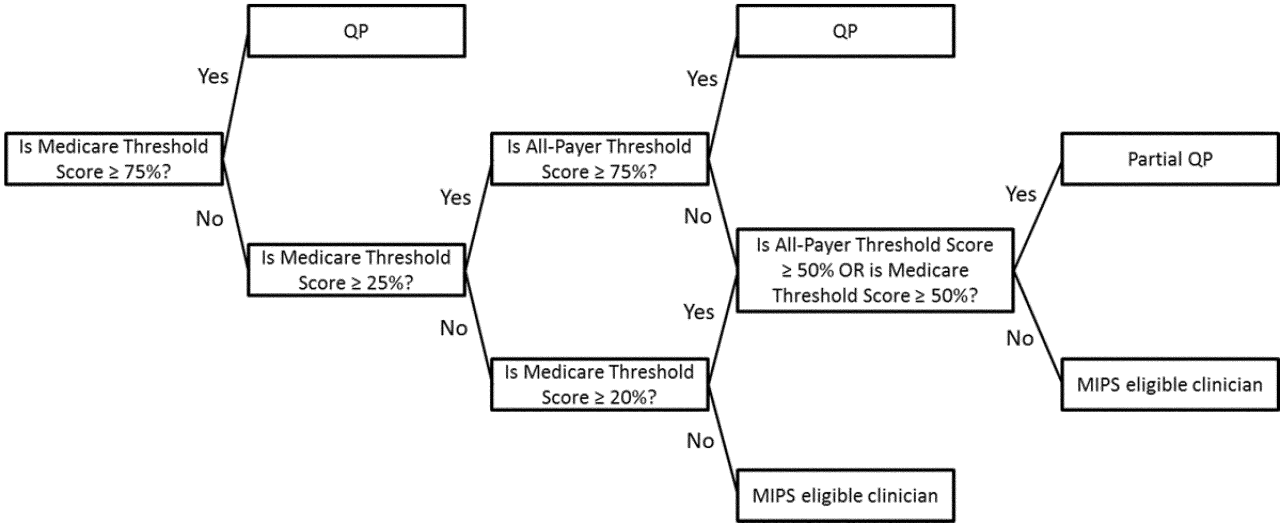


FIGURE 5: QP Determination Tree, Payment Years 2023 and Later



Unlike the Medicare Option, where we have access to all of the information necessary to determine whether an APM meets the criteria to be an Advanced APM, we cannot determine whether an other payer arrangement meets the criteria to be an Other Payer Advanced APM without receiving information about the payment arrangement from an external source. Similarly, we do not have the necessary payment amount and patient count information to determine under the All-Payer Combination Option whether an eligible clinician meets the payment amount or patient count threshold to be a QP without receiving certain information from an external source.

In the CY 2018 Quality Payment Program final rule, we established additional policies to implement the All-Payer Combination Option and finalized certain modifications to our previously finalized policies (82 FR 53844 through 53890). A detailed summary of those policies can be found at 82 FR 53874 through 53876 and 53890 through 53891. In relevant part, we finalized the following:

Payer Initiated Process

- We finalized at § 414.1445(a) and (b)(1) that certain other payers, including payers with payment arrangements authorized under Title XIX (the Medicaid statute), Medicare Health Plan payment arrangements, and payers with payment arrangements aligned with a CMS Multi-Payer Model, can request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter. We finalized that Remaining Other Payers, including

commercial and other private payers, could request that we determine whether other payer arrangements are Other Payer Advanced APMs starting in 2019 prior to the 2020 QP Performance Period, and annually each year thereafter. We generally refer to this process as the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process), and we finalized that the Payer Initiated Process would generally involve the same steps for each payer type for each QP Performance Period. If a payer uses the same other payer arrangement in other commercial lines of business, we finalized our proposal to allow the payer to concurrently request that we determine whether those other payer arrangements are Other Payer Advanced APMs as well. This policy is relevant only to the initial year of Payer Initiated Other Payer Advanced APM determinations for which these submissions can be made only by payers with arrangements under Title XIX, Medicare Health Plans, or arrangements aligned with CMS multi-payer models.

Eligible Clinician Initiated Process

- We finalized at § 414.1445(a) and (b)(2) that, through the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements would have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs. The Eligible Clinician Initiated Process can be used to submit requests for determinations before the beginning of a QP Performance Period for other payer arrangements authorized under Title XIX. The Eligible Clinician Initiated Process is available for the 2019 QP Performance Period and each year thereafter.

Submission of Information for Other Payer Advanced APM Determinations

- We finalized that, for each other payer arrangement for which a payer requests us to make an Other Payer Advanced APM determination, the payer must complete and submit the Payer Initiated Submission Form by the relevant Submission Deadline.
- We finalized that, for each other payer arrangement for which an APM Entity or eligible clinician requests us to make an Other Payer Advanced APM determination, the APM Entity or eligible clinician must complete and submit the Eligible Clinician Initiated Submission Form by the relevant Submission Deadline.
- We removed the requirement, previously established at § 414.1445(b)(3), that payers must attest to the accuracy of information submitted by eligible clinicians, and we also removed the related attestation requirement at § 414.1460(c). Instead, we finalized an additional requirement at § 414.1445(d) that an APM Entity or eligible clinician that submits information under § 414.1445(c) must certify that, to the best of its knowledge, the information it submits to us is true, accurate, and complete.

QP Determinations Under the All-Payer Combination Option

- We finalized at § 414.1440(e) that eligible clinicians may request that we make QP determinations at the individual eligible clinician level and that APM Entities may request that we make QP determinations at the APM Entity level.
- We finalized at § 414.1440(d)(1) that we will make QP determinations under the All-Payer Combination Option based on eligible clinicians' participation in Advanced APMs and Other Payer Advanced APMs for three time periods of the QP Performance Period: January 1 through March 31; January 1 through June 30; and January 1 through August 31. We finalized that we will use patient or payment data for the same time periods to calculate both the Medicare and the other payer portion of the Threshold Score calculation under the All-Payer Cominbation Option.
- We finalized at § 414.1440(e)(4) that, to request a QP determination under the All-Payer Combination Option, APM Entities or eligible clinicians must submit all of the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline.

In this section of the final rule, we address policies within the following topics: Other Payer Advanced APM Criteria; Other Payer Advanced APM determinations; and Calculation of the All-Payer Combination Option Threshold Scores and QP Determinations.

(2) Summary of Proposals

In the CY 2019 PFS proposed rule (83 FR 35999–36006), we included the following proposals, each of which is discussed below:

Other Payer Advanced APM Criteria

- We proposed to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity use CEHRT.
- We proposed to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement.
- We proposed the following clarification to § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

- We proposed to revise § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

- We also proposed to revise our regulation at § 414.1420(c)(3)(i) to provide that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year that did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.e.(4)(b) of this final rule), we would continue to apply the current regulation for purposes of those determinations. This proposed revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

Determination of Other Payer Advanced APMs

- We proposed details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we aligned the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.
- We proposed to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers proposed in section III.I.4.e.(4)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

- We proposed to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We proposed to modify our regulation at § 414.1440(d) by adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.
- We also clarified that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We proposed to codify this clarification by adding § 414.1440(d)(4).
- We proposed to extend the weighting methodology that is used to ensure that an eligible clinician does not receive a lower score on the Medicare portion of their all-payer calculation under the All-Payer Combination Option than the Medicare Threshold Score they received at the APM Entity level in order to apply a similar policy to the proposed TIN level Medicare Threshold Scores.

(3) Other Payer Advanced APM Criteria

(a) Overview

In general, our goal is to align the Advanced APM criteria under the Medicare Option and the Other Payer Advanced APM criteria under the All-Payer Combination Option as permitted by statute and as feasible and appropriate. We believe this alignment helps simplify the Quality Payment Program and encourage participation in Other Payer Advanced APMs (82 FR 53847).

(b) Investment Payments

Some stakeholders have requested that we take into account ''business risk'' costs such as IT, personnel, and other administrative costs associated with APM Entities' participation in Other Payer Advanced APMs when implementing the financial risk standard. We did not propose to modify our financial risk standard in response to this suggestion, and note that financial risk in the context of Other Payer Advanced APMs is defined both in the Act (at section 1833(z)(2)(B)(iii)(II)(cc) for payment years 2021 and 2022, and section 1833(z)(3)(B)(iii)(II)(cc) for subsequent years) and our regulations at § 414.1420(d) so as to require that APM Entities in the payment arrangement must assume financial risk when actual expenditures exceed expected expenditures. However, we note that a payment arrangement with an other payer, like some APMs, can be structured so that the APM provides an investment payment to the participating APM Entities to assist with the practice transformation that may be required for participation in the payment arrangement. This investment payment could be structured in various ways; for example, it could be structured similarly to the Medicare ACO Investment Model under, which expected shared savings payment were pre-paid to encourage new ACOs to form in rural and underserved areas and to assist existing ACOs in meeting certain criteria; or it could be structured so that the payment is made specifically to encourage participating APM Entities to continue to make staffing, infrastructure, and operations investments as a means of practice transformation; or it could have a different structure entirely.

Although CMS did not solicit comments regarding our statement on investment payments, the following is a summary of the public comments we received:

Comment: Many commenters expressed concern that CMS will continue the current policy that does not include investment payments in the definition and calculation of risk. The commenters stated that this approach fails to recognize the significant investment that APM Entities and eligible clinicians make in start-up and overhead costs in the development and operations of APMs. Some commenters suggested that CMS should develop a method to capture and quantify such risk.

Response: We reiterate that our policy has not changed. As we discussed in the CY 2017 Quality Payment Program final rule, we continue to believe that there would be significant complexity involved in creating an objective and enforceable standard for determining whether an entity's investment risk or business risk exceeds a nominal amount (81 FR 77420). Therefore, we maintain our view that investment risk or business risk is not analogous to performance risk in the APM context because the costs of those activities and investments are not incorporated into the performance-based financial calculations of an APM, and therefore, are not appropriate for consideration for purposes of the Advanced APM financial risk criterion (81 FR 77420). Other Payer Advanced APMs, like Advanced APMs, can be designed so that they include investment payments for participants, but those investment payments will not be considered financial risk when assessing whether a payment arrangement meets the Other Payer Advanced APM financial risk criterion.

(c) Use of CEHRT

(i) Overview

In the CY 2017 Quality Payment Program final rule, we finalized that to be an Other Payer Advanced APM, the other payer arrangement must require at least 50 percent of participating eligible clinicians in each APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care (81 FR 77465). This CEHRT use criterion directly paralleled the criterion established for Advanced APMs in § 414.1415(a)(1)(i).

In the CY 2018 Quality Payment Program final rule, we finalized that we would presume that an other payer arrangement meets the 50 percent CEHRT use criterion if we receive information and documentation from the eligible clinician through the Eligible Clinician Initiated Process showing that the other payer arrangement requires the requesting eligible clinician to use CEHRT to document and communicate clinical care (see § 414.1445(c)(2)).

(ii) Increasing the CEHRT Use Criterion for Other Payer Advanced APMs

We proposed to change the current CEHRT use criterion for Other Payer

Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT; this aligns with our proposals for the CEHRT use criterion for Advanced APMs.

According to data collected by ONC, since the CY 2017 Quality Payment Program final rule was published, EHR adoption has been widespread, and we want to encourage continued adoption. Additionally, in response to the CY 2017 Quality Payment Program proposed rule stakeholders encouraged us to raise the CEHRT use criterion to 75 percent (see 81 FR 77411). We believe that this proposed change aligns with the increased adoption of CEHRT among providers and suppliers that is already happening, and will encourage further CEHRT adoption. (83 FR 35990).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported increasing the CEHRT use criterion as of January 1, 2020, to 75 percent of participating eligible clinicians in each APM Entity.

Response: We appreciate the support for our proposal to change the Other Payer Advanced APM CEHRT use criterion to 75 percent.

Comment: Many commenters expressed concern with the proposed change to the current CEHRT use criterion stating that raising it to 75 percent of participating eligible clinicians in each APM Entity may be too burdensome. A few commenters noted that the CEHRT use criterion should not be increased by any amount. One commenter stated that the CEHRT use criterion should remain at 50 percent and allow APM entities to attest that APM participants are using health IT. Some commenters stated the increase is premature as the All-Payer Combination Option is beginning in 2019. Some commenters suggested that the increase in the threshold should occur over a longer period of time to accommodate multi-year cycles of APM contracts.

Response: We do not believe that such an increase in the Other Payer Advanced APM minimum CEHRT use threshold will be burdensome for APM participants. According to data collected by ONC, certified EHR adoption has been widespread with over 3 in 4 office-based physicians adopted a certified EHR in CY 2015, and we want to continue to encourage such adoption and use of CEHRT. Further, regarding the comments that the increase in the threshold should occur over a longer period of time to accommodate multi-year cycles of APM contracts, we remind the commenters that, although we proposed the same increase in the Advanced APM minimum CEHRT use threshold beginning January 1, 2019, the proposed increase for Other Payer Advanced APMs would not apply until January 1, 2020. We believe this is a sufficient amount of lead time, especially given the widespread adoption of EHRs.

After considering public comments, we are finalizing our proposal to change the current CEHRT use criterion for Other Payer Advanced APMs so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the other payer arrangement must require at least 75 percent of participating eligible clinicians in each APM Entity to use CEHRT.

(iii) Evidence of CEHRT Use

In the CY 2017 Quality Payment Program final rule, we adopted a CEHRT use criterion for Other Payer Advanced APMs that directly paralleled the CEHRT use criterion for Advanced APMs wherein Other Payer Advanced APMs must require at least 50 percent of eligible clinicians in each participating APM Entity, or each hospital if hospitals are the APM Entities, to use CEHRT to document and communicate clinical care.

We have since heard from payers and other stakeholders that CEHRT is often used under other payer arrangements even if it is not expressly required under the payment arrangement. Because CEHRT use is increasingly common among eligible clinicians, payers may not believe it is necessary to specifically require the use of CEHRT under the terms of an Other Payer payment arrangement.

Given this, we believe our current policy may needlessly exclude certain existing payment arrangements that could meet the statutory requirements for Other Payer Advanced APMs—including some where the majority of eligible clinicians use CEHRT, even if they are not explicitly required to do so under the terms of their payment arrangements.

We proposed that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement. We specifically proposed to modify the regulation at § 414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters expressed support for CMS' proposal that a payer or eligible clinician must provide documentation to CMS that CEHRT is used by at least 50 percent of eligible clinicians in 2019, and 75 percent of eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement.

Response: We appreciate the support for our proposal to allow for documentation that CEHRT is used at required levels by eligible clinicians.

After considering public comments, we are finalizing our proposal that a payer or eligible clinician must provide documentation to CMS that CEHRT is used to document and communicate clinical care under the payment arrangement by at least 50 percent of eligible clinicians in 2019, and 75 percent of the eligible clinicians in 2020 and beyond, whether or not such CEHRT use is explicitly required under the terms of the payment arrangement. Specifically, we are finalizing our proposal to modify the regulation at § 414.1420(b) to specify that to be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent of eligible clinicians participating in the arrangement in 2019 (or, beginning in 2020, 75 percent) of such eligible clinicians.

(d) MIPS Comparable Quality Measures

(i) Overview

In the CY 2017 Quality Payment Program final rule, we explained that one of the criteria for a payment arrangement to be an Other Payer Advanced APM is that it must apply quality measures comparable to those under the MIPS quality performance category (81 FR 77465).

In the CY 2017 Quality Payment Program proposed rule, we proposed that to be an Other Payer Advanced APM, a payment arrangement must have quality measures that are evidence-

based, reliable, and valid; and that at least one measure must be an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We generally refer to these measures in the remainder of this discussion as ''MIPS-comparable quality measures.'' We did not specify in our regulation that the outcome measure is required to be evidence-based, reliable, and valid (81 FR 77466). We finalized these policies in the CY 2017 Quality Payment Program final rule and codified them in the regulation at § 414.1420(c).

(ii) General Quality Measures: Evidence-Based, Reliable, and Valid

In the CY 2017 Quality Payment Program final rule, we codified at § 414.1420(c)(2) that at least one of the quality measures used in the payment arrangement with an APM Entity must have an evidence-based focus, be reliable, and valid, and meet at least one of the following criteria:

- Used in the MIPS quality performance category as described in § 414.1330;
- Endorsed by a consensus-based entity;
- Developed under section 1848(s) of the Act;
- Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or
- Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid.

It has come to our attention that, as with the comparable policy for Advanced APMs as discussed at 81 FR 28302, some have read the regulation at § 414.1420(c)(2) to mean that measures on the MIPS final list or submitted in response to the MIPS Call for Quality Measures necessarily are MIPS–comparable quality measures, even if they have not been determined to be evidence-based, reliable, and valid. We did not intend to imply that any measure that was merely submitted in response to the annual call for quality measures or developed using Quality Payment Program funding would automatically qualify as MIPS-comparable regardless of whether the measure was endorsed by a consensus-based entity, adopted under MIPS, or otherwise determined to be evidence-based, reliable, and valid. While we believe such measures may be evidence-based, reliable, and valid, we did not intend to consider them so for purposes of § 414.1420(c)(2) without independent verification by a consensus-based entity or based on our own assessment and determination that they are evidence-based, reliable, and valid. We further believe the same principle applies to QCDR measures. If QCDR measures are endorsed by a consensus-based entity they are presumptively considered MIPS-comparable quality measures for purposes of § 414.1420(c)(2); otherwise we would have needed independent verification, or to make our own assessment and determination, that the measures are evidence-based, reliable, and valid before considering them to be MIPS-comparable (see 81 FR 77415 through 77417).

Because of the potential ambiguity in the existing definition and out of an abundance of caution in order to avoid any adverse impact on APM entities, eligible clinicians or other stakeholders, we have used the more permissive interpretation of the text, wherein measures developed under section 1848(s) of the Act and submitted in response to the MIPS Call for Quality Measures will meet the quality criterion in implementing the program thus far, and intend to use this interpretation for the 2019 QP Performance Period. Recognizing that APMs and other payer arrangements that we might consider for Advanced APM and Other Payer Advanced APM determinations are well into development for 2019, we proposed to use this interpretation until our new proposal described below is effective on January 1, 2020.

Therefore, at § 414.1420(c)(2), we proposed, effective January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must meet at least one of the following criteria:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Otherwise determined by CMS to be evidenced-based, reliable, and valid.

That is, for QP Performance Period 2020 and all future QP Performance Periods, we would treat any measure that is either included in the MIPS final list of measures or has been endorsed by a consensus-based entity as presumptively evidence-based, reliable, and valid. All other measures would need to be independently determined by CMS to be evidence-based, reliable, and valid, in order to be considered MIPS-comparable quality measures.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: A few commenters supported the proposal that at least one of the quality measures used in the payment arrangement with and APM Entity must meet at least one of the three proposed criteria to assure that it is evidence-based, reliable, and valid.

Response: We appreciate the support for our proposal.

Comment: One commenter urged CMS to include a fourth way to determine a quality measure is ''MIPS-like'' by clarifying that all Medicare Advantage Star Rating measures are determined to be evidence-based, reliable, and valid by CMS. The commenter stated that these metrics were determined by CMS to be valid and reliable enough to use as a basis of MA plan payment.

Response: We believe that all active Medicare Advantage Star Rating quality measures (*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html*) are evidenced-based, reliable, and valid when used at the health plan level. However, if a payer has changed the unit of analysis from applying it at the health plan level to using it at the provider level, as would likely be necessary in this context, this may have affected the reliability and validity of the measure. As such, we believe it is important that all such measures be independently determined by CMS to be evidenced-based, reliable, and valid in the context of their use in the payment arrangement in order to satisfy the Other Payer Advanced APM criterion. We would note that this determination that a quality measure is MIPS-comparable would be made using the information collected by CMS as part of the data submission process for Other Payer Advanced APM determinations.

After considering public comments, we are finalizing our proposal to revise § 414.1420(c)(2) to clarify, effective as of January 1, 2020, that at least one of the quality measures used in the payment arrangement with an APM Entity must either be finalized on the MIPS final list of measures, as described in § 414.1330; endorsed by a consensus-based entity; or determined by CMS to be evidenced-based, reliable, and valid.

(iii) Outcome Measures: Evidence-Based, Reliable, and Valid

In § 414.1420(c)(3), we generally require that, to be an Other Payer Advanced APM, the payment arrangement must use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. We note that the current regulation does not require that the outcome measure be evidence-based, reliable, and valid.

We proposed to revise § 414.1420(c)(3), to explicitly require that, unless there is no applicable

outcome measure on the MIPS quality measure list, at least one outcome measure that is used in the payment arrangement must be evidence-based, reliable, and valid. This proposal would have an effective date of January 1, 2020, and would specifically require that an outcome measure must also be MIPS-comparable. This proposal aligns with the similar proposal for Advanced APMs discussed at section III.I.4.e.(3)(d)(ii) of this final rule, so that an outcome measure used in the payment arrangement must also be:

- Finalized on the MIPS final list of measures, as described in § 414.1330;
- Endorsed by a consensus-based entity; or
- Determined by CMS to be evidence-based, reliable, and valid.

The proposal would have an effective date of January 1, 2020. This proposed effective date is intended to provide stakeholders sufficient notice of, and opportunity to respond to, this change in our regulation because the current regulation does not explicitly require that an outcomes measures must be evidence-based, reliable, and valid and, as a result some Other Payer Advanced APMs that were submitted for determination in CY 2018 for the CY 2019 performance year may not include outcomes measures that are evidence-based, reliable, and valid.

We also proposed that, for such payment arrangements that are determined to be Other Payer Advanced APMs for the 2019 performance year and did not include an outcome measure that is evidence-based, reliable, and valid, and that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.e.(4)(b) of this final rule), we will continue to apply the current regulation for purposes of those determinations. Additionally, payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later, will be assessed under the rules of the current regulation meaning they do not need to include an outcome measure that is evidence-based, reliable, and valid to be an Other Payer Advanced APM. For all other payment arrangements the proposed revised regulation would apply beginning in CY 2020.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter supported the proposal that at least one outcome measure must be among the quality measures used in the payment arrangement with an APM Entity, and that the outcome measure must meet at least one of the three proposed criteria to assure that it is evidence-based, reliable, and valid.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to revise § 414.1420(c)(3), effective January 1, 2020, to explicitly require that, unless there is no applicable outcome measure on the MIPS quality measure list, at least one outcome measure that applies in the payment arrangement must either be finalized on the MIPS final list of measures as described in § 414.1330, endorsed by a consensus-based entity, or determined by CMS to be evidence-based, reliable, and valid.

(e) Financial Risk for Monetary Losses

(i) Overview

In the CY 2018 Quality Payment Program final rule, we finalized our proposal to add a revenue-based nominal amount standard to the generally applicable nominal amount standard for Other Payer Advanced APMs that is parallel to the generally applicable revenue-based nominal amount standard for Advanced APMs. Specifically, we finalized that an other payer arrangement would meet the total risk component of the proposed nominal risk standard if, under the terms of the other payer arrangement, the total amount that an APM Entity potentially owes the payer or foregoes is equal to at least: For the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities. This standard is in addition to the previously finalized expenditure-based standard. We explained that a payment arrangement would only need to meet one of the two standards. We would use this standard only for other payer arrangements where financial risk is expressly defined in terms of revenue in the payment arrangement.

(ii) Generally Applicable Nominal Amount Standard

We proposed to amend § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2019 through 2024. This change is consistent with the proposed amendment to our regulation to maintain the generally applicable revenue-based nominal standard at 8 percent for Advanced APMs during the same timeframe.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters expressed support for the proposal to maintain the general applicable revenue-based nominal amount standard at 8 percent for QP Performance Periods 2021 through 2024.

Response: We appreciate the support for our proposal to maintain the generally applicable revenue-based nominal amount standard.

After considering public comments, we are finalizing our proposal to revise § 414.1420(d)(3)(i) to maintain the generally applicable revenue-based nominal amount standard at 8 percent of the total combined revenues from the payer of providers and suppliers in participating APM Entities for QP Performance Periods 2021 through 2024.

(4) Determination of Other Payer Advanced APMs

(a) Overview

In the CY 2017 Quality Payment Program final rule, we specified that an APM Entity or eligible clinician must submit, by a date and in a manner determined by us, information necessary to identify whether a given payment arrangement satisfies the Other Payer Advanced APM criteria (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we codified at § 414.1445 the Payer Initiated Other Payer Advanced APM Determination Process and the Eligible Clinician Initiated Other Payer Advanced APM Determination Process pertaining to the determination of Other Payer Advanced APMs, as well as specifying the information required for Other Payer Advanced APM determinations (82 FR 53814 through 53873).

(b) Multi-Year Other Payer Advanced APM Determinations

In the CY 2018 Quality Payment Program final rule, we finalized that Other Payer Advanced APM determinations made in response to requests submitted either through the Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process) or the Eligible Clinician Initiated Other Payer

Advanced APM Determination Process (Eligible Clinician Initiated Process) would be in effect for only one year at a time. We sought additional comment regarding the current duration of payment arrangements and whether creating a multi-year determination process would encourage the creation of more multi-year payment arrangements as opposed to payment arrangements that are for one year only. We also sought comment on what kind of information should be submitted annually after the first year to update an Other Payer Advanced APM determination (82 FR 53869 through 53870).

After consideration of this feedback, we proposed to maintain the annual submission process with the modifications outlined below for both the Payer Initiated Process and the Eligible Clinician Initiated Process. We proposed that beginning with the 2019 and 2020 submission periods for Other Payer Advanced APM determinations for performance year 2020, after the first year that a payer, APM Entity, or eligible clinician (which we refer to as the ''requester'' in the remainder of this discussion) submits a multi-year payment arrangement that we determine to be an Other Payer Advanced APM for that year, the requester would need to submit information only on changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement. In the initial submission, the requester would certify as usual that the information provided about the payment arrangement using the Payer Initiated Process or Eligible Clinician Initiated Process, as applicable, is true, accurate, and complete; would authorize CMS to verify the information; and would certify that they would submit revised information in the event of a material change to the payment arrangement. For multi-year payment arrangements, we proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal that the requester would need to submit information only on any changes to the payment arrangement that are relevant to the Other Payer Advanced APM criteria for each successive year for the remaining duration of the payment arrangement.

Response: We appreciate the support for our proposal to allow for multi-year submissions of payment arrangements.

After considering public comments, we are finalizing our proposal to maintain the annual submission process with the modifications outlined above for both the Payer Initiated Process and the Eligible Clinician Initiated Process.

For multi-year payment arrangements, we proposed to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we would continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported our proposal to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Commenters supported the proposal that this process remain in place through the earlier of the end of the multi-payment arrangement or 5 years.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to require as part of the submission that the certifying official for the requester must agree to review the submission at least once annually, to assess whether there have been any changes to the information since it was submitted, and to submit updated information notifying us of any changes to the payment arrangement that would be relevant to the Other Payer Advanced APM criteria, and thus, to our determination of the arrangement to be an Other Payer Advanced APM, for each successive year of the arrangement. Absent the submission by the requester of updated information to reflect changes to the payment arrangement, we will continue to apply the original Other Payer Advanced APM determination for each successive year through the earlier of the end of that multi-year payment arrangement or 5 years.

(c) Payer Initiated Other Payer Advanced APM Determination Process (Payer Initiated Process)—Remaining Other Payers

In the CY 2018 Quality Payment Program final rule, we finalized that we will allow certain other payers, including payers with payment arrangements authorized under Title XIX, Medicare Health Plan payment arrangements (Medicare Advantage plans, section 1876 cost plans PACE organization operated under section 1894 of the Act, and similar plans, other than an APM under section 1833(z)(3)(C) of the Act, that provide Medicare benefits under demonstration or waiver authority), and payers with payment arrangements aligned with a CMS Multi-Payer Model to use the Payer Initiated Process to request that we determine whether their other payer arrangements are Other Payer Advanced APMs starting prior to the 2019 QP Performance Period and each year thereafter (82 FR 53854). We codified this policy at § 414.1445(b)(1).

We also finalized that the Remaining Other Payers, including commercial and other private payers, may request that

we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP Performance Period and each year thereafter (82 FR 53867).

In the CY 2019 PFS proposed rule, we proposed details regarding the Payer Initiated Process for the Remaining Other Payers that were not among those other payers permitted to use the Payer Initiated Process to submit their arrangements for Other Payer Advanced APM Determinations in 2018 (Remaining Other Payers). To the extent possible, we are aligning the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

In the CY 2018 Quality Payment Program final rule, we finalized that the Payer Initiated Process will be voluntary for all payers (82 FR 53855). We note that the Payer Initiated Process will be similarly voluntary for payers that were permitted to submit payment arrangements in 2018 and for Remaining Other Payers starting in 2019.

Guidance and Submission Form: As we have for the other payers included in the Payer Initiated Process (82 FR 53874), we intend to make guidance available regarding the Payer Initiated Process for Remaining Other Payers prior to their first Submission Period, which will occur during 2019. We intend to modify the submission form (which we refer to as the Payer Initiated Submission Form) for use by Remaining Other Payers to request Other Payer Advanced APM determinations, and to make this Payer Initiated Submission Form available to Remaining Other Payers prior to the first Submission Period. We proposed that a Remaining Other Payer will be required to use the Payer Initiated Submission Form to request that we make an Other Payer Advanced APM determination. We intend for the Payer Initiated Submission Form to include questions that are applicable to all payment arrangements and some questions that are specific to a particular type of payment arrangement, and we intend for it to include a way for payers to attach supporting documentation.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters supported the proposal to require Remaining Other Payers to use the Payer Initiated Submission Form to request that CMS make an Other Payer Advanced APM determination.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal that Remaining Other Payers will use the Payer Initiated Submission Form to request that CMS make an Other Payer Advanced APM determination.

We proposed that Remaining Other Payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement. Remaining Other Payers may submit other payer arrangements with different tracks within that arrangement as one request along with information specific to each track.

We solicited comment on this proposal.

We did not receive any comment in response to this proposal.

We are finalizing our proposal that Remaining Other Payers may submit requests for review of multiple other payer arrangements through the Payer Initiated Process, though we would make separate determinations as to each other payer arrangement and a payer would be required to use a separate Payer Initiated Submission Form for each other payer arrangement.

Submission Period: We proposed that the Submission Period for the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations will open on January 1 of the calendar year prior to the relevant QP Performance Period for which we would make Other Payer Advanced APM determinations.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter supported the CMS proposal that the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations would open on January 1.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal that the Payer Initiated Process for use by Remaining Other Payers to request Other Payer Advanced APM determinations would open on January 1.

The finalized timeline for the Payer Initiated Process for Remaining Other Payers as well as the previously finalized timeline for the Payer Initiated Process for Medicaid and Medicare Health Plans, is summarized in Table 59 alongside the final timeline for the Eligible Clinician Initiated Process.

TABLE 59: Finalized Other Payer Advanced APM Determination Process for Medicaid, Medicare Health Plans, and Remaining Other Payers for QP Performance Period 2020

	Payer Initiated Process	Date	Eligible Clinician (EC) Initiated Process*	Date
Medicaid	Guidance sent to states, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2019
	Submission Period Closes	April 2019	Submission Period Closes	November 2019
	CMS contacts states and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and states and posts Other Payer Advanced APM List	December 2019
Medicare Health Plans	Guidance made available to Medicare Health Plans, then Submission Period Opens	April 2019	Guidance made available to ECs, then Submission Period Opens	September 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Medicare Health Plans and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Medicare Health Plans and posts Other Payer Advanced APM List	December 2020
Remaining Other Payers	Guidance made available to Remaining Other Payers, then Submission Period Opens	January 2019	Guidance made available to ECs, then Submission Period Opens	September 2020
	Submission Period Closes	June 2019	Submission Period Closes	November 2020
	CMS contacts Remaining Other Payers and posts Other Payer Advanced APM List	September 2019	CMS contacts ECs and Remaining Other Payers and posts Other Payer Advanced APM List	December 2020

*Note that APM Entities or eligible clinicians may use the Eligible Clinician Initiated Process.

CMS Determination: Upon the timely receipt of a Payer Initiated Submission Form, we will use the information submitted to determine whether the other payer arrangement meets the Other Payer Advanced APM criteria. We proposed that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we will inform the payer and allow them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information. For each other payer arrangement for which the Remaining Other Payer does not submit sufficient information in a timely fashion, we will not make a determination in response to that request submitted via the Payer Initiated Submission Form. As a result, the other payer arrangement will not be considered an Other Payer Advanced APM for the year. These determinations are final and not subject to reconsideration.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal that if we find that the Remaining Other Payer has submitted incomplete or inadequate information, we would inform the payer and allow them to submit additional information no later than 15 business days from the date we inform the payer of the need for additional information.

CMS Notification: We intend to notify Remaining Other Payers of our determination for each request as soon as practicable after the relevant Submission Deadline. We note that Remaining Other Payers may submit information regarding an other payer arrangement for a subsequent QP Performance Period even if we have determined that the other payer arrangement is not an Other Payer Advanced APM for a prior year.

CMS Posting of Other Payer Advanced APMs: We intend to post on the CMS website a list (which we refer to as the Other Payer Advanced APM List) of all other payer arrangements that we determine to be Other Payer Advanced APMs. Prior to the start of the relevant QP Performance Period, we intend to post a list of the payment arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process, and Other Payer Advanced APMs under Title XIX through the Eligible Clinician Initiated Process. After the QP Performance Period, we will update this list to include payment arrangements that we determine to be Other Payer Advanced APMs based on other requests through the Eligible Clinician Initiated Process. We intend to post the list of other payer arrangements that we determine to be Other Payer Advanced APMs through the Payer Initiated Process prior to the start of the relevant QP Performance Period, and then to update the list to include payment arrangements that we determine to be Other Payer Advanced APMs based on requests received through the Eligible Clinician Initiated Process.

(d) Payer Initiated Process—CMS Multi-Payer Models

In the CY 2018 Quality Payment Program final rule, we finalized that beginning for the first QP Performance Period under the All-Payer Combination Option, payers with a payment arrangement aligned with a CMS Multi-Payer Model may request that we determine whether that aligned payment arrangement is an Other Payer Advanced APM.

In the CY 2019 PFS proposed rule, we proposed to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for

Remaining Other Payers we have proposed in section III.I.4.g.(3)(c) of this final rule, or through the existing Medicaid or Medicare Health Plan payment arrangement submission process, as applicable.

We solicited comment on this proposal.

We did not receive any comment in response to this proposal.

We are finalizing our proposal to eliminate the Payer Initiated Process and submission form that are specifically for CMS Multi-Payer Models.

(5) Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

(a) Overview

In the CY 2017 Quality Payment Program final rule, we finalized our overall approach to the All-Payer Combination Option (81 FR 77463). Beginning in 2021, in addition to the Medicare Option, an eligible clinician may alternatively become a QP through the All-Payer Combination Option, and an eligible clinician need only meet the QP threshold under one of the two options to be a QP for the payment year (81 FR 77459). We finalized that we will conduct the QP determination sequentially so that the Medicare Option is applied before the All-Payer Combination Option (81 FR 77459).

In the CY 2017 Quality Payment Program final rule, we finalized that we will calculate Threshold Scores under the Medicare Option through both the payment amount and the patient count methods, compare each Threshold Score to the relevant QP and Partial QP Thresholds, and use the most advantageous scores to make QP determinations (81 FR 77457). We finalized the same approach for the All-Payer Combination Option wherein we will use the most advantageous method for QP determinations with the data that has been provided (81 FR 77475).

(b) QP Determinations Under the All-Payer Combination Option

In the CY 2018 Quality Payment Program final rule, we finalized that an eligible clinician may request a QP determination at the eligible clinician level, and that an APM Entity may request a QP determination at the APM Entity Level (82 FR 53880 through 53881). In the event that we receive a request for QP determination from an individual eligible clinician and also separately from that individual eligible clinician's APM Entity, we would make a determination at both levels. The eligible clinician could become a QP on the basis of either of the two determinations (82 FR 53881).

We proposed to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single (meaning the same) APM Entity. Therefore, this option would be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It would also be available to any other TIN for which all clinicians who have reassigned their billing rights to the TIN are participating in the same APM Entity.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity.

We proposed that, similar to our existing policies for individual and APM Entity requests for QP determinations under the All-Payer Combination Option, we would assess QP status based on the most advantageous result for each individual eligible clinician. That is, if we receive any combination of QP determination requests (at the TIN-level, APM Entity level, or individual level) we will make QP assessments at all requested levels and determine QP status on the basis of the QP assessment that is most advantageous to the eligible clinician.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Many commenters supported the proposal to assess QP status based on the most advantageous result for each individual eligible clinician.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal to assess QP status based on the most advantageous result for each individual eligible clinician.

(c) Use of Individual or APM Entity Information for Medicare Payment Amount and Patient Count Calculation Under the All-Payer Combination Option

(i) Flexibility in the Medicare Option and All-Payer Combination Option Threshold Methods

In the CY 2018 Quality Payment Program final rule, we finalized that when we make QP determinations at the individual eligible clinician level, we would use the individual eligible clinician payment amounts and patient counts for the Medicare calculations in the All-Payer Combination Option. When we make QP determinations at the APM Entity level, we will use APM Entity level payment amounts and patient counts for the Medicare calculations in QP determinations under the All-Payer Combination Option. Eligible clinicians assessed at the individual eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the individual eligible clinician level only under the All-Payer Combination Option. We codified these policies at § 414.1440(d)(2) (82 FR 53881).

We noted in the CY 2019 PFS proposed rule that some may have read our regulation at § 414.1440(d)(2) to suggest that consistency is required across the two thresholds requiring eligible clinicians or APM Entities to meet the minimum Medicare threshold needed to qualify for the All-Payer Combination Option and the All-Payer threshold using the same method—either payment amounts or patient counts. Although we did not directly address this specific question in our current regulation or in prior rulemaking, we are clarifying that eligible clinicians or APM Entities can meet the minimum Medicare threshold for the All-Payer Combination option using one method (whichever is most favorable), and the All-Payer threshold for the All-Payer Combination Option using either the same, or the other method. All data submitted to us for Other Payer Advanced APM determinations and, when applicable, QP determinations using the All-Payer Combination Option will be considered and evaluated; and eligible clinicians (or APM Entities or TINs, as appropriate) may submit all data relating to both the payment amount and patient count methods. To avoid any potential ambiguity for the future, we proposed a change to § 414.1440(d)

to codify this clarification. We proposed to add a new § 414.1440(d)(4) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method. We note that, in the preamble in the CY 2019 PFS proposed rule, we indicated that we would codify this proposed policy by adding a new § 414.1440(d)(4) to our regulations. However, the corresponding proposed regulation text included the proposed policy as an amendment to the regulation text at § 414.1440(d)(1). We intended to propose the policy reflected in the propoed regulation text, and due to a clerical error, inadvertently neglected to revise the description of the proposal in the preamble. As such, rather than adding a new § 414.1440(d)(4), we intended to propose to amend the regulation at § 414.1440(d)(1) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Some commenters supported the proposal to allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

Response: We appreciate the support for our proposal.

After considering public comments, we are finalizing our proposal with the correction noted above, that we are amending the text in our regulation at § 414.1440(d)(1) to expressly allow eligible clinicians or APM Entities to meet the minimum Medicare threshold using the most favorable of the payment amount or patient count method, and then to meet the All-Payer threshold using either the same method or the other method.

(ii) Extending the Medicare Threshold Score Weighting Methodology to TIN Level All-Payer Combination Option Threshold Score Calculations

In the CY 2018 Quality Payment Program final rule, we explained that we recognize that in many cases an individual eligible clinician's Medicare Threshold Scores would likely differ from the corresponding Threshold Scores calculated at the APM Entity group level, which would benefit those eligible clinicians whose individual Threshold Scores would be higher than the group Threshold Scores and disadvantage those eligible clinicians whose individual Threshold Scores are equal to or lower than the group Threshold Scores (82 FR 53881–53882). In situations where eligible clinicians are assessed under the Medicare Option as an APM Entity group, and receive a Medicare Threshold Score at the APM Entity group level, we believe that the Medicare portion of their All-Payer calculation under the All-Payer Combination Option should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group.

To accomplish this outcome, we finalized a modified weighting methodology. We finalized that when the eligible clinician's Medicare Threshold Score calculated at the individual level would be lower than the Medicare Threshold Score calculated at the APM Entity group level, we would apply a weighting methodology to calculate the Threshold Score for the eligible clinician. This methodology allows us to apply the APM Entity group level Medicare Threshold Score (if higher than the individual eligible clinician level Medicare Threshold Score), to the eligible clinician, under either the payment amount or patient count method, but weighted to reflect the individual eligible clinician's Medicare volume. We multiply the eligible clinician's APM Entity group Medicare Threshold Score by the total Medicare payments or patients made to that eligible clinician as follows:

$$\frac{[\textit{APM Entity Medicare Threshold Score} \times \textit{Clinician Medicare Payments or Patients}] + \textit{Individual Other Payer Advanced APM Payments or Patients}}{\textit{Individual Payments or Patients (All Payers except those excluded)}}$$

In the CY 2019 PFS proposed rule, we proposed to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level. In this scenario, we believe that the Medicare portion of the TIN's All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by participating in an APM Entity group (82 FR 53881–53882). We note this extension of the weighting methodology would only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity, because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We would multiply the TIN's APM Entity group Medicare Threshold Score by the total Medicare payments or patients for that TIN as follows:

$$\frac{[\textit{APM Entity Medicare Threshold Score X TIN Medicare Payments or Patients}] + \textit{TIN Other Payer Advanced APM Payments or Patients}}{\textit{TIN Payment or Patients (All Payers except those excluded)}}$$

We proposed to calculate the TIN's Threshold Scores both on its own and with this weighted methodology, and then use the most advantageous score when making a QP determination. We believe that, as it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. Additionally, the proposed application of this weighting approach in the case of a TIN level QP determination would be consistent with our established policy.

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: Commenters supported the proposal to extend the same weighting

methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

Response: We appreciate support for our proposal.

After considering public comments, we are finalizing our proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

(6) Summary of Final Policies

In this section, we are finalizing the following policies:

Other Payer Advanced APM Criteria:

• We are finalizing our proposal to change the CEHRT use criterion so that in order to qualify as an Other Payer Advanced APM as of January 1, 2020, the percentage of eligible clinicians participating in the other payer arrangement who are using CEHRT must be 75 percent.

• We are finalizing our proposal to allow payers and eligible clinicians to submit evidence as part of their request for an Other Payer Advanced APM determination that CEHRT is used by the requisite percentage of eligible clinicians participating in the payment arrangement (50 percent for 2019, and 75 percent for 2020 and beyond) to document and communicate clinical care, whether or not CEHRT use is explicitly required under the terms of the payment arrangement. We codifying this change at § 414.1420(b).

• We are finalizing the following clarification to § 414.1420(c)(2), effective January 1, 2020, to provide that at least one of the quality measures used in the payment arrangement in paragraph (c)(1) of this regulation must be:

++ Finalized on the MIPS final list of measures, as described in § 414.1330;

++ Endorsed by a consensus-based entity; or

++ Determined by CMS to be evidenced-based, reliable, and valid.

• We are finalizing our proposal to revise § 414.1420(c)(3) to require that, effective January 1, 2020, unless there is no applicable outcome measure on the MIPS quality measure list, an Other Payer Advanced APM must use an outcome measure, that meets the proposed criteria in paragraph (c)(2) of this regulation.

• We are also finalizing our proposal at § 414.1420(c)(3)(i) that, for payment arrangements determined to be Other Payer Advanced APMs for the 2019 performance year which did not include an outcome measure that is evidence-based, reliable, and valid, that are resubmitted for an Other Payer Advanced APM determination for the 2020 performance year (whether for a single year, or for a multi-year determination as proposed in section III.I.4.g.(3)(b) of this final rule), we would continue to apply the current regulation for purposes of those determinations. This revision also applies to payment arrangements in existence prior to the 2020 performance year that are submitted for determination to be Other Payer Advanced APMs for the 2020 performance year and later.

Determination of Other Payer Advanced APMs

• We are finalizing details regarding the Payer Initiated Process for Remaining Other Payers. To the extent possible, we are aligning the Payer Initiated Process for Remaining Other Payers with the previously finalized Payer Initiated Process for Medicaid, Medicare Health Plans, and CMS Multi-Payer Models.

• We are finalizing our proposal to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers that we are finalizing as described in section III.I.4.g.(3)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

Calculation of All-Payer Combination Option Threshold Scores and QP Determinations

• We are finalizing our proposal to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who reassigned billing rights under the TIN participate in a single APM Entity. We are finalizing this proposal to revise § 414.1440(d), by adding this third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing under the TIN participate in a single APM Entity, as well as to assess QP status at the most advantageous level for each eligible clinician.

• We also are finalizing our clarification that, in making QP determinations using the All-Payer Combination Option, eligible clinicians may meet the minimum Medicare threshold using one method, and the All-Payer threshold using the same or a different method. We are finalizing our proposal with a correction to codify this clarification by amending § 414.1440(d)(1).

• We are finalizing our proposal to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level.

5. Quality Payment Program Technical Correction: Regulation Text Changes

a. Overview

We proposed certain technical revisions to our regulations in order to correct several technical errors and to reconcile the text of several of our regulations with the final policies we adopted through notice and comment rulemaking.

b. Regulation Text Changes

We proposed a technical correction to § 414.1415(b)(1) of our regulations to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM (83 FR 36005). The addition of the word ''quality'' better aligns with section 1833(z)(3)(D) of the Act and with the policy that was finalized in the CY 2017 Quality Payment Program final rule (81 FR 77406), and corrects a clerical error we made in the course of revising the text of § 414.1415(b)(1) for inclusion in the CY 2017 QPP final rule. This proposed revision would not change our current policy for this Advanced APM criterion.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing the technical correction to § 414.1415(b)(1) to specify that an Advanced APM must require quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

We also proposed technical corrections to § 414.1420(d)(3)(ii)(B) (83 FR 36005). These changes align with the generally applicable nominal amount standard for Other Payer Advanced APMs that was finalized in the CY 2017 Quality Payment Program final rule, and the change to the generally applicable nominal amount standard in the CY 2018 Quality Payment Program final rule where we established a revenue-based nominal amount standard as part of the Other Payer Advanced APM

criteria (82 FR 53849–53850). We finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and that a payment arrangement's level of marginal risk must be at least 30 percent of losses in excess of the expected expenditures, and the maximum allowable minimum loss rate must be 4 percent (81 FR 77471). Due to a clerical oversight, we inadvertently published two conflicting provisions in regulation text. At § 414.1420(d)(3)(i), we correctly finalized that a payment arrangement must require APM Entities to bear financial risk for at least 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement, and at § 414.1420(d)(3)(ii)(B) we incorrectly finalized that the risk arrangement must have a total potential risk of at least 4 percent of expected expenditures. We are effectuating this change by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable Nominal Amount Standard provision at § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii).

We solicited comment on this proposal.

The following is a summary of the public comments received in response to our request for comment and our responses:

Comment: One commenter thanked the agency for making the technical correction to clarify that an Other Payer payment arrangement must require APM Entities to bear financial risk for at least 3 percent, not 4 percent.

Response: We thank the commenter for their support of this technical correction.

After considering public comments, we are finalizing this technical correction by removing the Other Payer Advanced APM Criteria, Financial Risk, Generally Applicable Nominal Amount Standard provision at § 414.1420(d)(3)(ii)(B) and consolidating § 414.1420(d)(3)(ii)(A) into § 414.1420(d)(3)(ii).

In the CY 2017 Quality Payment Program final rule, we finalized a capitation standard for the financial risk criterion under the Advanced APM Criteria and the Other Payer Advanced APM Criteria, respectively. We finalized that full capitation arrangements would meet the Advanced APM financial risk criterion and Other Payer Advanced APM financial risk criterion, and would not separately need to meet the generally applicable financial risk standard and generally applicable nominal amount standard in order to satisfy the financial risk criterion for Advanced APMs and Other Payer Advanced APMs (81 FR 77431; 77472). We proposed to clarify the application of the capitation standard by revising § 414.1415(c) and § 414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to clarify the application of the capitation standard by revising § 414.1415(c) and § 414.1420(d) to refer to the full capitation exception that is expressed in paragraphs (c)(6) and (d)(7), respectively.

In finalizing §§ 414.1415(c)(6) and 414.1420(d)(7), we specified that a capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services for which payment is made through the APM furnished to a population of beneficiaries, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. This language does not completely reflect our definition of capitation risk arrangements as discussed in the preamble at 81 FR 77430 where we state that, ''capitation risk arrangements, as defined here, involve full risk for the population of beneficiaries covered by the arrangement, recognizing that it might require no services whatsoever or could require exponentially more services than were expected in calculating the capitation rate. . . . [a] capitation risk arrangement adheres to the idea of a global budget for all items and services to a population of beneficiaries during a fixed period of time.'' Therefore, we proposed to revise these regulations to align the Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1415(c)(6), and the Other Payer Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1420(d)(7) with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430–77431 (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise the Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1415(c)(6), and the Other Payer Advanced APM Criteria, Financial Risk, Capitation provision at § 414.1420(d)(7) to align with the definition of capitation risk arrangements that we expressed in the preamble of the CY 2017 Quality Payment Program final rule at 81 FR 77430–77431.

We also proposed a technical correction to remove the ''; or'' and replace it with a ''.'' at § 414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under § 414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under § 414.1420(d)(3)(i) (83 FR 36006). As indicated in the CY 2018 Quality Payment Program final rule at 82 FR 53849–53850, where we established a revenue-based nominal amount standard for Other Payer Advanced APMs, in order to meet the generally applicable nominal amount standard under the Other Payer Advanced APM criteria, the total amount that an APM Entity potentially owes the payer or foregoes under a payment arrangement must be equal to at least: For the 2019 and 2020 QP Performance Periods, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to remove the ''; or'' and replace it with a ''.'' at § 414.1420(d)(3)(i) because the paragraph that follows that section does not specify a standard that is necessarily an alternative to the standard under § 414.1420(d)(3)(i), but rather expresses a standard that is independent of the standard under § 414.1420(d)(3)(i).

We also proposed to revise § 414.1440(d)(3) to correct a typographical error by replacing the ''are'' with ''is'' in the third clause of the second sentence (83 FR 36006).

We solicited comment on this proposal.

We did not receive any comments in response to this proposal.

We are finalizing our proposal to revise § 414.1440(d)(3) to correct a typographical error by replacing the ''are'' with ''is'' in the third clause of the second sentence.

c. Summary of Final Policies

We are finalizing these technical corrections to our regulations at §§ 414.1415(b)(1), 414.1420(d)(3)(ii),

414.1415(c), 414.1420(d), 414.1415(c)(6), 414.1420(d)(7), 414.1420(d)(3)(i), and 414.1440(d)(3) as proposed.

IV. Requests for Information

This section addressed two requests for information (RFI).

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the CY 2019 PFS proposed rule (83 FR 35704 through 36368), we included an RFI related to promoting interoperability and electronic health care information exchange (83 FR 36006 through 36009). We received approximately 79 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2019 PFS proposed rule (83 FR 35704 through 36368), we included an RFI related to price transparency and improving beneficiary access to provider and supplier charge information (83 FR 36009 through 36010). We received approximately 94 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

V. Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success

A. Statutory and Regulatory Background

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Shared Savings Program to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. See 42 U.S.C. 1395jjj.

The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). We viewed this final rule as a starting point for the program, and because of the scope and scale of the program and our limited experience with shared savings initiatives under FFS Medicare, we built a great deal of flexibility into the program rules.

Through subsequent rulemaking, we have revisited and amended Shared Savings Program policies in light of the additional experience we gained during the initial years of program implementation as well as from testing through the Pioneer ACO Model, the Next Generation ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. A major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). We have also made use of the annual calendar year (CY) Physician Fee Schedule (PFS) rules to address updates to the Shared Savings Program quality measures, scoring, and quality performance standard, the program's beneficiary assignment methodology and certain other issues.[34]

Policies applicable to Shared Savings Program ACOs have continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), CMS established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program.

The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). Accordingly, we revised the program's regulations in the CY 2018 PFS final rule to reflect these new requirements.

On February 9, 2018, the Bipartisan Budget Act of 2018 was enacted (Pub. L. 115–123), amending section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to a prospectively assigned beneficiary, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period, permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and mandating that any such voluntary identification will supersede claims-based assignment, and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

On August 17, 2018 a proposed rule, titled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' (hereinafter referred to as the ''August 2018 proposed rule''), appeared in the **Federal Register** (83 FR 41786). This proposed rule would provide a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are also accountable for repaying any shared losses). As part of the proposed redesign of the program, we proposed to

[34] See for example: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule (78 FR 74230, Dec. 10, 2013). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67548, Nov. 13, 2014). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2016; Final Rule (80 FR 70886, Nov. 16, 2015). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2017; Final Rule (81 FR 80170, Nov. 15, 2016). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2018; Final Rule (82 FR 52976, Nov. 15, 2017).

establish two tracks under the program—the BASIC track and the ENHANCED track. These new participation options were designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. The August 2018 proposed rule would also provide new tools to support coordination of care across settings and strengthen beneficiary engagement; ensure rigorous benchmarking; and promote the use of interoperable electronic health record technology among ACO providers/suppliers. We received 470 timely pieces of correspondence in response to the August 2018 proposed rule. In the following sections of this final rule, we address a subset of the proposals described in the August 2018 proposed rule. We summarize and respond to the significant public comments on these proposals and discuss our final policies with respect to these issues after taking into consideration the public comments we received on this subset of proposals. We are not addressing the other topics included in the August 2018 proposed rule at this time. We will summarize and respond to public comments on these other proposed policies in a forthcoming final rule. We also received comments that are outside the scope of the August 2018 proposed rule. We may consider these comments when evaluating current Shared Savings Program policies and contemplating future refinements to the program.

B. Finalization of Certain Provisions of the Shared Savings Program August 2018 Proposed Rule

In this section of the final rule, we discuss the proposal, the comments received, and the final action that we are taking for the following proposals in the August 2018 proposed rule:

- A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018, and the methodology for determining financial and quality performance for this 6-month performance year from January 1, 2019 through June 30, 2019. We believe it is necessary to finalize the extension before these ACOs' participation agreements expire on December 31, 2018, so that they can continue their participation in the program without interruption. It is also necessary to finalize the methodology for determining ACO quality and financial performance for the extension period in advance of the 6-month performance year beginning on January 1, 2019.
- Implementation of the provisions of section 50331 of the Bipartisan Budget Act of 2018 on voluntary alignment. The Bipartisan Budget Act was enacted earlier this year, and we believe it is most consistent with the requirements of the statute to revise our voluntary alignment policies effective with assignment for performance years starting on January 1, 2019, to reflect the additional flexibility given to beneficiaries in selecting their primary care provider.
- A modification to the definition of primary care services used in assigning beneficiaries to ACOs to reflect recent code changes. Including these codes in the definition of primary care services will improve the accuracy of the assignment methodology and help to ensure that beneficiaries are assigned to the ACO that is responsible for coordinating their overall care.
- Relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years. We believe it is necessary to finalize the changes to the extreme and uncontrollable circumstances policies for the Shared Savings Program as quickly as possible to ensure that relief is available for ACOs affected by the recent hurricanes in North Carolina and Florida and other disasters during 2018.
- Revisions to program requirements to further promote interoperability among ACO providers and suppliers. We believe it is necessary to finalize changes to our CEHRT use requirements to align with the Quality Payment Program.

We are also making technical changes to update the authority citation for 42 CFR part 425 to conform with OFR requirements.

The changes will be effective on December 31, 2018. Applicability or implementation dates may vary, depending on the policy, and the timing specified in this final rule. By indicating that a provision is applicable to a performance year (PY) or agreement period, activities related to implementation of the policy may precede the start of the performance year or agreement period.

1. Participation Options for Agreement Periods Beginning in 2019

In this final rule, we are addressing a subset of the proposals in the August 2018 proposed rule for participation options for agreement periods beginning in 2019. In the August 2018 proposed rule, we stated that we would forgo an application cycle for a January 1, 2019 agreement start date and proposed to allow for a July 1, 2019 agreement start date. We proposed an approach for determining financial and quality performance for two 6-month performance years during 2019, with the first from January 1, 2019 through June 30, 2019, for ACOs with participation agreements expiring on December 31, 2018, that elect a voluntary 6-month extension, and the second from July 1, 2019 through December 31, 2019, for ACOs entering a new agreement period beginning July 1, 2019. We also proposed an approach for determining financial and quality performance for the performance period from January 1, 2019 through June 30, 2019 for an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and enters a new agreement period beginning on July 1, 2019, referred to as ''early renewals.''

In this final rule, we are addressing our proposals to allow for a voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, and to establish a methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. These proposals were necessary to prevent some ACOs from experiencing an involuntary gap in participation as a result of our decision to forgo an application cycle in 2018 for a January 1, 2019 agreement start date. Therefore, in this section of the final rule, we summarize and respond to comments and address final actions specific to our proposals regarding the 6-month extension and the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. As we describe in this section, some modifications to our proposals are necessary because of the limited scope of this final rule.

In a forthcoming final rule, we anticipate summarizing and responding to public comments on the other proposed policies related to determining financial and quality performance in 2019 for the following: (1) The performance period from January 1, 2019 through June 30, 2019, for ACOs starting a 12-month performance year on January 1, 2019, that terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019; and (2) the 6-month performance year from July 1, 2019 through December 31, 2019, for ACOs entering an agreement period beginning on July 1, 2019.

a. Voluntary Extension for a 6-Month Performance Year From January 1, 2019 Through June 30, 2019, for ACOs Whose Current Agreement Period Expires on December 31, 2018

In section II.A.7. of the August 2018 proposed rule (83 FR 41847), we explained that we were forgoing the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements, initial use of the Skilled Nursing Facility (SNF) 3-day rule waiver, and entry into the Track 1+ Model, and we proposed to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the proposed BASIC track or ENHANCED track, which would be offered under the proposed redesign of the program's participation options. We proposed the July 1, 2019 start date as a one-time opportunity, and thereafter we would resume our typical process of offering an annual application cycle that allows for review and approval of applications in advance of a January 1 agreement start date.

We proposed that ACOs that entered a first or second agreement period with a start date of January 1, 2016 could elect to extend their agreement period for an optional fourth performance year, defined as the 6-month period from January 1, 2019 through June 30, 2019. This election to extend the agreement period would be voluntary and an ACO could choose not to extend its agreement period, in which case it would conclude its participation in the program with the expiration of its current agreement period on December 31, 2018.

We proposed that the ACO's voluntary election to extend its agreement period must be made in the form and manner and according to the timeframe established by CMS, and that an ACO executive who has the authority to legally bind the ACO must certify the election. We explained our expectation that this election process, if finalized, would begin in 2018 following the publication of the final rule, as part of the annual certification process in advance of 2019 (described in section II.A.7.c.(2) of the August 2018 proposed rule (83 FR 41855)). We noted that this optional 6-month agreement period extension would be a one-time exception for ACOs with agreements expiring on December 31, 2018, and would not be available to other ACOs that are currently participating in a 3-year agreement in the program, or to future program entrants.

In the August 2018 proposed rule, we noted that under the existing provision at § 425.210, the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. Further, all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS. We proposed that an ACO that elects to extend its participation agreement by 6 months must notify its ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities of this continuation of participation and must require their continued compliance with the program's requirements for the 6-month performance year from January 1, 2019 through June 30, 2019.

As discussed in section II.A.2. of the August 2018 proposed rule (83 FR 41799 through 41800), we proposed modifications to the definition of ''agreement period'' in § 425.20 to broaden the definition to generally refer to the term of the participation agreement. We also proposed to add a provision at § 425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO (83 FR 41849). For consistency, we also proposed minor formatting changes to the existing provision at § 425.200(b)(2) and (b)(3) to italicize the header text.

We also proposed to revise the definition of ''performance year'' in § 425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement. We also proposed revisions to § 425.200(c) to make necessary formatting changes and specify additional exceptions to the definition of performance year as a 12-month period. Specifically, we proposed to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019. Similarly, we proposed to add a provision specifying that for an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019 (83 FR 41849).

In light of the proposed modifications to § 425.200(c) to establish two 6-month performance years during CY 2019, we proposed revisions to the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in a 6-month performance year during CY 2019 (83 FR 41849).

We also considered forgoing an application cycle for a 2019 start date altogether and allowing ACOs to enter agreement periods under the proposed BASIC track and ENHANCED track for the first time beginning on January 1, 2020. This approach would allow ACOs additional time to consider the redesign of the program, make organizational and operational plans, and implement business and investment decisions, and would avoid the complexity of needing to determine performance based on 6-month performance years during CY 2019. However, we noted that our proposed approach of offering an application cycle during 2019 for an agreement period start date of July 1, 2019 would allow for a more rapid progression of ACOs to the redesigned participation options, starting in mid-2019. We further noted that, under this alternative, we would also want to offer ACOs that started a first or second agreement period on January 1, 2016, a means to continue their participation between the conclusion of their current 3-year agreement period (December 31, 2018) and the start of their next agreement period (January 1, 2020), should the ACO wish to continue in the program. We indicated that under that alternative, which would postpone the start date for the new participation options to January 1, 2020, we would allow ACOs that started a first or second agreement period on January 1, 2016, to elect a 12-month extension of their current agreement period to cover the duration of CY 2019.

We sought comment on these proposals and the related considerations, as well as the alternatives considered.

Comment: Regarding the program's application cycles, most commenters generally supported CMS' decision to forgo an application cycle during CY 2018 for a January 1, 2019 agreement start date. Several commenters explained their support for this decision was due to the significant revisions to program policies contained in the proposed rule.

Response: We thank commenters for their support of our decision to forgo the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements.

Comment: Of the comments addressing the length of the extension for ACOs with agreement periods expiring December 31, 2018, a few commenters generally supported the proposed participation options for agreement periods beginning in 2019, including the proposed 6-month extension. Several commenters stated their support for CMS' proposal to allow ACOs with agreement periods ending December 31, 2018, to extend their agreements through June 30, 2019. Several commenters suggested that CMS allow ACOs whose agreement periods expire on December 31, 2018, an option to extend their current participation agreement by either 6 months or 12 months. In addition, many commenters supported allowing these ACOs the opportunity to elect a voluntary 12-month extension of their current agreement period, for a fourth performance year from January 1, 2019 through December 31, 2019. One commenter, whose comment was primarily focused on the applicability of policies to Track 1 ACOs, specifically recommended that this 12-month extension option should be offered for Track 1 ACOs. One commenter suggested that CMS permit Track 3 ACOs a 12-month extension for the performance year from January 1, 2019 through December 31, 2019, and that CMS apply certain aspects of the proposed program redesign, including the use of factors based on regional FFS expenditures in establishing, updating and adjusting the ACO's historical benchmark and the availability of beneficiary incentive programs, during this optional fourth 12-month performance year, enabling these Track 3 ACOs to gain experience with these policies before deciding whether to continue their participation in the Shared Savings Program in the ENHANCED track.

Some commenters explained that providing a 12-month extension option would give ACOs additional time to analyze program changes and prepare for the application process. One commenter expressed concern that a 6-month extension would provide a limited and inadequate amount of time for ACOs to consider participation options under a redesigned program, if a final rule establishing a July 1, 2019 start date is not issued until later in 2018. This commenter expressed the belief that this limited time to consider participation options in advance of a July 1, 2019 start date (if finalized) and general uncertainty about program policies would result in program attrition, due to ACOs and ACO participants electing not to continue in the program at the end of their current agreement. One commenter explained a 12-month extension would give ACOs additional time to evaluate whether they have the appropriate structure in place, implement processes to comply with new regulations, and make necessary changes to their ACO participant and ACO provider/supplier networks.

One commenter explained a 12-month extension would provide current ACOs with additional time and experience under their current agreement periods. Some commenters explained that providing a 12-month extension could avoid the complexity and increased burden on providers, practices, ACOs, and CMS that could potentially result from ACOs' participation in two, 6-month performance years in CY 2019. Other commenters raised concerns about making ACO participant list changes, and modifying agreements with their ACO participants, to allow for participation in two, 6-month performance years during CY 2019, with each performance year under a separate participation agreement: The first 6-month performance year under their current participation agreement (in an extension of their current agreement period); and the second 6-month performance year under a new participation agreement under one of the proposed redesigned participation options. Some commenters requesting a 12-month extension, or the choice between a 6-month or a 12-month extension, also raised concerns about the methodology for determining financial and quality performance for two, 6-month performance years during CY 2019. We summarize and respond to comments related to the methodology for determining performance for the 6-month performance year from January 1, 2019 through December 31, 2019, and other program policies applicable to ACOs participating in this 6-month performance year, in sections V.B.1.b. and V.B.1.c. of this final rule.

Response: We are not addressing in this final rule, comments on the timing for implementing the proposed redesign of the Shared Savings Program's participation options. However, we believe it is important to allow for continuity in participation for ACOs whose participation agreements expire December 31, 2018.

We appreciate commenters' concerns about preparing to enter a new agreement period in light of uncertainty around the participation options that may be available. However, we note that, based on the proposals in the August 2018 proposed rule, ACOs whose agreement periods expire on December 31, 2018, that were interested in continuing their participation in the program have had an opportunity to identify their likely ACO participants for the proposed 6-month performance year from January 1, 2019 through June 30, 2019, and have received preliminary feedback from CMS for ACO participant list additions for the performance year beginning on January 1, 2019. Moreover, we believe these ACOs generally have begun preparing the necessary revisions to their agreements with ACO participants and ACO providers/suppliers and, if under a two-sided model to extend their repayment mechanism in anticipation of the possibility that we would finalize the proposed 6-month extension period. We believe these ACOs have also been weighing their participation options in advance of applying to renew for a subsequent agreement period, and will have additional time to make these determinations during the 6-month extension (if elected). In particular, ACOs reaching the conclusion of their second agreement period under Track 1, would have been weighing their participation options under two-sided models, given the current requirement that ACOs transition to a two-sided model by the start of their third agreement period. In fact, the 6-month extension allows ACOs completing their second agreement period in Track 1 to continue participation under their current agreement period and thereby receive additional time under a one-sided model that otherwise would not have been available to these ACOs under the program's current regulations.

We also believe it is important to ensure we retain the flexibility to allow ACOs to more rapidly transition, starting as early as July 1, 2019, to the proposed new participation options, should they be finalized, including the participation options that would be Advanced APMs that would allow eligible clinicians participating in the ACO to qualify for incentive payments

under the Quality Payment Program. We believe that rapid transition to the new participation options would drive more meaningful systematic change in ACOs, which have the potential to control their assigned beneficiaries' Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus to achieve significant change in spending.

At this time, we believe the proposed 6-month extension for a 6-month performance year from January 1, 2019 through June 30, 2019, strikes an appropriate balance between these factors. To reduce the possibility for selective participation bias that could adversely affect the Trust Funds, we believe the same option for extending their current participation agreement should be made available to all eligible ACOs whose agreement periods expire December 31, 2018, as opposed to offering ACOs the option to choose between either a 6-month or a 12-month extension, or offering extensions of different lengths to ACOs based on their current participation track. For example, we believe that if we offered a choice regarding the length of the extension, only ACOs that would expect to benefit from being rebased under new program policies would elect a 6-month extension in order to allow the regional rebasing policies to apply sooner.

We also decline to adopt the commenter's suggestions that we finalize certain aspects of the proposed program redesign, such as the proposed modifications to the methodology for establishing, adjusting and updating an ACO's historical benchmark, and certain payment and program flexibilities for eligible ACOs participating under two-sided models, and apply these policies to a subset of the ACOs electing the voluntary extension. Continuing to apply the current benchmarking methodology during the optional fourth performance year maintains ACOs' existing historical benchmarks, allowing them to continue to build on their experience within their current agreement period and provides a more predictable and stable benchmark during the 6-month extension period. We also decline to allow only ACOs that are eligible for and elect the extension to have access to and make use of additional program and payment flexibilities (such as a SNF 3-day rule waiver, unless previously approved, or a beneficiary incentive program) as a way of allowing these organizations to gain experience with these policies in advance of their broader availability (if finalized) to eligible ACOs participating in the program. Our proposals to extend the availability of a SNF 3-day rule waiver and to give ACOs the opportunity to offer beneficiary incentive programs were developed in conjunction with our proposed changes to the participation options for ACOs participating in the Shared Savings Program. Therefore, we believe these proposals need to be considered together as part of a forthcoming final rule addressing our proposals for the overall redesign of the Shared Savings Program. Further, we believe it would be cumbersome to determine ACOs' eligibility for these flexibilities prior to the start of the performance year beginning January 1, 2019, particularly given the absence of a formal application cycle during CY 2018 during which ACOs could elect to apply for such opportunities.

Comment: One commenter pointed to the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41926), and our estimate that a 12-month extension for ACOs whose participation agreements expire on December 31, 2018, would reduce overall Federal spending by approximately an additional $100 million, as further justification for allowing a 12-month rather than a 6-month extension.

Response: We believe it is important to allow for continuity in participation for ACOs whose agreement periods expire on December 31, 2018. We also believe it is important to ensure ACOs more rapidly transition to new participation options in the event we finalize a mid-year start date for those participation options in 2019. At this time, we believe the proposed 6-month extension for a 6-month performance year from January 1, 2019 through June 30, 2019, strikes an appropriate balance between these factors. The estimated impact of a 12-month extension for ACOs whose current agreement periods expire on December 31, 2018, is not comparable to the impact estimated for a 6-month extension for this same group of ACOs. To explain further, the impact estimate for a 12-month extension was estimated under a different hypothetical baseline. Differences in participation resulting from a 6-month or a 12-month extension were not a major factor in the impact estimate because under the proposed approach, a 12-month extension would not have changed the ultimate date that renewing ACOs would be required to transition to performance-based risk under the proposed redesign. For example, for Track 1 ACOs, a 12-month extension for performance year 2019 under Track 1 would result in the Track 1 ACO being eligible to participate in proposed BASIC track Level B during performance year 2020, whereas with a 6-month extension for a performance year from January 1, 2019 through June 30, 2019, under Track 1, would permit the ACO up to 1.5 years under proposed BASIC track Level B, because the ACO would not automatically transition from Level B to Level C at the start of performance year 2020 under the policies included in the proposed rule. In either event, however, the ACO would be required to participate in performance-based risk under Level C, D, or E of the BASIC track by performance year 2021. There were also a number of other competing factors working in different directions, such as the benchmark the ACO participates under, and the availability of Advanced APM incentive payments, which ultimately led to our projection that the 12-month extension would result in somewhat greater savings over 10 years when compared to the modeling of the proposed 6-month extension.

Comment: One commenter expressed confusion over whether the voluntary election for a 6-month performance year from January 1, 2019 through June 30, 2019, was an option for ACOs within an agreement period (such as an ACO that entered an agreement period on January 1, 2018) as part of the proposed early renewal process.

Response: The optional 6-month extension is only available for ACOs with agreements expiring on December 31, 2018, and would not be available to other ACOs that are currently participating in a 3-year agreement period in the program because their agreements are not expiring. Thus, these ACOs do not require the option of a 6-month extension because their current agreement periods will continue during 2019 and they will not experience a gap in participation as a result of our decision to forgo the application cycle in 2018 for an agreement start date of January 1, 2019.

Comment: One commenter suggested that all Track 3 ACOs should be offered an extension of their current agreement period, regardless of the ACO's agreement period start date.

Response: We proposed that the one-time, 6-month extension would only be available to ACOs whose agreement periods expire on December 31, 2018, in order to ensure that these ACOs would be able to continue participation in the Shared Savings Program without any gap. At this time, we decline the commenter's alternative suggestion that we offer a similar 6-month extension to ACOs whose agreement periods expire in subsequent years. These ACOs would not need a 6-month extension because we anticipate a typical, annual application cycle would be available in

future years so that these ACOs could renew their participation agreements and continue their participation in the program without interruption.

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on how ACOs should modify their agreements with their ACO participants for the 2019 performance periods. Several ACOs, with agreement periods expiring on December 31, 2018, submitted comments describing the burden of executing updated participation agreements with their ACO participants to account for the 6-month extension and the start of a new agreement period under one of the new participation options. These commenters explained that expecting the program would offer an application cycle in CY 2018 for a January 1, 2019 agreement start date, their newly executed ACO participant agreements were structured according to the program's current policies (under the program's regulations and, as applicable, the terms of the Track 1+ Model) and do not account for the 6-month extension or modified participation options under the proposed redesign of the program. One commenter expressed concern that the extension would cause some ACO participants to be operating under a different ACO participation agreement, depending on whether they started participating in the ACO prior to January 1, 2019, or after January 1, 2019, resulting in different sets of expectations, for example with respect to the distribution of shared savings. According to one commenter, the time and cost spent on revising agreements with their ACO participants would significantly burden the ACO and its participants, and delay the execution of many initiatives to reduce costs and improve the quality of care as the ACO would spend time executing revised agreements with its ACO participants rather than focusing on other aspects of its operations. One commenter requested that ACOs whose agreement periods expire on December 31, 2018, be given ample time to secure extensions to their agreements with ACO participants for 2019.

Response: To prepare for the extension period, ACOs electing to extend their participation agreement with CMS must update their ACO participant agreements and SNF affiliate agreements, as applicable, before the beginning of the next performance year to reflect the extension of their current agreement period. As part of the annual certification process in advance of 2019, ACOs electing the 6-month extension will be required to certify that they have notified their ACO participants and SNF affiliates, if applicable, of their continued participation in the Shared Savings Program in 2019, and that their ACO participant agreements and SNF affiliate agreements, if applicable, have been updated. However, ACOs will not be required to submit ACO participant agreement or SNF affiliate agreement extensions to CMS.

ACOs electing the extension would need to extend all current ACO participant and/or SNF affiliate agreements on or before December 31, 2018, so that entities will continue to be ACO participants or SNF affiliates, as applicable, for the performance year beginning on January 1, 2019. Additionally, the ACO will need to execute ACO participant agreements with any new ACO participants to be added to its ACO participant list effective January 1, 2019. We also note that these ACOs would have been required to revise their ACO participant and SNF affiliate agreements, as applicable, if they had been renewing their participation agreements for a new agreement period beginning January 1, 2019. We also note that we now allow ACOs, ACO participants and SNF affiliates to digitally sign their agreements, which should help to reduce any burden associated with extending agreements. We believe that the timing of the issuance of this final rule will permit sufficient time for ACOs electing to extend their participation agreements to take the necessary steps to extend their ACO participant and SNF affiliate agreements, as applicable, before the start of the 6-month performance year beginning January 1, 2019.

In response to the commenter's concern that the extension would cause some ACO participants to be operating under different sets of expectations (depending on whether they started participating in the ACO prior to January 1, 2019 or after January 1, 2019), we note that for ACOs that elect the 6-month extension, the payment methodology under the ACO's current track would be applicable to determining the ACO's shared savings or shared losses, if applicable, for the 6-month performance year from January 1, 2019 through June 30, 2019. This is the same payment methodology that has applied to the ACO for the duration of its agreement period, beginning on January 1, 2016.

Further, we note that with the exception of the requirements specified at § 425.116, the ACO and its ACO participants have significant flexibility to determine the contractual terms that would apply with respect to all ACO participant agreements, including with respect to the use/distribution of shared savings (and payment of shared losses).

Comment: One commenter explained that current and prospective ACOs and their leaders are evaluating their options with respect to not only the Shared Savings Program start date, but also to participation in other potential models such as the Direct Provider Contracting (DPC) models anticipated to be tested by CMS' Innovation Center. The commenter urged CMS to take the whole payment model landscape into account and to take any measures necessary to maximize the level of certainty for healthcare providers and to incentivize participation in higher-risk models over lower-risk models. For example, the commenter recommended that participants in the Shared Savings Program or current Innovation Center models should not be excluded from switching to a DPC model if and when such a model becomes available, regardless of where they are in their current agreement period or the lifecycle of their current model.

Response: We work to align and otherwise create synergies between the Shared Savings Program and the payment and service delivery models tested by the Innovation Center. We have policies in place to take into account overlap between the Shared Savings Program and Innovation Center models, which are designed to test new payment and service delivery models for the purpose of innovating in the areas of healthcare delivery and shared accountability for quality and financial performance, whenever possible. We continue to monitor these policies and make refinements as we gain experience and lessons learned from these interactions. When new models are announced, we encourage ACOs and their leaders to engage in dialogue with the Innovation Center and Shared Savings Program staff to inform their decision-making regarding the participation options.

After considering the comments received, we are finalizing our proposal to allow ACOs that entered a first or second agreement period beginning on January 1, 2016, to voluntarily elect a 6-month extension of their current agreement period for a fourth performance year from January 1, 2019 through June 30, 2019. For the reasons discussed, we believe this extension is necessary in order to avoid an involuntary gap in participation and to provide ACOs with an opportunity to prepare for a more rapid transition to the proposed new participation options, including new Advanced APMs that would allow eligible clinicians

participating in these ACOs to qualify for incentive payments under the Quality Payment Program.

We received no comments on the proposed modifications to the definitions of ''agreement period'' and ''performance year'' in § 425.20 or to the regulation at § 425.200 to establish the 6-month extension and to make certain technical and conforming changes. We are finalizing as proposed the modifications to the definition of ''agreement period'' in § 425.20 to broaden the definition to generally refer to the term of the participation agreement and the revisions to § 425.200(a) to allow for agreement periods greater than 3 years. We are also finalizing our proposal to add a provision at § 425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO. For consistency, we are also finalizing as proposed the minor formatting changes to the existing provisions at § 425.200(b)(2) and (b)(3) to italicize the header text.

We are also finalizing as proposed the revision to the definition of ''performance year'' in § 425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement. Therefore, we are also finalizing the proposed revisions to § 425.200(c) to make necessary formatting changes and specify an additional exception to the definition of performance year as a 12-month period. Specifically, we are finalizing our proposal to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

In light of the modifications we are finalizing to § 425.200(c) to establish a 6-month performance year during CY 2019, we are also finalizing the proposed revisions to the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019. As described elsewhere in this final rule, ACOs electing the voluntary 6-month extension will be required to report quality measures for the 2019 reporting period, based on CY 2019, consistent with the existing quality reporting process and methodology.

b. Methodology for Determining Financial and Quality Performance for the 6-Month Performance Year From January 1, 2019 Through June 30, 2019

(1) Background and Description of Methodology

Under our proposed approach to determining performance for the 6-month performance year from January 1, 2019 through June 30, 2019, after the conclusion of CY 2019, CMS would reconcile the financial and quality performance of ACOs that participated in the Shared Savings Program during 2019. For ACOs that extended their agreement period for the 6-month performance year from January 1, 2019 through June 30, 2019, CMS would first reconcile the ACO based on its performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO's participation for only half of the calendar year. In the August 2018 proposed rule, we explained this approach would avoid a more burdensome interim payment process that could accompany an alternative proposal to instead implement, for example, an 18-month performance year. Consistent with the 18- and 21-month performance years offered for the first cohorts of Shared Savings Program ACOs, such a policy could require ACOs to establish a repayment mechanism that otherwise might not be required, create uncertainty over whether the ACO may ultimately need to repay CMS based on final results for the extended performance year, and delay ACOs seeing a return on their investment in program participation if eligible for shared savings.

We explained our belief that the proposed approach would allow continuity in program operations, including operations that occur on a calendar year basis. Specifically, the proposed approach would allow payment reconciliation to remain on a calendar year basis, which would be most consistent with the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, risk adjustment, county expenditures and regional adjustments. We explained that deviating from a 12-month reconciliation calculation by using fewer than 12 months of performance year expenditures could interject actuarial biases relative to the benchmark expenditures, which are based on 12-month benchmark years. As a result, we believed the proposed approach of reconciling ACOs based on a 12-month period would protect the actuarial soundness of the financial reconciliation methodology. We also explained our belief that the alignment of the proposed approach with the standard methodology used to perform the same calculations for 12-month performance years that correspond to a calendar year would make it easier for ACOs and other program stakeholders to understand the proposed methodology.

As is the case with typical calendar year reconciliations in the Shared Savings Program, we anticipated results with respect to participation during CY 2019 would be made available to ACOs in summer 2020. We explained that this would allow those ACOs that are eligible to share in savings as a result of their participation in the program during CY 2019 to receive payment of shared savings following the conclusion of the calendar year consistent with the standard process and timing for annual payment reconciliation under the program.

In section II.A.7.b.2 of the August 2018 proposed rule (83 FR 41851 through 41853), we described in detail our proposed approach to determining an ACO's performance for the 6-month performance year from January 1, 2019 through June 30, 2019. We also proposed that these policies would apply to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). Our proposed policies addressed the following: (1) The ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries; (3) the quality reporting period; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark; and (5) the methodology for determining shared savings and shared losses. We proposed to specify these policies for reconciling the 6-month period from January 1, 2019 through June 30, 2019, in paragraph (b) of a new section of the regulations at § 425.609.

We proposed to use the ACO participant list for the performance year beginning January 1, 2019, to determine

beneficiary assignment as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400. As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41855 through 41856), we proposed to allow all ACOs, including ACOs entering a 6-month performance year, to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019. Related considerations are discussed in section V.B.1.c.(2) of this final rule.

To determine beneficiary assignment, we proposed to consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to determine the assigned population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019.
- For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year we could use an assignment window from October 1, 2017 through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO at the end of CY 2019 unless they meet any of the exclusion criteria under § 425.401(b) during the calendar year.

As discussed in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856), to determine ACO performance during a 6-month performance year, we proposed to use the ACO's quality performance for the 2019 reporting period, and to calculate the ACO's quality performance score as provided in § 425.502. We also proposed to use a different quality measure sampling methodology depending on whether an ACO participates in both a 6-month performance year (or performance period) beginning on January 1, 2019, and a 6-month performance year beginning on July 1, 2019, or only participates in a 6-month performance year from January 1, 2019 through June 30, 2019. As described in section V.B.1.c.(4) of this final rule, given the limited scope of this final rule, at this time, we are finalizing only our proposal to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period for ACOs that extend their prior participation agreement for the 6-month performance year from January 1, 2019 to June 30, 2019.

Consistent with current program policy, we proposed to determine assignment for the benchmark years based on the most recent certified ACO participant list for the ACO effective for the performance year beginning January 1, 2019. This would be the participant list the ACO certified prior to the start of its agreement period unless the ACO has made changes to its ACO participant list during its agreement period as provided in § 425.118(b). If the ACO has made subsequent changes to its ACO participant list, we would adjust its historical benchmark to reflect the most recent certified ACO participant list. See the Medicare Shared Savings Program, ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf*.

For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to determine the benchmark and calculate performance year expenditures for assigned beneficiaries as though the performance year were the entire calendar year. The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program. We would apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in § 425.602 (for ACOs in a first agreement period) or § 425.603 (for ACOs in a second agreement period), except that data from CY 2019 would be used in place of data for the 6-month performance year in certain calculations, as follows:

- The benchmark would be adjusted for changes in severity and case mix between benchmark year 3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).
- The benchmark would be updated to CY 2019 according to the methodology for using growth in national Medicare FFS expenditures for assignable beneficiaries described under §§ 425.602(b) (for ACOs in a first agreement period) and 425.603(b) (for ACOs in a second agreement period beginning January 1, 2016).

For determining financial performance during the 6-month performance year from January 1, 2019 through June 30, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under the terms of the participation agreement that was in effect on January 1, 2019: § 425.604 (Track 1), § 425.606 (Track 2) or § 425.610 (Track 3) and, if applicable, the terms of the ACO's participation agreement for the Track 1+ Model authorized under section 1115A of the Act. (See discussion in section II.F. of the August 2018 proposed rule (83 FR 41912 through 41914) concerning applicability of proposed policies to Track 1+ Model ACOs.) However, some exceptions to the otherwise applicable methodology were needed because we proposed to calculate the expenditures for assigned beneficiaries over the full CY 2019 for purposes of determining shared savings and shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019. We proposed to use the following steps to calculate shared savings and shared losses:

- Average per capita Medicare expenditures for Parts A and B services for CY 2019 would be calculated for the ACO's performance year assigned beneficiary population.
- We would compare these expenditures to the ACO's updated benchmark determined for the calendar year as previously described.
- We would apply the MSR and MLR (as applicable).

++ The ACO's assigned beneficiary population for the performance year starting on January 1, 2019, would be used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population is below 5,000 beneficiaries, we proposed that the MSR/MLR would be determined based on the number of assigned beneficiaries as described in section II.A.6.b. of the August 2018 proposed rule (83 FR 41837 through 41839).

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019 must be below its updated benchmark for the year by at least the MSR established for the ACO.

++ To be responsible for sharing losses with the Medicare program, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019 must be above its updated benchmark for the year by at least the MLR established for the ACO.

• We would determine the shared savings amount if we determine the ACO met or exceeded the MSR, and if the ACO met the minimum quality performance standards established under § 425.502 as described in the August 2018 proposed rule and section V.B.1.c.(4) of this final rule, and otherwise maintained its eligibility to participate in the Shared Savings Program. We would determine the shared losses amount if we determine the ACO met or exceeded the MLR. To determine these amounts, we would do the following:

++ We would apply the final sharing rate or loss sharing rate to first dollar savings or losses.

++ For ACOs that generated savings that met or exceeded the MSR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable final sharing rate based on the ACO's track and its quality performance as calculated under § 425.502.

++ For ACOs that generated losses that met or exceeded the MLR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable shared loss rate based on the ACO's track and its quality performance as calculated under § 425.502 (for ACOs in tracks where the loss sharing rate is determined based on the ACO's quality performance).

• We would adjust the shared savings amount, if any, for sequestration by reducing by 2 percent and compare the sequestration-adjusted shared savings amount to the applicable performance payment limit based on the ACO's track.

• We would compare the shared losses amount, if any, to the applicable loss sharing limit based on the ACO's track.

• We would pro-rate any shared savings amount, as adjusted for sequestration and the performance payment limit, or any shared losses amount, as adjusted for the loss sharing limit, by multiplying by one half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount would be the final amount of shared savings that would be paid to the ACO for the 6-month performance year or the final amount of shared losses that would be owed by the ACO for the 6-month performance year.

We sought comment on these proposals.

Comment: In general, some commenters supported CMS' proposed policies governing how shared savings and shared losses would be calculated for the 6-month performance year from January 1, 2019 through June 30, 2019. Some commenters noted there is significant complexity with this approach and urged CMS to clarify and provide additional guidance and education to ACOs concerning how certain operational details will be addressed. Commenters raised concerns about certain aspects of the methodology for determining quality and financial performance for a 6-month performance year under the proposed approach, and other aspects of program participation affected by a 6-month performance year, which we summarize elsewhere within section V.B.1.b. and V.B.1.c. of this final rule, including (but not limited to) the approach to determining beneficiary assignment, flexibilities for making ACO participant list changes, quality reporting considerations, and interactions with the Quality Payment Program policies.

Response: We appreciate commenters' support for the proposed approach for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019. As discussed in the August 2018 proposed rule, we continue to believe in the importance of using this approach to maintain alignment with program calculations made on a 12-month basis. This approach maintains alignment with the program's existing methodology by using 12 months of expenditure data (for CY 2019) in determining the ACO's financial performance and a 12-month period for quality measure assessment. In sections V.B.1.b. and V.B.1.c. of this final rule we respond to comments on the specific aspects of the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, and other aspects of program participation affected by a 6-month performance year. We acknowledge that this approach will add complexity to program policies and certain operational processes. To assist ACOs in understanding the operational details of participation in a 6-month performance year from January 1, 2019 through June 30, 2019, we anticipate providing education and offering outreach to ACOs on these policies through the various methods available, including guidance documents, webinars, FAQs and a weekly newsletter.

Comment: A few commenters expressed support for the proposed approach to determining beneficiary assignment for the 6-month performance year from January 1, 2019 through June 30, 2019.

Response: In finalizing the 6-month agreement period extension for ACOs that started a first or second agreement period on January 1, 2016, we believe it is appropriate to finalize our proposed approach to determining beneficiary assignment for the performance year from January 1, 2019 through June 30, 2019. To determine beneficiary assignment for the 6-month performance year, we proposed to consider the allowed charges for primary care services furnished to beneficiaries during a 12-month assignment window, allowing for a 3-month claims run out. For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019. For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on beneficiaries' use of primary care services in the most recent 12 months for which data are available. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year, we could use an assignment window from October 1, 2017 through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO for the performance year unless they meet any of the exclusion criteria under § 425.401(b) during the calendar year. This approach would maintain alignment with our methodology for assigning beneficiaries to ACOs participating in a 12-month performance year, and allow us to use the same methodology to determine beneficiary assignment for all ACOs participating in a performance year beginning January 1, 2019. This approach would also be consistent with the methodology used to assign beneficiaries for the historical benchmark period.

Comment: One commenter noted that the proposal to pro-rate shared savings and shared losses to reflect the 6-month period of participation from January 1, 2019 through June 30, 2019, fails to account for habitual behavior of Medicare beneficiaries. The commenter explained that most annual wellness visits are performed in the 3rd and 4th quarters of the calendar year, and quarter 1 and quarter 2 of the calendar year typically show lower healthcare utilization. According to the commenter, Medicare beneficiaries tend to wait to visit the doctor until their deductible is met, which usually occurs towards the end of the calendar year. The commenter indicated that this delay occurs even for preventive services, like annual wellness visits, that are free at the point of delivery. The commenter also seems to have an incorrect understanding that we are using only quarter 1 and quarter 2 data to determine financial performance for the 6-month performance year from January 1, 2019 through June 30, 2019, suggesting that an approach that only accounts for 6 months of expenditures would result in quality and financial performance determinations that do not fairly reflect the ACO's quality of care and expenditures for assigned beneficiaries. Another commenter explained that Medicare expenditures demonstrate strong and well-known seasonality which would skew performance results when comparing performance from the first 6 months of the calendar year against a pro-rated benchmark which represents an annual average.

Response: Under the proposed approach to determining financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, as restated in this section of this final rule, we would continue to determine beneficiary assignment and expenditures on a 12-month basis. To determine beneficiary assignment, we would consider the allowed charges for primary care services furnished to the beneficiary during a 12-month assignment window, allowing for a 3-month claims run out. We would maintain the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, and risk adjustment. To determine shared savings and shared losses, we would calculate average per capita Medicare expenditures for Parts A and B services for CY 2019 for the ACO's performance year assigned beneficiary population and compare this amount to the updated historical benchmark. We would then pro-rate any shared savings or shared losses by multiplying the amounts by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. We believe this approach addresses the commenters' concerns, because we would capture assigned beneficiaries' expenditures for the entire CY 2019, which we would compare to a benchmark also based on 12 months of expenditures to maintain consistency and avoid any seasonality or other variation in expenditures that could result from the use of different timeframes. We continue to believe that this approach to reconciling ACOs for the 6-month performance year from January 1, 2019 through June 30, 2019, based on expenditures for the 12-month period corresponding to CY 2019 would protect the actuarial soundness of the financial reconciliation methodology.

Comment: A few commenters urged CMS to apply the regional benchmarking methodology in determining the historical benchmark for ACOs that first entered the program in 2013 or 2016 that elect a 6-month extension. One commenter stated that under the program's current policies, the regional rebasing methodology would apply to ACOs that renew for a second or third agreement period beginning January 1, 2019. This commenter also pointed to CMS' proposal in the August 2018 proposed rule to incorporate regional expenditures in benchmark calculations beginning with an ACO's first agreement period for agreement periods beginning on July 1, 2019, and in subsequent years to underscore the urgency for ACOs that may be entering their seventh performance year of program participation without any regional adjustment to be under a benchmarking approach that could help to sustain their accountable care programs and allow them to drive further cost reductions. Several other commenters suggested that CMS rebase the historical benchmark for ACOs electing the extension from January 1, 2019 through June 30, 2019, so that the ACO's historical benchmark years would be 2016, 2017, and 2018 (as opposed to 2013, 2014, and 2015 under the ACO's current agreement period), using a regional rebasing methodology. One commenter explained that rebasing these ACOs' benchmarks using regional factors would remove the drawback related to a delay in agreement period renewal for the organizations on the leading edge of the Shared Savings Program. This commenter also explained that benchmark rebasing would account for non-claims based payments during 2016, 2017, 2018 in the ACO's historical benchmark, and would eliminate the delay in aligning the benchmark with the full range of services included in calculating performance year expenditures.

Response: We appreciate the comments, but we decline to accept the commenters' suggestions to reset the benchmark for ACOs electing the 6-month extension to their current agreement period. As proposed, the 6-month extension allows for continued participation under the ACO's current agreement period, which would not meet the conditions for applying the program's methodology for rebasing the ACO's historical benchmark under § 425.603(a). Accordingly, we would continue to update and adjust the benchmarks for ACOs electing this extension using the methodology specified under §§ 425.602 and 425.603(b), as applicable. We also note that for ACOs with second agreement periods beginning on January 1, 2016, that elect the voluntary 6-month extension, the benchmark rebasing methodology that was used to determine their benchmark for their second agreement period accounts for a portion of the savings they generated in their prior agreement period as an adjustment to their historical benchmark. This adjustment coupled with the additional time they will be allowed to participate under their existing historical benchmark should continue to provide a strong incentive during the extension period.

(2) Use of Authority Under Section 1899(i)(3) of the Act

In the August 2018 proposed rule (83 FR 41851), we explained our belief that the proposal to determine shared savings and shared losses for the 6-month performance year starting on January 1, 2019, using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year, requires the use of our authority under section 1899(i)(3) of the Act to use other payment models. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. We explained our belief that the proposed approach to calculating the expenditures for assigned beneficiaries

over the full calendar year, comparing this amount to the updated benchmark for 2019, and then pro-rating any shared savings (or shared losses, which already are implemented using our authority under section 1899(i)(3) of the Act) for the 6-month performance year involves an adjustment to the estimated average per capita Medicare Part A and Part B FFS expenditures determined under section 1899(d)(1)(B)(i) of the Act that is not based on beneficiary characteristics. Such an adjustment is not contemplated under the plain language of section 1899(d)(1)(B)(i) of the Act. As a result, we stated it would be necessary to use our authority under section 1899(i)(3) of the Act to calculate performance year expenditures and determine the final amount of any shared savings (or shared losses) for a 6-month performance year during 2019, in the proposed manner.

In order to use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to calculate shared savings and shared losses for the proposed 6-month performance year from January 1, 2019 through June 30, 2019, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. We explained our belief that the proposed approach of allowing ACOs that started a first or second agreement period on January 1, 2016, to extend their agreement period for a 6-month performance year and of allowing entry into the program's redesigned participation options beginning on July 1, 2019, if finalized, would support continued participation by current ACOs that must renew their agreements to continue participating in the program, while also resulting in more rapid progression to two-sided risk by ACOs within current agreement periods and ACOs entering the program for an initial agreement period. As discussed in the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41915 through 41928), we explained our belief that this approach would continue to allow for lower growth in Medicare FFS expenditures based on projected participation trends. Therefore, we did not believe that the proposed methodology for determining shared savings or shared losses for ACOs in a 6-month performance year during 2019 would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we noted that the proposed approach to measuring ACO quality performance for a 6-month performance year based on quality data reported for CY 2019 would maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would also have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they may be required to pay in tracks where the loss sharing rate is determined based on the ACO's quality performance. Therefore, we noted our expectation that this proposed approach to reconciling ACOs for a 6-month performance year during 2019 would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries.

As discussed in the Regulatory Impact Analysis section of this final rule (section VII.), we believe the approach to determining shared savings and shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs that elect to voluntarily extend their agreement period meets the requirements for use of our authority under section 1899(i)(3) of the Act. The considerations we described in the August 2018 proposed rule were relevant in making this determination. Specifically, we do not believe that the methodology for determining shared savings or shared losses for ACOs in a 6-month performance year from January 1, 2019 through June 30, 2019, (as finalized in this section) will result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Finalizing the voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, will support continued participation by these ACOs, and therefore, also allow for lower growth in Medicare FFS expenditures based on projected participation trends. Further, we believe the approach we are finalizing for reconciling ACOs for a 6-month performance year from January 1, 2019 through June 30, 2019, will lead to continued improvement in the quality of care furnished to Medicare FFS beneficiaries. As described in section V.B.1.c.(4) of this final rule, the approach to measuring ACO quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, based on quality data reported for CY 2019, will maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs will have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they may be required to pay in two-sided risk tracks where the loss sharing rate is determined based on the ACO's quality performance.

(3) Final Policies

After consideration of the public comments received, we are finalizing, with modifications, the proposed approach to determine financial and quality performance for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, as specified in paragraphs (a) and (b) of a new section of the regulations at § 425.609. These modifications are necessary because this final rule only addresses the 6-month extension period, and does not address our proposal to establish a July 1, 2019 agreement start date. In summary, we will do the following to determine an ACO's financial and quality performance during the 6-month performance year from January 1, 2019 through June 30, 2019: We will compare the ACO's historical benchmark updated to CY 2019 to the expenditures during CY 2019 for the ACO's performance year assigned beneficiaries. If the difference is positive and is greater than or equal to the MSR and the ACO has met the quality performance standard, the ACO will be eligible for shared savings. If the ACO is in a two-sided model and the difference between the updated benchmark and assigned beneficiary expenditures is negative and is greater than or equal to the MLR (in absolute value terms), the ACO will be liable for shared losses. ACOs will share in first dollar savings and losses. The amount of any shared savings will be determined using the applicable final sharing rate, which is determined based on the ACO's track for the applicable agreement period, and taking into account the ACO's quality performance for 2019.

We will adjust the amount of shared savings for sequestration, and then cap the amount of shared savings at the applicable performance payment limit for the ACO's track. Similarly, the amount of any shared losses will be determined using the loss sharing rate for the ACO's track and, as applicable, for ACOs in tracks with a loss sharing rate that depends upon quality performance, the ACO's quality performance for 2019.We will then cap the amount of shared losses at the applicable loss sharing limit for the ACO's track. We will then pro-rate any shared savings or shared losses by

multiplying by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount will be the final amount of shared savings earned or shared losses owed by the ACO for the 6-month performance year.

Because we are not addressing the proposed July 1, 2019 agreement period start date for the proposed new BASIC track and ENHANCED track at this time, we note the following differences between our proposed approach (which contemplated that ACOs may be participating in both a 6-month performance year from January 1, 2019 through June 30, 2019, and a 6-month performance year from July 1, 2019 through December 31, 2019) and our final policies (which are limited to the 6-month performance year from January 1, 2019 through June 30, 2019, for eligible ACOs that elect to extend their agreement period, which would otherwise expire on December 31, 2018):

- We are omitting references that we proposed to include in § 425.609(b) in order to establish the applicability of these policies to ACOs that begin a 12-month performance year on January 1, 2019, but elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (early renewals). We are also making clarifying revisions to the introductory text in § 425.609(b).
- As described in section V.B.1.c.(4) of this final rule we are finalizing a subset of our proposals for identifying the ACO participant list used in determining quality reporting samples for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. We are finalizing our proposal to use the ACO's latest certified ACO participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period.
- We are not addressing at this time the proposals for modifying the MSR/MLR to address small population sizes (83 FR 41837 through 41839). Therefore, the policies for determining shared savings and shared losses in the event the ACO's assigned population falls below 5,000, as specified under the program's current regulations at § 425.110, would apply to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Therefore, we will specify in § 425.609(b)(3)(ii)(C)(*1*) that the ACO's performance year assigned beneficiary population is used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. For two-sided model ACOs that selected a fixed MSR/MLR at the start of the ACO's agreement period, this fixed MSR/MLR is applied. In the event an ACO's performance year assigned population identified in § 425.609(b)(1) is below 5,000 beneficiaries, the MSR/MLR is determined according to § 425.110(b).
- We are also reserving paragraph (c) of § 425.609 in the event that we finalize policies for a second 6-month performance year during CY 2019 in the future.

In section V.B.1.c. of this final rule, we discuss our decision to finalize other provisions from the August 2018 proposed rule related to determining performance for the 6-month performance year, as specified in paragraphs (d) and (e) of § 425.609.

c. Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year

In the August 2018 proposed rule (83 FR 41854), we proposed that program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance year, unless otherwise stated. We received no comments on this general proposal and we are finalizing this general approach as proposed. As we explained in the August 2018 proposed rule, this approach will allow routine program operations to continue to apply for ACOs participating under a shorter performance year. Further, it will ensure consistency in the applicability and implementation of our requirements across all program participants, including ACOs participating in a 6-month performance year.

In section V.B.1.b. of this final rule, we describe limited exceptions to our general policies for determining financial and quality performance which are necessary to ensure calculations can continue to be performed on a calendar year basis and using the most relevant data.

In this section, we describe program participation options affected by our decision to forgo an application cycle in CY 2018 for a January 1, 2019 start date, and offer a voluntary extension to allow ACOs whose agreement periods expire on December 31, 2018, to continue their participation in the program for a 6-month performance year from January 1, 2019 through June 30, 2019. We discuss modifications to program policies to allow for the 6-month performance year and related revisions to the program's regulations. As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41854 through 41860), these proposals were developed, in part, based on our proposal to offer an application cycle in CY 2019 for a July 1, 2019 start date. Therefore, we considered that some ACOs would participate in the program for both the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019, while other ACOs would only participate in one of these performance years. In this final rule, we do not address the considerations related to the proposed July 1, 2019 agreement period start date because we are not addressing the proposal to offer that start date at this time.

(1) Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 1, 2019

Eligible ACOs may apply for use of a SNF 3-day rule waiver at the time of application for an initial agreement or to renew their participation. Further, as described in sections II.B.2.a. and II.F. of the August 2018 proposed rule (83 FR 41860, 41912), ACOs within a current agreement period under Track 3, or the Track 1+ Model may apply for a SNF 3-day rule waiver, which, if approved, would begin at the start of their next performance year.

In light of our decision to forgo an application cycle in CY 2018 for a January 1, 2019 agreement period start date, we are also not offering an opportunity for ACOs to apply for a start date of January 1, 2019, for initial use of a SNF 3-day rule waiver. We proposed that, if finalized, the next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date. Absent further rulemaking to establish participation options for a start date in 2019 that includes an opportunity for ACOs within existing agreement periods in Track 3 or the Track 1+ Model to apply for a SNF 3-day rule waiver, these ACOs would not have the opportunity to apply to begin use of the waiver until January 1, 2020.

(2) Annual Certifications and ACO Participant List Modifications

At the end of each performance year, ACOs complete an annual certification process. At the same time as this annual certification process, CMS also requires ACOs to review, certify and electronically sign official program

documents to support the ACO's participation for the upcoming performance year. As we stated in the August 2018 proposed rule (83 FR 41855), requirements for this annual certification, and other certifications that occur on an annual basis, continue to apply to all currently participating ACOs in advance of the performance year beginning on January 1, 2019.

Each ACO is required to certify its list of ACO participant TINs before the start of its agreement period, before every performance year thereafter, and at such other times as specified by CMS in accordance with § 425.118(a). A request to add ACO participants must be submitted prior to the start of the performance year in which these additions would become effective. An ACO must notify CMS no later than 30 days after termination of an ACO participant agreement, and the entity is deleted from the ACO participant list effective as of the termination date of the ACO participant agreement. Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used to determine beneficiary assignment for the performance year and therefore also the ACO's quality reporting samples and financial performance. See § 425.118(b)(3) and see also Medicare Shared Savings Program ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/aco-participant-list-agreement.pdf*. As we explained in the August 2018 proposed rule (83 FR 41855), these policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

As we explained in the August 2018 proposed rule (83 FR 41855), ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, would have the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from January 1, 2019, to June 30, 2019. To prepare for the possible implementation of this 6-month performance year, we allowed ACOs that started a first or second agreement period on January 1, 2016, to submit change requests in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists, and if applicable, SNF affiliate lists.

The program's current regulations prevent duplication of shared savings payments; thus, under § 425.114, ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in another Medicare initiative that involves shared savings. In addition, under § 425.306(b)(2), each ACO participant that submits claims for services used to determine the ACO's assigned population must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims run out for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment, then CMS will not consider any services billed through the TIN of the ACO participant when performing assignment for the benchmark or performance year; and the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

Comment: Some commenters urged CMS to provide ACOs with opportunities to add and delete ACO participants throughout the performance years (or performance periods) during 2019 and to clarify when such opportunities would be available. These commenters urged CMS to provide additional guidance and education to ACOs on when participant list changes would be permitted. One commenter suggested that CMS should provide an additional opportunity for ACOs with agreement periods expiring on December 31, 2018, to add ACO participants and/or SNF affiliate TINs and CCNs for performance year 2019 because of the short period of time between the issuance of the proposed rule (August 9, 2018) and the final deadline for adding ACO participants for performance year 2019 (September 28, 2018). The commenter explained that the proposed rule caused confusion and uncertainty, and as a result, the commenter believes many ACO participants missed the deadline to be added to the ACO participant lists of other ACOs. The commenter suggested that we should offer an additional opportunity to add ACO participants, with the deadline set for 1 month after publication of a final rule.

Response: During 2018, we allowed ACOs that started a first or second agreement period on January 1, 2016, to submit ACO participant change requests in accordance with usual program procedures to indicate additions, updates, and deletions to their existing ACO participant lists and, if applicable, SNF affiliate lists. We noted that the final disposition of any change request submitted by an ACO that started a first or second agreement period on January 1, 2016, would be contingent upon issuance of a final rule establishing an opportunity for these ACOs to continue their participation during 2019 without a gap in participation. As discussed in section V.B.1. of this final rule, we are finalizing the proposed 6-month extension for ACOs whose current participation agreement expire on December 31, 2018.

As a result, all ACOs, including those ACOs that will be eligible to elect the voluntary 6-month extension that we are finalizing this final rule, had multiple opportunities to submit change requests to add ACO participants and/or SNF affiliates for performance years starting on January 1, 2019. We also launched a new ACO management system during 2018 that is more user friendly, provides faster feedback, and encourages ACOs to submit change requests to add ACO participants and SNF affiliates with fewer errors than the system that was available in previous years. We do not believe it is operationally feasible to extend the date for ACOs to submit change requests after September 28, 2018, the date we communicated to ACOs as being the deadline to add ACO participants to be effective for performance years beginning on January 1, 2019. Allowing change requests seeking to add new ACO participants to be submitted very close to the end of the calendar year would not provide sufficient time to review and screen providers/suppliers for program integrity issues and create 2019 assignment list reports, and may have other operational impacts (such as on timely production of certain other program reports). We note, however, ACO participants can be terminated and deleted from the ACO participant list at any time during a performance year. The ACO participant is no longer an ACO participant as of the termination effective date of the ACO participant agreement. Absent unusual circumstances, however, the ACO participant data will continue to be utilized for certain operational purposes.

(3) Repayment Mechanism Requirements

ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. The repayment mechanism must be in effect for the duration of an ACO's participation in a two-sided model and for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate the amount of

shared losses owed and to collect this amount from the ACO (§ 425.204(f)(4)). We noted in our ''Repayment Mechanism Arrangements'' guidance document that we would consider this standard to be satisfied by a repayment mechanism arrangement that remains in effect for 24 months after the end of the agreement period. See Medicare Shared Savings Program & Medicare ACO Track 1+ Model, Repayment Mechanism Arrangements, Guidance Document (July 2017, version #6), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf (herein Repayment Mechanism Arrangements Guidance).*

In the August 2018 proposed rule (83 FR 41856), we noted that ACOs that started a first or second agreement period on January 1, 2016, in a two-sided model would have in place under current program policies a repayment mechanism arrangement that would cover the 3 years between January 1, 2016 and December 31, 2018, plus a 24-month tail period until December 31, 2020. We would expect an ACO with an agreement period ending December 31, 2018, that extends its agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, to likewise extend the term of its repayment mechanism so that it will be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period (that is, until June 30, 2021). This would allow us sufficient time to perform financial calculations for the 6-month performance year from January 1, 2019 through June 30, 2019, and to use the arrangement to collect shared losses for that performance year, if necessary.

In a forthcoming final rule, we expect to summarize and respond to comments on our proposed changes to § 425.204(f) regarding repayment mechanism requirements for ACOs that are in a two-sided model.

Comment: One commenter expressed concern over the lack of current guidance on the required amount of a repayment mechanism arrangement (particularly for Track 1+ Model ACOs) and on how to execute changes to an existing repayment mechanism arrangement in order to support an ACO's participation during the 6-month performance year from January 1, 2019 through June 30, 2019. The commenter also indicated that changing repayment mechanism amounts mid-year would likely result in extra costs to an ACO.

Response: We appreciate the commenter's concern. We may require a Track 1+ Model ACO to adjust its repayment mechanism amount if, during the ACO's agreement period, changes in the ACO's participant composition occur that result in the application of a relatively higher or lower loss sharing limit. For example, if a Track 1+ Model ACO reports changes to its composition during the annual certification process in advance of the next performance year, and we determine that the ACO no longer qualifies for a revenue-based loss sharing limit, we may require the ACO to demonstrate that its repayment mechanism is sufficient to support losses for a higher amount under a benchmark-based loss sharing limit (83 FR 41841). We will notify an ACO if there is a significant change in its repayment mechanism amount warranting modification of its repayment mechanism arrangement and will specify the process for submitting to us revised repayment mechanism arrangement documentation for review. With regard to ACOs participating under Track 2 or Track 3, we clarify that, for the 6-month performance year from January 1, 2019 through June 30, 2019, we will not require any such ACO that elects to extend its participation agreement for such performance year to modify the amount we previously approved for the ACO's repayment mechanism arrangement.

In addition, we have notified ACOs participating under a two-sided model that if they elect the 6-month extension from January 1, 2019 through June 30, 2019 then we expect that they will extend their repayment mechanisms in accordance with § 425.204(f)(4). As we noted in our *Repayment Mechanism Arrangements Guidance,* we would consider § 425.204(f)(4) to be satisfied by a repayment mechanism arrangement that remains in effect for 24 months after the end of the agreement period. Accordingly, an ACO participating under a two-sided model that elects the 6-month extension from January 1, 2019 through June 30, 2019, should extend the term of its repayment mechanism until June 30, 2021.

We acknowledge that amending certain repayment mechanism arrangements could come at additional costs to ACOs. However, we believe it necessary that the repayment mechanism arrangements comply with Shared Savings Program and Track 1+ Model policy to ensure the ACO can repay losses for which it may be liable.

(4) Quality Reporting and Quality Measure Sampling

As described in the August 2018 proposed rule (83 FR 41856 through 41858), to determine an ACO's quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to use the ACO's quality performance for the 2019 reporting period as determined under § 425.502. Under this proposed approach, we would account for the ACO's quality performance using quality measure data reported for the 12-month CY 2019.

As we explained in the August 2018 proposed rule, the following considerations support this proposed approach. For one, use of a 12-month period for quality measure assessment maintains alignment with the program's existing quality measurement approach, and aligns with the proposed use of 12 months of expenditure data (for CY 2019) in determining the ACO's financial performance. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019. Second, the measure specifications for the quality measures used under the program require 12 months of data. See for example, the Shared Savings Program ACO 2018 Quality Measures Narrative Specification Document (January 20, 2018), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2018-reporting-year-narrative-specifications.pdf.* Third, in light of our proposal to use 12 months of expenditures (based on CY 2019) in determining shared savings and shared losses for a 6-month performance year, it would also be appropriate to hold ACOs accountable for the quality of the care furnished to their assigned beneficiaries during this same timeframe. Fourth, and lastly, using an annual quality reporting cycle for the 6-month performance year would avoid the need to introduce new reporting requirements, and therefore, potential additional burden on ACOs.

The ACO participant list is used to determine beneficiary assignment for purposes of generating the quality reporting samples. Beneficiary assignment is performed using the applicable assignment methodology under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. The samples for claims-based measures are typically

determined based on the assignment list for calendar year quarter 4. The sample for quality measures reported through the CMS Web Interface is typically determined based on the beneficiary assignment list for calendar year quarter 3. The CAHPS for ACOs survey sample is typically determined based on the beneficiary assignment list for calendar year quarter 2.

For purposes of determining the quality reporting samples for the 2019 reporting period, we proposed to use the ACO's most recent certified ACO participant list available at the time the quality reporting samples are generated, and the assignment methodology most recently applicable to the ACO for a 2019 performance year. We explained our belief that the use of the ACO's most recent certified ACO participant list to assign beneficiaries according to the assignment methodology applicable based on the ACO's most recent participation in the program during 2019 would result in the most relevant beneficiary samples for 2019 quality reporting. Additionally, we believed this proposed approach to determining the ACO's quality reporting samples was also appropriate for an ACO that participated in only one 6-month performance year during 2019 because the most recent certified ACO participant list applicable for the performance year would also be the certified ACO participant list that is used to determine financial performance.

We proposed two approaches to determine the certified ACO participant list, assignment methodology, and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019. One approach was applicable to ACOs that enter a new agreement period under the proposed July 1, 2019 agreement start date, including ACOs that extended their prior participation agreement for the 6-month performance year from January 1, 2019, to June 30, 2019. For ACOs that enter a new agreement period beginning on July 1, 2019, we proposed to use the certified ACO participant list for the performance year starting on July 1, 2019, to determine the quality reporting samples for the 2019 reporting period. This most recent certified ACO participant list would therefore be used to determine the quality reporting samples for the 2019 reporting year. A second approach was proposed for an ACO that extends its participation for the first 6 months of 2019, but does not enter a new agreement period beginning on the proposed July 1, 2019 agreement start date. This second approach is relevant to the policies we are finalizing in this final rule, for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs whose current participation agreements expire on December 31, 2018, and that voluntarily elect to extend their agreement period for a fourth performance year. Under this approach, we proposed to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. Beneficiary assignment for purposes of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from January 1, 2019 through June 30, 2019, under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. We anticipated that the assignment windows for the quality reporting samples would be as follows, based on our operational experience: (1) Samples for claims-based measures would be determined based on the assignment list for calendar year quarter 4; (2) the sample for CMS Web Interface measures would be determined based on the assignment list for calendar year quarter 3; and (3) the sample for the CAHPS for ACOs survey would be determined based on the assignment list for calendar year quarter 2. We noted that this approach would maintain alignment with the assignment windows currently used for establishing quality reporting samples for these measures.

We proposed to specify the certified ACO participant list that would be used in determining the quality reporting samples for measuring quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, in a new section of the regulations at § 425.609(b).

Comment: Some commenters requested clarification about how quality reporting will take place for 6-month performance periods based on 12 months of data. Specifically, these commenters stated their assumption that all ACOs would only be responsible for reporting quality one time, during the typical January to March timeframe following the end of 2019. One commenter expressed concern that the proposed approach for two 6-month performance years and two financial reconciliations for performance years in CY 2019 would also require two separate quality reporting samples for measures reported through the CMS Web Interface. The commenter was concerned about the burden that would be imposed on ACOs by such a requirement, given that annual quality reporting requires a significant amount of ACO resources.

Response: We proposed to determine quality performance for the 6-month performance years during 2019 based on an ACO's quality performance during the 12-month CY 2019 in order to align with the program's existing quality reporting methodology, measure specifications which require 12-months of data, and the APM scoring standard under MIPS. In addition, because we proposed to use quality performance during all of CY 2019, we proposed that ACOs would only have to report quality once for CY 2019, regardless of whether they complete their participation in the program following the conclusion of the 6-month performance year from January 1, 2019 through June 30, 2019, or they renew for a new agreement period beginning on July 1, 2019 (if finalized as proposed). Therefore, ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019 (if finalized as proposed), would report quality for one beneficiary sample for CY 2019.

We also note that for the 2019 reporting period, ACOs would be required to report quality data through the CMS Web Interface, according to the method and timing of submission established by CMS. The period for reporting quality data through the CMS Web Interface typically occurs for a 12-week period between January and March, following the conclusion of the calendar year. Thus, ACOs that participate in a 6-month performance year from January 1, 2019 through June 30, 2019, along with all other Shared Savings Program ACOs would be required to report for the 2019 reporting period, and would report quality data through the CMS Web Interface during the designated reporting period in early 2020. Further, ACOs participating in the 6-month performance year from January 1, 201 through June 30, 2019, would be required to contract with a CMS-approved vendor to administer the CAHPS for ACOs survey for the 2019 reporting period, consistent with program-wide policies applicable to all other ACOs. We would apply the program's sampling methodology, as we have described in the August 2018 proposed rule and this section of this final rule, to determine the beneficiaries eligible for the samples for claims-based measures (as calculated by CMS), CMS

Web Interface reporting, and the CAHPS for ACOs survey.

After consideration of the comments, we are finalizing without modification our proposal to determine an ACO's quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, using the ACO's quality performance for the 12-month CY 2019 (2019 reporting period) as determined under § 425.502. We are also finalizing a subset of our proposals for identifying the ACO participant list used in determining quality reporting samples for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Given the limited scope of this final rule we are finalizing our proposal to use an ACO's latest certified ACO participant list for the performance year from January 1, 2019 through June 30, 2019, (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. We are not addressing at this time our proposals related to the proposed July 1, 2019 agreement start date, including the policies for determining the quality reporting samples for ACOs that extend their participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, and continue their participation in the program in a new agreement period beginning on July 1, 2019. We anticipate summarizing and responding to comments received on these proposals in a forthcoming final rule.

(5) Applicability of Extreme and Uncontrollable Circumstances Policies

In section II.E.4 of the August 2018 proposed rule (83 FR 41899 through 41906), we proposed to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial and quality performance results for performance year 2017 to performance year 2018 and subsequent years. As discussed in section V.B.2.d of this final rule, we are finalizing this proposal. In section II.E.4. of the August 2018 proposed rule, we indicated that if finalized, these policies would apply to ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019.

There were no comments directed specifically at our proposals with respect to the applicability of these policies for addressing the impact of extreme and uncontrollable circumstances on ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. We direct readers to review section V.B.2.d. of this final rule, for a more comprehensive discussion of the modifications to the program's extreme and uncontrollable circumstances policies that we are finalizing with this final rule.

We are finalizing as proposed the policies for determining the financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, for ACOs affected by extreme and uncontrollable circumstances during CY 2019. In addition, we are also finalizing our proposal to specify, in a new section of the regulations at § 425.609(d), the following policies related to determining the financial and quality performance for the 6-month performance year from January 1, 2019 through June 30, 2019, for an ACO affected by extreme and uncontrollable circumstances during CY 2019: (1) In calculating the amount of shared losses owed by the ACO, CMS makes adjustments to the amount determined under § 425.609(b), as specified in § 425.606(i) (Track 2) or § 425.610(i) (Track 3), as applicable; and (2) in determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(6) Payment and Recoupment for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41858), we proposed policies regarding CMS' notification to ACOs of shared savings and shared losses and the timing for ACOs' repayment of shared losses for both the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, and the 6-month performance year from July 1, 2019 through December 31, 2019.

In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to payment and recoupment for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this final rule would include a discussion of our proposal to reduce the shared savings payment for one 6-month performance year (or performance period) by the amount of any shared losses owed for the other 6-month performance year (or performance period).

In the August 2018 proposed rule, we proposed that the following policies would be applicable to ACOs that elect a 6-month extension for the performance year from January 1, 2019 through June 30, 2019. Because we proposed to perform financial reconciliation for this 6-month performance year after the end of CY 2019, we anticipated that financial performance reports for the 6-month performance year would be available in Summer 2020, similar to the expected timeframe for issuing financial performance reports for the 12-month 2019 performance year (and for 12-month performance years generally).

We proposed to apply the same policies regarding notification of shared savings and shared losses and the timing of repayment of shared losses to ACOs in a 6-month performance year that apply under our current regulations to ACOs in 12-month performance years. For the 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to specify in a new regulation at § 425.609 that CMS would notify the ACO of shared savings or shared losses, consistent with the notification requirements specified in § 425.604(f) (Track 1), § 425.606(h) (Track 2), and § 425.610(h) (Track 3). Specifically, we proposed that the following approach: (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due; (2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program; (3) if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

We proposed to specify policies on payment and recoupment for ACOs in a 6-month performance year during CY 2019 in a new section of the regulations at § 425.609(e).

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on whether there will be any disruptions in providing performance results to ACOs participating in a 6-month performance year in CY 2019.

Response: We anticipate determining financial and quality performance for ACOs participating in the 6-month performance year from January 1, 2019 through June 30, 2019, according to the typical annual projected timeline for making these determinations, and for issuing performance reports to ACOs. The ACO's annual financial reconciliation report, quality performance reports, and additional informational reports and files, are

typically made available in the summer following the conclusion of a 12-month performance year. We also plan to provide ACOs that participate in the 6-month performance year from January 1, 2019 through June 30, 2019, quarterly reports for the third and fourth quarter of CY 2019 (see discussion in section V.B.1.c.(8) of this final rule). We anticipate that we will make available to ACOs an annual schedule for report delivery for 2019. For example, see the 2018 Shared Savings Program report schedule included as Table 12 in the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (May 2018, version 6) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html*.

We are finalizing without modification our proposal to specify in a new section of the regulations at § 425.609(e) that CMS will notify the ACO of shared savings or shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, consistent with the notification requirements specified in §§ 425.604(f), 425.606(h), and 425.610(h), as applicable. Specifically, we will notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. CMS will provide written notification to an ACO of the amount of shared losses, if any, that the ACO must repay to the program. If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(7) Interactions With the Quality Payment Program

In the August 2018 proposed rule (83 FR 41859), we took into consideration how the proposed July 1, 2019 start date could interact with other Medicare initiatives, particularly the Quality Payment Program timelines relating to participation in APMs. In the CY 2018 Quality Payment Program final rule with comment period, we finalized a policy for APMs that start or end during the QP Performance Period. Specifically, under § 414.1425(c)(7)(i), for Advanced APMs that start during the QP Performance Period and are actively tested for at least 60 continuous days during a QP Performance Period, CMS will make QP determinations and Partial QP determinations for eligible clinicians in the Advanced APM using claims data for services furnished during those dates on which the Advanced APM is actively tested. CMS performs QP determinations for eligible clinicians in an APM entity three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31 (§ 414.1425(b)(1)). We explained that this meant that an APM (such as a two-sided model of the Shared Savings Program) would need to begin operations by July 1 of a given performance year in order to be actively tested for at least 60 continuous days before August 31—the last date on which QP determinations are made during a QP Performance Period (as specified in § 414.1425(b)(1)). Therefore, we believed that our proposed July 1, 2019 start date for the proposed new participation options under the Shared Savings Program would align with Quality Payment Program rules and requirements for participation in Advanced APMs. However, we did not address QP determinations for eligible clinicians participating in an ACO whose agreement period expires on December 31, 2018, that elects a voluntary extension for the 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue in the program past June 30, 2019.

Further, as described in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856), our proposal to use a 12-month period for quality measure assessment for either 6-month performance year during 2019 would maintain alignment with the program's existing quality measurement approach, and align with the proposed use of 12 months of expenditure data (for CY 2019) in determining the ACO's financial performance for a 6-month performance year. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program (83 FR 41856). We explained that ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019.

Comment: One commenter indicated that, as proposed, it appears ACOs in a two-sided model may lose Advanced APM Entity status and sought clarity on the Advanced APM status for all participating ACOs. This commenter was specifically concerned about the Advanced APM status of the Track 1+ Model.

Response: We believe the comment reflects the need for clarification about whether eligible clinicians in an ACO that is participating in a track that meets the Advanced APM criteria and that elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, but does not continue its participation in the Shared Savings Program past June 30, 2019, would be eligible to become QPs during the 2019 QP Performance Period. Eligible clinicians who become QPs will earn the Advanced APM incentive payment and will not be subject to the MIPS reporting requirements and payment adjustments for the applicable year. The commenter may have been concerned that an agreement period that ends prior to the end of the QP performance period (August 31, 2019) would be considered an early termination and that the ACO would therefore lose its status as participating in an Advanced APM, which is not the case under our previously-finalized policy for Advanced APMs that start or end during a performance period. For an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, the agreement period would end during the QP performance period. However, because the ACO would have been active for more than 60 days, it would continue to be an APM entity in an Advanced APM in 2019 (§ 414.1425(c)(7)). Therefore, clinicians who obtain QP status based on the March 31, 2019, or June 30, 2019 snapshot through participation in an ACO with a 6-month extension of its agreement period will: Maintain QP status, be exempt from MIPS, and receive the APM incentive payment, as long as their ACO completes its agreement period by remaining in the program through June 30, 2019.

We also believe there is a need to clarify what happens to an eligible clinician's QP status if they are participating in an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019 through June 30, 2019, and either voluntarily terminates or is involuntarily terminated prior to June 30, 2019. If their ACO terminates or is involuntarily terminated any time after March 31, 2019, and before August 31, 2019, then eligible clinicians previously determined to have had QP status would lose their status as a result of the termination, and would instead be scored under MIPS using the APM Scoring Standard (§ 414.1425(c)(5) and (6)). If their ACO terminates before March 31, 2019, then the eligible clinicians would not be scored under the APM Scoring Standard and will be

assessed under regular MIPS scoring rules (§§ 414.1370(e) and 414.1425(b)(1)).

Comment: Some commenters requested clarification on how quality reporting for a 6-month performance period based on 12-months of data for 2019 will satisfy the MIPS quality reporting requirements for MIPS eligible clinicians in ACOs that elect to extend their participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019. One commenter indicated there was no discussion of how the proposed 6-month extension period would impact scoring under the APM scoring standard.

Response: We believe the comments reflect the need for clarification about whether 2019 quality performance for a 6-month performance year under the Shared Savings Program will count the same as a full year of performance for purposes of the APM scoring standard if the ACO ends its current agreement period at the end of the 6-month extension and chooses to not renew its agreement with a July 1, 2019 start date (if finalized as proposed). That is, would the 2019 quality reporting for the 6-month performance year count toward the final MIPS score in the same way that it would for an ACO that is participating in a full 12-month performance year in the program.

As discussed in this section of this final rule, we are finalizing a policy of using a 12-month period for quality performance assessment for the 6-month performance year from January 1, 2019 through June 30, 2019, in order to maintain alignment with the program's existing quality measurement approach, and with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) participating in an ACO that completes a 6-month performance year from January 1, 2019 through June 30, 2019, would continue to be scored under MIPS using the APM Scoring Standard, based on quality data submitted for all of 2019 during the regular submission period in early 2020. Thus, for a Track 1 ACO in a 6-month performance year from January 1, 2019 through June 30, 2019, whose agreement period expires and the ACO does not renew to continue program participation, the ACO would be scored under the MIPS APM scoring rules for quality reporting based on the entire CY 2019.

(8) Sharing CY 2019 Aggregate Data With ACOs in 6-Month Performance Year From January 1, 2019 Through June 30, 2019

Under the program's current regulations at § 425.702, we share aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year, during each quarter, and in conjunction with the annual reconciliation. In the August 2018 proposed rule (83 FR 41859), for ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement for an additional 6-month performance year from January 1, 2019 through June 30, 2019, we proposed to continue to deliver aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the 6-month performance year. This would give ACOs a more complete understanding of the Medicare FFS beneficiary population that is the basis for reconciliation for the 6-month performance year by allowing them to continue to receive data, including demographic characteristics and expenditure/utilization trends for their assigned population for the entire calendar year. We believed this proposed approach would allow us to maintain transparency by providing ACOs with data that relates to the entire period for which the expenditures for the beneficiaries assigned to the ACO for the 6-month performance year would be compared to the ACO's benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year 2019. Otherwise, we could be limited to providing ACOs with aggregate reports only for the first and second quarters of 2019, even though under our proposed methodology for assessing the financial performance of ACOs in a 6-month performance year, the financial reconciliation for the 6-month performance year would involve consideration of expenditures from outside this period during 2019. We proposed to specify this policy in revisions to § 425.702.

Comment: Some commenters urged CMS to provide additional guidance and education to ACOs on whether there will be any disruptions in sharing claims files with ACOs participating in a 6-month performance year in CY 2019.

Response: In the August 2018 proposed rule, we did not describe in detail the applicability of the program's policies on sharing beneficiary-identifiable claims data with ACOs under § 425.704. We proposed, generally, that unless otherwise stated, program requirements under 42 CFR part 425 that are applicable to the ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance year. Therefore, we would continue to provide beneficiary-identifiable claims data (referred to as claim and claim line feed files) to ACOs only during their participation in the program, including during the 6-month performance year from January 1, 2019 through June 30, 2019. ACOs would receive monthly Part A, B and D claim and claim line feed files during the 6-month performance year based on the ACO participant list they certify before the start of the performance year. Consistent with the program's current data sharing policies, we would discontinue delivery of beneficiary-identifiable data to ACOs when their participation agreement is no longer in effect.

After consideration of the comments received, we are finalizing our proposal to deliver to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019, aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the performance year. This policy is specified in revisions to § 425.702.

(9) Technical or Conforming Changes To Allow for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41859 through 41860), we proposed to make certain technical, conforming changes to certain provisions of the regulations, including additional changes to provisions discussed elsewhere in the proposed rule, to reflect our proposal to add a new provision at § 425.609 to govern the calculation of the financial and quality results for the proposed 6-month performance years within CY 2019.

In this final rule, we are addressing only the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposed 6-month performance year from July 1, 2019 through December 31, 2019, and the proposed 6-month performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

The following proposals discussed in the August 2018 proposed rule would be applicable to ACOs that elect a 6-month extension for the performance year from January 1, 2019 through June 30, 2019.

Our proposal that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§ 425.315) would apply with respect to applicable payment determinations for performance years within CY 2019. To clarify, we proposed to amend § 425.315 to incorporate a reference to the proposed provision for notification of shared savings and shared losses for ACOs in a 6-month performance year within CY 2019, as specified in § 425.609(e).

Our proposal to add a reference to § 425.609 in § 425.100 in order to include ACOs that participate in a 6-month performance year during 2019 in the general description of ACOs that are eligible to receive payments for shared savings under the program.

Our proposal to amend § 425.400(a)(1)(ii), which describes the step-wise process for determining beneficiary assignment for each performance year, to specify that this process would apply to ACOs participating in a 6-month performance year within CY 2019, and that assignment would be determined based on the beneficiary's utilization of primary care services during the entirety of CY 2019, as specified in § 425.609.

Our proposal to further revise § 425.400(c)(1)(iv), on the use of certain Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) codes in determining beneficiary assignment, to specify that it would be used in determining assignment for performance years starting on January 1, 2019, and subsequent years. We note that we also proposed certain other revisions to this provision in section II.E.3. of the August 2018 proposed rule (83 FR 41896), as discussed in section V.B.2.c. of this final rule.

Our proposal to revise § 425.401(b), describing the exclusion of beneficiaries from an ACO's prospective assignment list at the end of a performance year or benchmark year and quarterly during each performance year, to specify that these exclusions would occur at the end of CY 2019 for purposes of determining assignment to an ACO in a 6-month performance year in accordance with §§ 425.400(a)(3)(ii) and 425.609.

Our proposal, as part of the proposed revisions to § 425.402(e)(2), which, as described in section II.E.2. of the August 2018 proposed rule (83 FR 41894), specifies that beneficiaries who have designated a provider or supplier outside the ACO as responsible for coordinating their overall care will not be added to the ACO's list of assigned beneficiaries for a performance year under the claims-based assignment methodology, to allow the same policy to apply to ACOs participating in a 6-month performance year during CY 2019. We are finalizing our proposed revisions to § 425.402(e)(2), as described in section V.B.2.b. of this final rule.

Our proposal to revise § 425.404(b), on the special assignment conditions for ACOs that include FQHCs and RHCs that provide services used in determining beneficiary assignment, to specify its applicability in determining assignment for performance years starting on January 1, 2019, and subsequent performance years.

We also proposed to incorporate references to § 425.609 in the regulations that govern establishing, adjusting, and updating the benchmark, including the existing provisions at §§ 425.602 and 425.603, to specify that the annual risk adjustment and update to the ACO's historical benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, would use factors based on the entirety of CY 2019. For clarity and simplicity, we proposed to add a paragraph to each of these sections to explain the following: (1) Regarding the annual risk adjustment applied to the historical benchmark, when CMS adjusts the benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, the adjustment will reflect the change in severity and case mix between benchmark year 3 and CY 2019; (2) Regarding the annual update to the historical benchmark, when CMS updates the benchmark for the 6-month performance year from January 1, 2019 through June 30, 2019, the update to the benchmark will be based on growth between benchmark year 3 and CY 2019.

We also proposed to incorporate references to § 425.609 in the following provisions regarding the calculation of shared savings and shared losses: §§ 425.604, 425.606, and 425.610. For clarity and simplicity, we proposed to add a paragraph to each of these sections explaining that shared savings or shared losses for the 6-month performance year from January 1, 2019 through June 30, 2019, are calculated as described in § 425.609. That is, all calculations will be performed using CY 2019 data in place of performance year data.

There were no comments directed specifically at our proposed technical and conforming changes to allow for 6-month performance years. We are finalizing as proposed the technical and conforming changes to the Shared Savings Program regulations as previously described in this section of this final rule, to allow them to apply to ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019.

(10) Payment Consequences of Early Termination

In the August 2018 proposed rule (83 FR 41845 through 41847), we proposed policies to govern the payment consequences of early termination for performance years beginning in 2019 and subsequent years, including for ACOs participating in 6-month performance years from January 1, 2019 through June 30, 2019, and July 1, 2019 through December 31, 2019, as well as for ACOs participating in 12-month performance years. We proposed to impose payment consequences for early termination by holding ACOs in two-sided models liable for pro-rated shared losses. This approach would apply to ACOs that voluntarily terminate their participation more than midway through a 12-month performance year and all ACOs that are involuntarily terminated by CMS. ACOs would be ineligible to share in savings for a performance year if the effective date of their termination from the program is prior to the last calendar day of the performance year; but, we would allow an exception for ACOs that are participating in a 12-month performance year under the program as of January 1, 2019, that terminate their agreement with an effective date of June 30, 2019, and enter a new agreement period under the proposed BASIC track or ENHANCED track beginning July 1, 2019. In these cases, we would perform separate reconciliations to determine shared savings and shared losses for the ACO's first 6 month period of participation in 2019 and for the ACO's 6-month performance year from July 1, 2019, to December 31, 2019, under the subsequent participation agreement.

In a forthcoming final rule we anticipate addressing comments received on proposals for the payment consequences of early termination from 12-month performance years and from 6-month performance years beginning on July 1, 2019, should we finalize the proposal to offer a July 1, 2019 start date for the new participation options. Therefore, in this section of this final rule we focus specifically on the proposals regarding the payment consequences of early termination as they relate to the 6-month performance

year from January 1, 2019 through June 30, 2019.

We proposed that an ACO would be eligible to receive shared savings for a 6-month performance year during 2019 if it completes the term of the performance year, regardless of whether the ACO chooses to continue its participation in the program. That is, we would reconcile ACOs that started a first or second agreement period January 1, 2016, that extend their agreement period for a fourth performance year, and complete this performance year (concluding on June 30, 2019).

For an ACO that participates for a portion of a 6-month performance year during 2019, we proposed the following: (1) If the ACO terminates its participation agreement effective before the end of the performance year, we would not reconcile the ACO for shared savings or shared losses (if a two-sided model ACO); (2) if CMS terminates a two-sided model ACO's participation agreement effective before the end of the performance year, the ACO would not be eligible for shared savings and we would reconcile the ACO for shared losses and pro-rate the amount reflecting the number of months during the performance year that the ACO was in the program. We proposed to specify these policies in amendments to § 425.221(b).

We also proposed to revise the regulation at § 425.221 to streamline and reorganize the provisions in paragraph (b), which we believed necessary to incorporate the proposed new requirements. We sought comment on these proposals.

We are not addressing our proposed modifications to program policies to impose payment consequences for early termination in this final rule. Accordingly, for ACOs participating in a performance year starting on January 1, 2019, we will continue to apply the program's current policies for payment consequences of early termination. We believe that continuing to use the current approach would be simpler, both from the standpoint of CMS as the regulatory entity and operator of the program, and for ACOs as regulated entities already familiar with the current policies. Under this approach, ACOs that terminate from a performance year starting on January 1, 2019, with an effective date of termination prior to the end of their performance year will not be eligible for shared savings or accountable for shared losses.

At this time, we are finalizing a subset of our proposed policies for determining payment consequences of early termination, to account for ACOs participating in a 6-month performance year from January 1, 2019 through June 30, 2019. Specifically, we are finalizing without modification our proposal that an ACO participating in a 6-month performance year from January 1, 2019 through June 30, 2019, is eligible for shared savings if the following conditions are met: CMS has designated or approved an effective date of termination that is the last calendar day of the performance year (June 30, 2019); the ACO has completed all close-out procedures specified in § 425.221(a) by the deadline specified by CMS (if applicable); and the ACO has satisfied the criteria for sharing in savings for the performance year. Consistent with our existing policies, if the participation agreement is terminated at any time by CMS under § 425.218, the ACO will not be eligible to receive shared savings for the performance year during which the termination becomes effective, and will not be accountable for any shared losses. Further, for an ACO participating in a 6-month performance year from January 1, 2019 through June 30, 2019, that elects to terminate early, we will apply the payment consequences of early termination consistent with the current regulations, and the ACO will not be eligible to receive shared savings for the performance year and will not be accountable for any shared losses.

We are finalizing the proposed revisions to § 425.221 to allow us to consistently apply current program policies on the payment consequences of early termination or agreement expiration to ACOs in a 6-month performance year from January 1, 2019 through June 30, 2019. We are amending § 425.221(b) to remove references to December 31st of a performance year and instead to refer to the last calendar day of the performance year, so that the regulatory provisions will apply to ACOs regardless of whether they are participating in a 12-month or 6-month performance year. We are not addressing at this time the other proposed revisions to the regulation at § 425.221, including the proposals to streamline and reorganize the provisions in paragraph (b).

2. Updating Program Policies

a. Overview

This section addresses various proposed revisions described in the August 2018 proposed rule (83 FR 41894 through 41911) that are designed to update policies under the Shared Savings Program. We proposed to revise our regulations governing the assignment process in order to align our voluntary alignment policies with the requirements of section 50331 of the Bipartisan Budget Act of 2018 and to update the definition of primary care services. We also proposed to extend the policies that we recently adopted for ACOs impacted by extreme and uncontrollable circumstances during 2017 to 2018 and subsequent performance years. We also solicited comment on considerations related to supporting ACOs' activities to address the national opioid crisis and the agency's meaningful measures initiative. We proposed to discontinue use of the quality performance measure that assesses the level of adoption of CEHRT by the eligible clinicians in an ACO and proposed instead that ACOs be required to certify upon application to participate in the Shared Savings Program and annually thereafter that the percentage of eligible clinicians participating in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds certain thresholds.

b. Revisions to Policies on Voluntary Alignment

(1) Background

Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO, if a system is available for electronic designation. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment otherwise determined by the Secretary. Section 50331 also requires the Secretary to establish a process under which a Medicare FFS beneficiary is notified of his or her ability to designate a primary care provider or subsequently to change this designation. An ACO professional is defined under section 1899(h) of the Act as a physician as defined in section 1861(r)(1) of the Act and a practitioner described in section 1842(b)(18)(C)(i) of the Act.

As we stated in the August 2018 proposed rule (83 FR 41894), we believe that section 50331 requires certain revisions to our current beneficiary voluntary alignment policies in § 425.402(e). Prior to enactment of the Bipartisan Budget Act of 2018, section 1899(c) of the Act required that beneficiaries be assigned to an ACO based on their use of primary care services furnished by a physician as

defined in section 1861(r)(1) of the Act, and beginning January 1, 2019, services provided in RHCs/FQHCs. In order to satisfy this statutory requirement, we currently require that a beneficiary receive at least one primary care service during the beneficiary assignment window from an ACO professional in the ACO who is a physician with a specialty used in assignment in order to be assigned to the ACO (see § 425.402(b)(1)). As currently provided in § 425.404(b), for performance year 2019 and subsequent performance years, for purposes of the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician. After identifying the beneficiaries who have received a primary care service from a physician in the ACO, we use a two-step, claims-based methodology to assign beneficiaries to a particular ACO for a calendar year (see § 425.402(b)(2) through (4)). In the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented this claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in 2017 for assignment for performance year 2018, may voluntarily align with an ACO by designating a ''primary clinician'' they believe is responsible for coordinating their overall care using *MyMedicare.gov*, a secure online patient portal. *MyMedicare.gov* contains a list of all of the Medicare-enrolled practitioners who appear on the Physician Compare website and beneficiaries may choose any practitioner present on Physician Compare as their primary clinician.

Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and is not excluded from assignment by the criteria in § 425.401(b), and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or a physician with one of the primary specialty designations included in § 425.402(c) (see § 425.402(e)). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year, superseding any assignment that might have otherwise occurred under the claims-based methodology. Further, beneficiaries may change their designation at any time through *MyMedicare.gov*; the new choice will be incorporated when we perform assignment for the subsequent performance year. Beneficiaries who designate a provider or supplier outside an ACO, who is a primary care physician, a physician with a specialty designation that is considered in the assignment methodology, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care will not be added to an ACO's list of assigned beneficiaries, even if they would otherwise meet the criteria for claims-based assignment.

(2) Summary of Proposed Revisions

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. Under our current methodology, a beneficiary may select any practitioner who has a record on the Physician Compare website as their primary clinician; however, we will only assign the beneficiary to an ACO if they have chosen a practitioner who is a primary care physician (as defined at § 425.20), a physician with one of the primary specialty designations included in § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. Therefore, we proposed to modify our current voluntary alignment policies at § 425.402(e)(2)(iii) to provide that we will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. Under this proposal, a beneficiary may select a practitioner with any specialty designation, for example, a specialty of allergy/immunology or surgery, as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional. Specifically, we proposed to revise § 425.402(e)(2)(iii) to remove the requirement that the ACO professional designated by the beneficiary be a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. In addition, the provision at § 425.402(e)(2)(iv) addresses beneficiary designations of clinicians outside the ACO as their primary clinician. The current policy at § 425.402(e)(2)(iv) provides that a beneficiary will not be assigned to an ACO for a performance year if the beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist as their primary clinician responsible for coordinating their overall care. Consistent with the proposed revisions to § 425.402(e)(2)(iii) to incorporate the requirements of section 50331 of the Bipartisan Budget Act, we proposed to revise § 425.402(e)(2)(iv) to indicate that if a beneficiary designates any provider or supplier outside the ACO as their primary clinician responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to allow a beneficiary to voluntarily align with an ACO, and does not impose any restriction with respect to whether the beneficiary has received any services from an ACO professional (see section 1899(c)(2)(B)(i) of the Act). As we explained in the August 2018 proposed rule (83 FR 41895), we believe the requirement in section 1899(c)(2)(B)(iii) of the Act that a beneficiary's voluntary identification shall supersede any claims-based alignment is also consistent with eliminating the requirement that the beneficiary have received a service from an ACO professional in order to be eligible to be assigned an ACO. Therefore, we proposed to remove the requirement at § 425.402(e)(2)(i) that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Under this proposal, a beneficiary who selects a primary clinician who is an ACO professional, but who does not receive any services from an ACO participant during the assignment window, will remain eligible for assignment to the ACO. We stated that we believe this approach would reduce burden on beneficiaries and their practitioners by not requiring practitioners to provide unnecessary care during a specified period of time in order for a beneficiary to remain eligible for assignment to the ACO. Consistent with this proposal, we proposed to remove § 425.402(e)(2)(i) in its entirety.

We noted that, under this proposal, if a beneficiary does not change their primary clinician designation, the beneficiary will remain assigned to the ACO in which that practitioner participates during the ACO's entire agreement period and any subsequent agreement periods under the Shared Savings Program, even if the beneficiary no longer seeks care from any ACO professionals. Because a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care, this proposed change could also impact assignment under certain Innovation Center models in which overlapping beneficiary assignment is not permitted. As we explained in the August 2018 proposed rule (83 FR 41895), we believe our proposed policy is consistent with the requirement under section 1899(c)(2)(B)(iii) of the Act that a voluntary identification by a beneficiary shall supersede any claims-based assignment. However, we also believe it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific Innovation Center models, such as the Comprehensive ESRD Care (CEC) Model. CMS implemented the CEC Model to test a new system of payment and service delivery that CMS believes will lead to better health outcomes for Medicare beneficiaries living with ESRD, while lowering costs to Medicare Parts A and B. Under the model, CMS is working with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals receive. We believe that an ESRD beneficiary, who is otherwise eligible for assignment to an entity participating in the CEC Model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC Model. Such a beneficiary could be disadvantaged if they were unable to receive the type of specialized care for their ESRD that will be available from an entity participating in the CEC Model. Furthermore, we believe it could be difficult for the Innovation Center to conduct a viable test of a specialty or disease-specific model, if we were to require that beneficiaries who have previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. Currently, the CEC Model completes its annual PY prospective assignment lists prior to the Shared Savings Program in order to identify the beneficiaries who may benefit from receiving specialized care from an entity participating in the CEC Model. Additionally, on a quarterly basis, a beneficiary may be assigned to the CEC Model who was previously assigned to a Track 1 or Track 2 ACO.

As a result, we believe that in some instances it may be necessary for the Innovation Center to use its authority under section 1115A(d)(1) of the Act to waive the requirements of section 1899(c)(2)(B) of the Act solely as necessary for purposes of testing a particular model. Therefore, we proposed to create an exception to the general policy that a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care. Specifically, we proposed that we would not assign such a beneficiary to the ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. Under this proposal, if a beneficiary selects a primary clinician who is a Shared Savings Program ACO professional and the beneficiary is also eligible for alignment to a specialty care or disease specific model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination that a waiver of the requirement in section 1899(c)(2)(B) is necessary solely for purposes of testing the Model, the Innovation Center or its designee would notify the beneficiary of their alignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify his or her primary clinician and may seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is an ACO professional in a Shared Savings Program ACO.

In the August 2019 proposed rule (83 FR 41896), we indicated that we would include a list of any models that meet these criteria on the Shared Savings Program website, to supplement the information already included in the beneficiary assignment reports we currently provide to ACOs (as described under § 425.702(c)), so that ACOs can know why certain beneficiaries, who may have designated an ACO professional as their primary clinician, are not assigned to them. Similar information would also be shared with 1–800–MEDICARE to ensure that Medicare customer service representatives are able to help beneficiaries who may be confused as to why they are not aligned to the ACO in which their primary clinician is participating.

Section 1899(c)(2)(B)(ii) of the Act, as amended by section 50331 of the Bipartisan Budget Act, requires the Secretary to establish a process under the Shared Savings Program through which each Medicare FFS beneficiary is notified of the ability to identify an ACO professional as his or her primary care provider and informed of the process that may be used to make and change such identification. In the August 2018 proposed rule (83 FR 41896), we stated our intent to implement section 1899(c)(2)(B)(ii) of the Act under the beneficiary notification process at § 425.312. We are not addressing this topic at this time. We will summarize and respond to public comments on this proposed policy in a forthcoming final rule.

We proposed to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance years starting on January 1, 2019, and subsequent performance years. We proposed to incorporate these new requirements in the regulations by redesignating § 425.402(e)(2)(i) through (iv) as § 425.402(e)(2)(i)(A) through (D), adding a paragraph heading for newly redesignated § 425.402(e)(2)(i), and including a new § 425.402(e)(2)(ii).

We noted that as specified in § 425.402(e)(2)(ii) a beneficiary who has designated an ACO professional as their primary clinician must still be eligible for assignment to an ACO by meeting the criteria specified in § 425.401(a). These criteria establish the minimum requirements for a beneficiary to be eligible to be assigned to an ACO under our existing assignment methodology, and we believe it is appropriate to impose the same basic limitations on the assignment of beneficiaries on the basis of voluntary alignment. We do not believe it would be appropriate, for example, to assign a beneficiary to an ACO if the beneficiary does not reside in the United States, or if the other eligibility requirements are not met.

We requested comments on our proposals to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. We also sought comment on our proposal to create a limited exception to our proposed policies on voluntary alignment to allow a beneficiary to be assigned to an entity participating in a model tested or expanded under section 1115A of the Act when certain criteria are met. In addition, we welcomed comments on how we might increase beneficiary awareness and further improve the electronic process through which a beneficiary may voluntarily identify an ACO professional as their primary care provider through *My.Medicare.gov* for purposes of assignment to an ACO.

Comment: Many commenters supported the proposed policies to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. In particular, many commenters supported the proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Commenters were in favor of removing this requirement because it would allow a beneficiary to select a NP, PA, or CNS, who is participating in an ACO, as their primary clinician to voluntarily align to the ACO even if they do not receive care from any physicians participating in the ACO. Commenters suggested this more inclusive policy supports CMS' goals of improving patient access and quality of care, and is consistent with patient-centered health care delivery. Additionally, some commenters specifically supported the proposal to allow a beneficiary to voluntarily designate any ACO professional, regardless of specialty, as their primary care provider for purposes of assignment to an ACO. In particular, commenters representing neurologists and palliative care practitioners were supportive of this proposed change. In addition, one commenter agreed that the proposed policy would allow ''the opportunity for patients to choose and establish a medical home with their clinician.'' The commenter also supported voluntary alignment because it results in prospective beneficiary attribution, which the commenter preferred over the preliminary prospective assignment methodology with retrospective reconciliation.

Response: We appreciate the commenters' support for the proposed policies to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018.

Comment: A few commenters proposed a change to section 1899(h)(1)(A) of the Act. Section 1899(c) of the Act requires the Secretary to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A). Section 1899(h)(1)(A) of the Act constitutes one element of the definition of the term ''ACO professional''. Specifically, this provision establishes that a physician (as defined in section 1861(r)(1)) is an ACO professional for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term physician as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. One commenter proposed a change to allow for ''private NP led practices and NP led clinics'' to be included as ACO professionals described in section 1899(h)(1)(A) of the Act. The commenter recommended this change in particular for rural areas, stating that NPs account for 1 in 4 medical providers in rural areas.

Response: Because commenters are requesting a change to the statute, these suggestions are outside the scope of this final rule. However, as many commenters noted above, the proposed changes to the voluntary alignment methodology will allow a beneficiary to align with a NP, PA, or CNS participating in an ACO and ultimately be assigned to the ACO regardless of whether they receive care from a physician in the ACO. Additionally, we agree these non-physician practitioners play an important role in coordinating patient care and providing primary care services, as such we have included primary care services furnished by NPs, PAs, and CNSs in step 1 of our two-step claims-based assignment methodology (see § 425.402(b)).

Comment: Some commenters opposed the proposed changes to the voluntary alignment methodology. One commenter expressed concern about beneficiary confusion if their practitioners participate in different ACOs or the beneficiary selects a practitioner outside of an ACO as their primary care provider. Similarly, one commenter expressed concern about an ACO's ability to maintain an assigned population of 5,000 beneficiaries if beneficiaries can select any ACO professional regardless of specialty as their primary care provider. A few commenters disagreed with including all practitioner specialties citing differences in training, education, knowledge, and experience. Another commenter expressed concern about whether specialists are willing to take on the role of a primary care physician and manage the overall care of beneficiaries assigned to the ACO through voluntary alignment. Some commenters disagreed with the proposal to remove the requirement that a beneficiary receive a primary care service from an ACO professional, with a physician specialty used in assignment, during the assignment window. One commenter stated that removing the requirement would exacerbate a ''leakage'' problem that they described as a scenario where assigned beneficiaries receive some or all of their care from providers and suppliers outside the ACO. One commenter suggested beneficiaries should be required to renew their selection of their primary care clinician one year following the beneficiary's entry into a long-term care setting. Another commenter suggested that beneficiaries who voluntarily align with an ACO be required to receive a minimum number of primary care services from ACO professionals within the same ACO in order to remain aligned to the ACO.

Response: We disagree with these comments. We believe that when a beneficiary selects a primary clinician, they are identifying their primary care provider, regardless of specialty or whether the beneficiary has received a recent primary care service. We believe they are informing CMS that they view the practitioner as their primary care provider and responsible for managing their overall care. We also believe all practitioners, regardless of specialty, play an important role in coordinating care for beneficiaries and if a beneficiary selects a practitioner as their primary clinician, the beneficiary should be treated as having made an informed election. Although we understand the concern that an ACO could lose assigned beneficiaries due to their voluntary alignment with another ACO, we note that our experience to date shows that the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO via our two-step claims-based assignment methodology under § 425.402(b). We

also believe requiring beneficiaries to renew their primary clinician selection would create additional unnecessary burden on beneficiaries. Beneficiaries who have designated a primary clinician must have established a *MyMedicare.gov* account, which likely indicates that they are actively engaged in reviewing and managing their health information. We believe these engaged beneficiaries will also manage and update their primary clinician selections as necessary. We also disagree with establishing a requirement that a beneficiary receive a minimum number of primary care services from ACO providers/suppliers in the ACO in order to honor a beneficiary's voluntary alignment selection. We believe our proposed approach is in accordance with the requirement under section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, that primary care provider selections take precedence over any claims-based assignment.

Comment: A few commenters suggested CMS simplify the process by which a beneficiary selects their primary clinician. Commenters suggested that, in addition to the electronic means of voluntary alignment, CMS allow beneficiaries to voluntarily align with their primary clinician through the ACO, at the point of care, through 1–800 Medicare, a smart phone application, or Physician Compare. One commenter noted they had experienced difficulties with CMS' operationalization of the voluntary alignment policy through *MyMedicare.gov*.

Response: Currently, if beneficiaries need help in designating a primary clinician, they can call 1–800 Medicare to have a representative walk them through the process or use the ''Empowering Patients to Make Decisions About Their Healthcare: Register for *MyMedicare.gov* and Select Your Primary Clinician'' fact sheet available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/vol-alignment-bene-fact-sheet.pdf*. We plan to continue to make refinements to our implementation of voluntary alignment in order to improve the user experience for beneficiaries and will take the commenters' suggestions into consideration in developing future policies regarding voluntary alignment.

Comment: One commenter disagreed with allowing beneficiaries to voluntarily align with an ACO professional. The commenter cited difficulty tracking the cost of beneficiaries who are not assigned to an ACO through our two-step claims-based assignment methodology. Another commenter suggested we not hold an ACO accountable for a voluntarily aligned beneficiary for a performance year if the beneficiary does not receive any services from their primary clinician in the ACO during that performance year. Another commenter opposed voluntary alignment because they believe the costs for voluntarily aligned beneficiaries are not reflected in an ACO's historical benchmark.

Response: Consistent with section 1899(c)(2)(B)(i) of the Act, we are required to allow beneficiaries to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO if a system is available for electronic designation. To aid ACOs in identifying and tracking costs and Medicare services for voluntarily aligned beneficiaries, we provide ACOs with quarterly aggregate reports (see § 425.702) that identify beneficiaries who have voluntarily aligned with the ACO, as well as monthly claim and claim line feed files (see § 425.704) to aid ACOs in their operations. Additionally, as previously stated, we have found the majority of beneficiaries who voluntarily align to an ACO would have been assigned to the same ACO in the applicable performance year based on our two-step assignment methodology. As required under section 1899(b)(2)(A) of the Act and the regulation at § 425.100(a), ACOs participating in the Shared Savings Program must agree to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. Beneficiaries who voluntarily align to an ACO are prospectively assigned to the ACO for the performance year. Under the prospective assignment methodology, ACOs are accountable for their assigned beneficiary population regardless of where the beneficiaries receive the plurality of their primary care services during the performance year. We believe this is an appropriate approach when a beneficiary selects a practitioner as their primary clinician. As we stated earlier, we believe that when a beneficiary selects a primary clinician, the beneficiary is making an informed decision and identifying for CMS the provider or supplier whom they consider to be responsible for managing their overall care. The historical benchmark reflects the beneficiary population who received the plurality of their primary care services from the ACO during the three benchmark years and, in our experience, there is a high correlation between the beneficiaries who are assigned based on our two-step claims-based assignment methodology and voluntarily aligned beneficiaries. As a result, we believe our current benchmarking methodology provides for a population of assigned beneficiaries during the benchmark years that is comparable to the population assigned during the performance years. We also note, in the future, when an ACO renews for a new agreement period and its previous performance years become historical benchmark years, beneficiaries who were voluntarily aligned to the ACO for those years will then be included in the historical benchmark calculations for the ACO's new agreement period.

Comment: One commenter stated the current voluntary alignment process can be confusing and causes unnecessary delays in assigning beneficiaries to the ACO in which their primary clinician participates. The commenter suggested a rolling voluntary alignment process allowing beneficiaries who voluntarily align with an ACO to be added to the assignment list for that ACO during a performance year.

Response: We understand that our policy of performing beneficiary assignment annually can cause a delay between when a beneficiary selects their primary clinician and when the beneficiary is assigned to the ACO. However, we believe this approach reduces complexity and burden. For example, ACOs are able to clearly identify a date by which to communicate to their beneficiaries regarding the opportunity to designate a primary clinician if they would like to align with an ACO professional.

Comment: One commenter expressed concern that physicians with a specialty designation not used in assignment would become subject to the exclusivity requirements, which would limit an ACO participant to participation in a single ACO. The commenter opposed any policy that would require an ACO participant to be exclusive to a single Shared Savings Program ACO in the event that a beneficiary voluntarily aligns to a practitioner billing under the TIN of that ACO participant.

Response: We agree with the concerns raised by the commenter and believe it is important to clarify the operational process we will implement if a beneficiary designates a clinician billing under the TIN of an ACO participant that participates in more than one Shared Savings Program ACO (as permitted under certain circumstances under § 425.306(b)) as their primary clinician. ACO participants that do not bill for services that are considered in assignment will not be required to be

exclusive to a single Shared Savings Program ACO as a result of the changes to the voluntary alignment methodology. In the circumstance where a beneficiary aligns with a clinician billing under an ACO participant TIN that is participating in more than one Shared Savings Program ACO, we will determine where the beneficiary received the plurality of their primary care services under our claims-based assignment methodology under § 425.402(b). If the beneficiary did not receive the plurality of their primary care services from ACO professionals in either ACO, we will not assign the beneficiary to either of the ACOs. However, consistent with § 425.402(c)(2)(iv), we will honor the beneficiary's selection of a primary clinician and will not align the beneficiary to another ACO in which their primary clinician is not participating.

We did not receive any public comments on the proposal not to voluntarily align a beneficiary to the ACO in which their primary clinician participates when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services (for example, CEC).

After considering the comments received in response to the proposals to revise the voluntary alignment methodology, we are finalizing the policies as proposed. Specifically, we are finalizing the policy to assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. We are also finalizing our proposal to remove the requirement that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12-month assignment window in order to be assigned to the ACO. Lastly, we are finalizing a policy not to voluntarily align a beneficiary to an ACO when the beneficiary is also eligible for assignment to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services. Accordingly, we are also finalizing the proposed revisions to § 425.402(e)(2) without modification.

c. Revisions to the Definition of Primary Care Services Used in Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician and all services furnished by RHCs and FQHCs. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment. We established the initial list of services that we considered to be primary care services in the November 2011 final rule (76 FR 67853). In that final rule, we indicated that we intended to monitor this issue and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS, as summarized in the CY 2018 PFS proposed rule (82 FR 34109 and 34110). Subsequently, in the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional chronic care management service codes, 99487, 99489, and G0506, and four behavioral health integration service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). These additions are effective for purposes of performing beneficiary assignment under § 425.402 for performance year 2019 and subsequent performance years.

Accounting for these recent changes, we define primary care services in § 425.400(c) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a Nursing Facility, excluding services furnished in a SNF which are reported on claims with place of service code 31).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the Annual Wellness Visits).

(3) G0463 (code for services furnished in electing teaching amendment hospitals).

(4) G0506 (code for chronic care management).

(5) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

As discussed in the CY 2018 PFS final rule (82 FR 53213), a commenter recommended that CMS consider including the advance care planning codes, CPT codes 99497 and 99498, in the definition of primary care services in future rulemaking. We indicated that we would consider whether CPT codes 99497 and 99498 or any additional existing HCPCS/CPT codes should be added to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program. In addition, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494, 99484 (82 FR 53078).

CPT codes 99304 through 99318 are used for reporting evaluation and management (E&M) services furnished by physicians and other practitioners in a SNF (reported on claims with POS code 31) or a nursing facility (reported on claims with POS code 32). Based on stakeholder input, we finalized a policy in the CY 2016 PFS final rule (80 FR 71271 through 71272) effective for performance year 2017 and subsequent performance years, to exclude services identified by CPT codes 99304 through 99318 from the definition of primary care services for purposes of the beneficiary assignment methodology when the claim includes the POS code 31 modifier designating the services as having been furnished in a SNF. We established this policy to recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their true primary care needs. We

continue to believe that it is appropriate for SNF patients to be assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the true primary care needs of these beneficiaries. As we discussed in the August 2019 proposed rule (83 FR 41897), ACOs serving special needs populations, including beneficiaries receiving long term care services, and other stakeholders have recently suggested that we consider an alternative method for determining operationally whether services identified by CPT codes 99304 through 99318 were furnished in a SNF. Instead of indirectly determining whether a beneficiary was a SNF patient when the services were furnished based on physician claims data, these stakeholders suggest we more directly determine whether a beneficiary was a SNF patient based on SNF facility claims data. These commenters recommended that CMS use contemporaneous SNF Medicare facility claims to determine whether a professional service identified by CPT codes 99304 through 99318 was furnished in a SNF, and therefore, should not be used for purposes of the beneficiary assignment methodology under § 425.402. Specifically, these commenters suggested that we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by determining whether the beneficiary also received SNF facility services on the same date of service.

In the August 2018 proposed rule (83 FR 41897 through 41899), we proposed to make changes to the definition of primary care services in § 425.400(c) to add new codes and to revise how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services to include certain additional codes. Specifically, we proposed to revise the definition of primary care services in § 425.400(c) to include the following HCPCS and CPT codes: (1) Advance care planning service codes; CPT codes 99497 and 99498; (2) administration of health risk assessment service codes; CPT codes 96160 and 96161; (3) prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure, CPT codes 99354 and 99355; (4) annual depression screening service code, HCPCS code G0444; (5) alcohol misuse screening service code, HCPCS code G0442; and (6) alcohol misuse counseling service code, HCPCS code G0443. In addition, in the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), CMS proposed to create three new HCPCS codes to reflect the additional resources involved in furnishing certain evaluation and management services: (1) GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care services, (2) GCG0X add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care, and (3) GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure. As we explained in the August 2018 proposed rule (83 FR 41897), we believe it would be appropriate to include these codes in the definition of primary care services under the Shared Savings Program because these codes are used to bill for services that are similar to services that are already included in the list of primary care codes at § 425.400(c). We also expect that primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists frequently furnish these services as part of their overall management of a patient. As a result, we believe that including these codes would increase the accuracy of the assignment process by helping to ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care.

The following provides additional information about the HCPCS and CPT codes that we proposed to add to the definition of primary care services:

• *Advance care planning (CPT codes 99497 and 99498):* Effective January 1, 2016, CMS pays for voluntary advance care planning under the PFS (80 FR 70955 through 70959). See CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN 909289, August 2016), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf*. Advance care planning enables Medicare beneficiaries to make important decisions that give them control over the type of care they receive and when they receive it. Medicare pays for advance care planning either as a separate Part B service when it is medically necessary or as an optional element of a beneficiary's Annual Wellness Visit. We believe it would be appropriate to include both Advance Care Planning codes 99497 and 99498 in the definition of primary care services under the Shared Savings Program because the services provided as part of advance care planning include counseling and other evaluation and management services similar to the services included in Annual Wellness Visits and other evaluation and management service codes that are already included in the list of primary care codes.

• *Administration of health risk assessment (CPT codes 96160 and 96161):* In the CY 2017 PFS final rule (81 FR 80330 through 80331), we added two new CPT codes, 96160 and 96161, to the PFS, effective for CY 2017, to be used for payment for the administration of health risk assessment. These codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code. For example, if a health risk assessment service were administered during a physician office visit, then the physician would bill for both the appropriate office visit code and the appropriate health risk assessment code. We believe it would be appropriate to include CPT codes 96160 and 96161 in the definition of primary care services because these add-on codes frequently represent additional practice expenses related to office visits for evaluation and management services that are already included in the definition of primary care services.

• *Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355):* These two codes are also ''add-on codes'' that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. Code 99354 is listed on a claim to report the first hour of additional face-to-face time with a patient and code 99355 is listed separately for each additional 30 minutes of face-to-face time with a patient beyond the time reported under code 99354. Codes 99354 and 99355 would be billed separately in addition to the base office or other outpatient evaluation and management or

psychotherapy service. (See Medicare Claims Processing Manual Chapter 12, Sections 30.6.15.1 Prolonged Services With Direct Face-to-Face Patient Contact Service (Codes 99354–99357) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf*; also see CMS, MLN Matters, Prolonged Services (Codes 99354–99359) (Article Number MM5972, Revised March 7, 2017), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5972.pdf*.) Although we do not currently include prolonged services codes CPT codes 99354 and 99355 on our list of primary care services, based on further review we believe it would be appropriate to include them on our list of primary care services to more accurately assign beneficiaries to ACOs based on all the allowed charges for the primary care services furnished to beneficiaries. In the August 2018 proposed rule (83 FR 41898), we noted that the definitions of codes 99354 and 99355 also include prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services. Therefore, we proposed to include the allowed charges for CPT codes 99354 and 99355, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

• *Annual depression screening (HCPCS code G0444), alcohol misuse screening (HCPCS code G0442), and alcohol misuse counseling (HCPCS code G0443):* Effective October 14, 2011, all Medicare beneficiaries are eligible for annual depression screening and alcohol misuse screening. (See CMS Manual System, Screening for Depression in Adults (Transmittal 2359, November 23, 2011) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2359CP.pdf*; and see CMS, MLN Matters, Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (Article Number MM7633, Revised June 4, 2012), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm7633.pdf*). Although these three codes have been in use since before the implementation of the Shared Savings Program in 2012, based on further review of these services, we believe that it would be appropriate to consider these services in beneficiary assignment. Annual depression screening may be covered if it is furnished in a primary care setting that has staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. Alcohol misuse screening and counseling are screening and behavioral counseling interventions in primary care to reduce alcohol misuse. All three of these codes include screening and counseling services similar to counseling and other evaluation and management services included in the codes already on the list of primary care codes.

In the CY 2019 PFS proposed rule (see 83 FR 35841 through 35844), we proposed to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for services represented by CPT codes 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient). All three of these codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base codes.

HCPCS code GPC1X is intended to capture the additional resource costs, beyond those involved in the base evaluation and management codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the base evaluation and management code for an established patient when the visit includes primary care services. In contrast, new HCPCS code GCG0X is an add-on code intended to reflect the complexity inherent to evaluation and management services associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care. As we stated in the August 2018 proposed rule (83 FR 41899), we believe it would be appropriate to include both proposed new HCPCS codes GCG0X and GPC1X in our definition of primary care services because they represent services that are currently included in CPT codes 99201 through 99215, which are already included in the list of primary care codes in § 425.400(c).

Finally, proposed new HCPCS code GPRO1 (prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure, in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) is modeled on CPT code 99354, a prolonged services code discussed earlier in this section which we proposed to add to our list of primary care services. HCPCS code GPRO1 is intended to reflect prolonged evaluation and management or psychotherapy service(s) of 30 minutes duration beyond the typical service time of the primary or base service, whereas existing CPT code 99354 reflects prolonged services of 60 minutes duration. As is the case for code 99354, code GPRO1 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. We stated that we believe it would be appropriate to include proposed HCPCS code GPRO1 on our list of primary care services for the same reasons we proposed to add CPT code 99354 to our list of primary care services. Because the proposed definition of HCPCS code GPRO1 also includes prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services, we proposed to include the allowed charges for HCPCS code GPRO1, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

We proposed to include these codes in the definition of primary care services when performing beneficiary assignment under § 425.402, for performance years starting on January 1, 2019, and subsequent years. However, we noted that our proposal to include the three proposed new ''add-on codes'', GPC1X, GCG0X, and GPRO1, was contingent on CMS finalizing its proposal to create these new codes for use starting in 2019.

As discussed in section V.B.2.c.(1) of this final rule, ACOs and other commenters have expressed concerns regarding our current policy of identifying services billed under CPT codes 99304 through 99318 furnished in a SNF by using the POS modifier 31. We continue to believe it is appropriate to exclude from assignment services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. However, as we explained in the August 2018 proposed rule (83 FR 41899), we agree with commenters that it might increase the accuracy of beneficiary assignment for these vulnerable and generally high cost beneficiaries if we were to revise our method for determining whether services identified by CPT codes 99304 through 99318 were furnished in a SNF to focus on whether the beneficiary also received SNF facility services on the same day. We believe it would be feasible for us to directly and more precisely determine whether services identified by CPT codes 99304 through

99318 were furnished in a SNF by analyzing our facility claims data files rather than by using the POS modifier 31 in our professional claims data files. Operationally, we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service. Therefore, we proposed to revise the regulation at § 425.400(c)(1)(iv)(A)(*2*), effective for performance years starting on January 1, 2019 and subsequent performance years, to remove the exclusion of claims including the POS code 31 and in its place to indicate more generally that we will exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF.

Under our current process, if CMS' HCPCS committee or the American Medical Association's CPT Editorial Panel modifies or replaces any of the codes that we designate as primary care service codes in § 425.400(c), we must revise the primary care service codes listed in § 425.400(c) as appropriate through further rulemaking before the revised codes can be used for purposes of assignment. As noted previously, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494 and 99484. Therefore, consistent with our current process, we proposed to revise the primary care service codes in § 425.400(c)(1)(iv) to replace HCPCS codes G0502, G0503, G0504 and G0507 with CPT codes 99492, 99493, 99494 and 99484 for performance years starting on January 1, 2019, and subsequent performance years.

We also noted that the regulations text at § 425.400(c)(1)(iv) includes brief descriptions for the HCPCS codes that we have designated as primary care service codes, but does not include such descriptions for the CPT codes that we have designated as primary care service codes. For consistency, we proposed a technical change to the regulations at § 425.400(c)(1)(iv)(A) to also include descriptions for the CPT codes. We also noted that one of the Chronic Care Management (CCM) codes, CPT code 99490, is inadvertently listed in the regulations text at § 425.400(c)(1)(iv)(A)(*6*) along with the codes for Transitional Care Management (TCM) services. We proposed a technical change to the regulations to move CPT code 99490 up to § 425.400(c)(1)(iv)(A)(*5*) with the other CCM codes.

We welcomed comments on the new codes we proposed to add to the definition of primary care services used for purposes of assigning beneficiaries to Shared Savings Program ACOs. In addition, we sought comment on our proposal to revise our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF. We also sought comment on the other proposed technical changes to § 425.400(c)(1)(iv). We also welcomed comments on any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking.

Comment: Some commenters supported the proposed changes to the definition of primary care services. One commenter suggested we include the Initial Preventive Physician Examination, or Welcome to Medicare Visit, as well as the annual wellness visit CPT codes in the definition.

Response: We appreciate the commenters' support for the proposed amendments to the definition of primary care services. We also note we currently include the Welcome to Medicare (G0402) and annual wellness visit (G0438 and G0439) CPT codes in the definition of primary care services under § 425.400(c).

Comment: Many commenters supported the proposal to modify § 425.400(c)(1)(iv)(A)(*2)* to remove the exclusion of claims including the POS code 31 and in its place indicate more generally that we will exclude services billed under CPT codes 99304 through 99318 from use in the assignment methodology when such services are furnished in a SNF, as determined based on whether there is a SNF facility claim with dates of service that overlap with the date of service for the professional service. One commenter supported this proposal because they noted it would better identify beneficiaries who have received short-term care and appropriately exclude them from assignment.

Response: We appreciate the commenters' support for the proposal to modify § 425.400(c)(1)(iv)(A)(*2)* to remove the exclusion of claims including the POS code 31 modifier and in its place to exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. We are finalizing the policy as proposed.

Comment: Concerning the proposal to remove the exclusion of claims including the POS code 31, one commenter suggested we use a longer claims run-out period to account for the institutional billing practices for SNFs. This commenter also stated they would ''welcome transparency related to POS 31 and 32 claims-based attribution'' in the claim and claims line feed files we provide to participating ACOs under § 425.704.

Response: As we noted in the 2011 Shared Savings Program final rule (76 FR 67837), a 3-month claims run-out results in a completion percentage of approximately 98.5 percent for physician services and 98 percent for Part A services. Additionally, the claim and claim line feed files furnished to ACOs under § 425.704 contain Parts A and B claims data regarding beneficiaries who are either prospectively assigned to the ACO or who may be assigned to the ACO at the end of the performance year, depending on the assignment methodology under which the ACO participates. As long as the beneficiary has not declined to share their claims data, and the claim does not include protected health information related to substance use disorder treatment, ACOs receive both the claims for physician services and the facility level claims that would be used to determine whether a service billed under CPT codes 99304 through 99318 was furnished in a SNF.

Comment: A few commenters suggested we only include the newly proposed CPT/HCPCS codes under step 1 of the two-step assignment methodology. The commenters stated these codes should be used for ''assigning beneficiaries on the basis of care furnished specifically by primary care physicians and not all ACO professionals.''

Response: We disagree with these comments. We continue to believe our current assignment methodology generally provides an appropriate balance between maintaining a strong emphasis on primary care while ultimately allowing for assignment of beneficiaries on the basis of how they actually receive their primary care services (80 FR 32748). We also note that the list of specialty types included in step 1 and step 2 of the assignment methodology was informed by CMS medical officers knowledgeable about the services typically performed by physicians and non-physician practitioners (80 FR 32750) as well as comments received in response to the 2014 Shared Savings Program proposed rule.

Comment: One commenter suggested an alternative assignment methodology that the commenter believed would be similar to a methodology discussed in the CY 2019 PFS proposed rule which would distinguish between primary and secondary specialties for practitioners

billing under the same TIN as part of a multispecialty group. The commenter stated this approach would improve the accuracy of the assignment methodology by focusing on evaluation and management services furnished by primary care providers, rather than specialists. Alternatively, this commenter suggested an assignment methodology similar to methodologies used by state agencies. According to the commenter, this assignment methodology would allow for exclusions, attribution, and tie-breaking steps to support a valid beneficiary population.

Response: We encourage the commenter to review our assignment methodology under the Shared Savings Program regulations at 42 CFR part 425, subpart E. Our current assignment methodology emphasizes primary care services provided by primary care clinicians in step one, before considering primary care services furnished by certain specialists in step two. However, we will continue to monitor this issue to determine whether there have been any changes or refinements that would allow us to more precisely identify both primary and secondary practitioner specialties in Medicare claims data and whether those changes should be accounted for in the assignment methodology used in the Shared Savings Program. Any changes to our assignment methodology would be proposed through future rulemaking for the Shared Savings Program.

As discussed earlier in this final rule, the proposal to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for the office or other outpatient evaluation and management services represented by CPT codes 99201 through 99215 is not being finalized. Therefore, the proposal to include HCPCS ''add-on codes'', GPC1X, GCG0X, and GPRO1 in the definition of ''primary care services'' will not be finalized at this time. We will revisit this proposal in future rulemaking and continue to monitor the annual rulemaking for the PFS to determine if we should propose any changes to the definition of primary care services for the Shared Savings Program to reflect proposed HCPCS/CPT coding changes.

We received no comments on the proposed technical changes to § 425.400(c)(1)(iv). After considering the comments received, we are finalizing our proposed revisions to the definition of primary care services, with the exception of the proposal to include the three add-on HCPCS codes GPC1X, GCG0X, and GPRO1. Specifically, we are revising the definition of primary care services in § 425.400(c) to add CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443. Additionally, we are finalizing, as proposed, the revisions to our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF and the proposed technical changes to § 425.400(c)(1)(iv).

Consistent with the approach we have taken in the past when implementing changes to the assignment methodology, we will adjust ACOs' historical benchmarks for the performance year starting on January 1, 2019, to account for the changes to the assignment methodology that we are finalizing in this final rule.

d. Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program

(1) Background

Following the 2017 California wildfires and Hurricanes Harvey, Irma, Maria, and Nate, stakeholders expressed concerns that the effects of these types of disasters on ACO participants, ACO providers/suppliers, and the assigned beneficiary population could undermine an ACO's ability to successfully meet the quality performance standards, and adversely affect financial performance, including, in the case of ACOs under performance-based risk, increasing shared losses. To address these concerns, we published an interim final rule with comment period titled Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017 (hereinafter referred to as the Shared Savings Program IFC) that appeared in the December 26, 2017 **Federal Register** (82 FR 60912). In the Shared Savings Program IFC, we established policies for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks for ACOs that were affected by extreme or uncontrollable circumstances during performance year 2017. The policies adopted in the Shared Savings Program IFC were effective for performance year 2017, including the applicable quality data reporting period for the performance year. We have considered the comments received on the Shared Savings Program IFC in developing the policies for 2018 and subsequent years.

The extreme and uncontrollable circumstances policies established in the Shared Savings Program for performance year 2017 align with the policies established under the Quality Payment Program for the 2017 MIPS performance period and subsequent MIPS performance periods (see CY 2018 Quality Payment Program final rule with comment, 82 FR 53780 through 53783 and Quality Payment Program IFC, 82 FR 53895 through 53900). In particular, in the Shared Savings Program IFC (82 FR 60914), we indicated that we would determine whether an ACO had been affected by an extreme and uncontrollable circumstance by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in performance year 2017 as determined under the Quality Payment Program or the ACO's legal entity was located in such an area. In the Quality Payment Program IFC (82 FR 53897), we explained that we anticipated that the types of events that could trigger the extreme and uncontrollable circumstances policies would be events designated a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, although we indicated that we would review each situation on a case-by-case basis.

Because ACOs may face extreme and uncontrollable circumstances in 2018 and subsequent years, we proposed to extend the policies adopted in the Shared Savings Program IFC for addressing ACO quality performance scoring and the determination of the shared losses owed for ACOs affected by extreme or uncontrollable circumstances to performance year 2018 and subsequent performance years. In addition, in the Shared Savings Program IFC, we indicated that we planned to observe the impact of the 2017 hurricanes and wildfires on ACOs' expenditures for their assigned beneficiaries during performance year 2017, and might revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking. We considered this issue further in the August 2018 proposed rule (see 83 FR 41904 through 41906).

(2) Proposed Revisions

The financial and quality performance of ACOs located in areas subject to extreme and uncontrollable circumstances could be significantly and adversely affected. Disasters may have several possible effects on ACO quality and financial performance. For instance, displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality

reporting, as well as, reduce the beneficiary response rate on survey measures. Further, for practices damaged by a disaster, the medical records needed for quality reporting may be inaccessible. We also believe that disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals. The effects of a disaster could include challenges in communication between the ACO and its participating providers and suppliers and in implementation of and participation in programmatic activities. Catastrophic events outside the ACO's control can also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period. These factors could jeopardize ACOs' ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

As we stated in the August 2018 proposed rule (83 FR 41900), because widespread disruptions could occur during 2018 or subsequent performance years, we believe it is appropriate to have policies in place to change the way in which we assess the quality and financial performance of Shared Savings Program ACOs in any affected areas. Accordingly, we proposed to extend the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program that were established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we proposed that the Shared Savings Program extreme and uncontrollable circumstances policies for performance year 2018 and subsequent performance years would apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. As we discussed in the Shared Savings Program IFC (82 FR 60914), we believe it is also appropriate to extend these policies to encompass the quality reporting period, unless the reporting period is extended, because if an ACO is unable to submit its quality data as a result of a disaster occurring during the quality data submission window, we would not have the quality data necessary to measure the ACO's quality performance for the performance year. For example, if an extreme and uncontrollable event were to occur in February 2019, which we anticipate would be during the quality data reporting period for performance year 2018, then the extreme and uncontrollable circumstances policies would apply for quality data reporting and quality performance scoring for performance year 2018, if the reporting period is not extended. We explained that we do not believe it is appropriate to extend this policy to encompass the quality data reporting period if the reporting period is extended because affected ACOs would have an additional opportunity to submit their quality data, enabling us to measure their quality performance in the applicable performance year. Accordingly, we also proposed that the policies regarding quality reporting would apply with respect to the determination of the ACO's quality performance in the event that an extreme and uncontrollable event occurs during the applicable quality data reporting period for a performance year and the reporting period is not extended. However, we noted that, because a disaster that occurs after the end of the performance year would have no impact on the determination of an ACO's financial performance for that performance year, it would not be appropriate to make an adjustment to shared losses in the event an extreme or uncontrollable event occurs during the quality data reporting period.

Comment: Commenters overwhelmingly supported adopting permanent policies to mitigate the impacts of extreme and uncontrollable circumstances. Several commenters supported finalizing the proposals without modification; however, the majority of commenters suggested modifications to the proposed policies or requested that CMS adopt additional means of providing relief to disaster affected ACOs. The comments and recommendations are discussed below in sections V.B.2.d.(1), (2), and (3) of this final rule.

Response: We appreciate commenters' support for adopting permanent policies to provide relief to ACOs that are affected by extreme and uncontrollable circumstances.

Comment: A few commenters recommended that CMS take into consideration whether an ACO has experienced an extreme and uncontrollable event during its agreement period when applying certain policies proposed in other sections of the August 2018 proposed rule, if finalized. These included proposed policies related to monitoring for financial performance, repayment mechanism amounts, reconciliation after termination and the determination of participant Medicare FFS revenue and prior participation for purposes of determining participation options.

Response: We thank commenters for their suggestions on ways to further limit the potential negative impacts of extreme and uncontrollable circumstances on ACOs affected by such events. We believe that these suggestions fall outside the scope of the proposals described in section II.E.4 of the August 2018 proposed rule that we are addressing in this final rule. We anticipate discussing our proposals related to other sections of the August 2018 proposed rule in a forthcoming final rule and will address comments related to those sections at that time.

(a) Modification of Quality Performance Scores for All ACOs in Affected Areas

As we explained in the Shared Savings Program IFC (82 FR 60914 through 60916), ACOs and their ACO participants and ACO providers/suppliers are frequently located across several different geographic regions or localities, serving a mix of beneficiaries who may be differentially impacted by hurricanes, wildfires, or other triggering events. Therefore, for 2017, we established a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, would qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. Specifically, we adopted a policy for performance year 2017 of determining whether an ACO had been affected by extreme and uncontrollable circumstances by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in the performance year, as determined under the Quality Payment Program as discussed in the Quality Payment Program IFC (82 FR 53898) or the ACO's legal entity was located in such an area. For 2017, we adopted a policy under which the location of an ACO's legal entity was determined based on the address on file for the ACO in CMS' ACO application and management system. We used 20 percent of the ACO's assigned beneficiary population as the minimum threshold to establish an ACO's eligibility for the policies regarding quality reporting and quality

performance scoring for 2017 because, as we stated in the Shared Savings Program IFC, we believe the 20 percent threshold provides a reasonable way to identify ACOs whose quality performance may have been adversely affected by an extreme or uncontrollable circumstance, while excluding ACOs whose performance would not likely be significantly affected.

The 20 percent threshold was selected to account for the effect of an extreme or uncontrollable circumstance on an ACO that has the minimum number of assigned beneficiaries to be eligible for the program (5,000 beneficiaries), and in consideration of the average total number of unique beneficiaries for whom quality information is required to be reported in the combined CAHPS survey sample (860 beneficiaries) and the CMS Web Interface sample (approximately 3,500 beneficiaries). (There may be some overlap between the CAHPS sample and the CMS Web Interface sample.) Therefore, we estimated that an ACO with an assigned population of 5,000 beneficiaries typically would be required to report quality information on a total of 4,000 beneficiaries. Thus, we indicated that we believe the 20 percent threshold ensures that an ACO with the minimum number of assigned beneficiaries would have an adequate number of beneficiaries across the CAHPS and CMS Web Interface samples in order to fully report on these measures. However, we also noted that it is possible that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas may have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may be equally impacted because the ACO legal entity may be unable to collect the necessary information from their ACO participants or may experience infrastructure issues related to capturing, organizing, and reporting the data to CMS. We stated that if less than 20 percent of the ACO's assigned beneficiaries reside in an affected area and the ACO's legal entity is not located in a county designated as an affected area, then we believe that there is unlikely to be a significant impact upon the ACO's ability to report or on the representativeness of the quality performance score that is determined for the ACO. For performance year 2017, we determined what percentage of the ACO's performance year assigned population was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. Although beneficiaries are assigned to ACOs under Track 1 and Track 2 based on preliminary prospective assignment with retrospective reconciliation after the end of the performance year, these ACOs were able to use their quarterly assignment lists, which include beneficiaries' counties of residence, for early insight into whether they were likely to meet the 20 percent threshold.

In the Shared Savings Program IFC, we modified the quality performance standard specified under § 425.502 by adding a new paragraph (f) to address potential adjustments to the quality performance scores for performance year 2017 of ACOs determined to be affected by extreme and uncontrollable circumstances. We also modified § 425.502(e)(4) to specify that an ACO receiving the mean Shared Savings Program ACO quality score for performance year 2017 based on the extreme and uncontrollable circumstances policies would not be eligible for bonus points awarded based on quality improvement in that year because quality data would not be available to determine if there was improvement from year to year.

In the Shared Savings Program IFC, we established policies with respect to quality reporting and quality performance scoring for the 2017 performance year. In anticipation of any future extreme and uncontrollable events, in the August 2018 proposed rule (83 FR 41901) we proposed to extend these policies, with minor modifications, to subsequent performance years as well. In order to avoid confusion and reduce unnecessary burdens on affected ACOs, we proposed to align our policies for 2018 and subsequent years with policies established for the Quality Payment Program in the final rule with comment period, entitled CY 2018 Updates to the Quality Payment Program (82 FR 53568). Specifically, we proposed to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the identification of the affected geographic areas and the applicable time periods. Generally, in line with the approach taken for 2017 in the Quality Payment Program IFC (82 FR 53897), we anticipated that the types of events that would be considered an automatic triggering event would be events designated as a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, but indicated that CMS would review each situation on a case-by-case basis. We also proposed that CMS would have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity. Additionally, we proposed to determine an ACO's legal entity location based on the address on file for the ACO in CMS' ACO application and management system.

In the Shared Savings Program IFC, we established a policy for performance year 2017 under which we determined the percentage of the ACO's assigned population that was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. We begin producing the final list of assigned beneficiaries after allowing for 3 months of claims run out following the end of a performance year. However, the quality reporting period ends before the 3-month claims run out period ends. Therefore, in the August 2018 proposed rule we expressed concern that if, for future performance years, we continue to calculate the percentage of affected beneficiaries based on the ACO's final list of assigned beneficiaries, it would not be operationally feasible for us to notify an ACO as to whether it meets the 20 percent threshold prior to the end of the quality reporting period because the final list of assigned beneficiaries is not available until after the close of the quality reporting period. We explained that we now believe it would be appropriate to base this calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which would be available with the quarter three program reports, generally in November of the applicable performance year. We also indicated this report would be available to ACOs participating in the proposed 6-month performance year from January 1, 2019 through June 30, 2019. By basing the calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, we would be able to notify ACOs earlier as to whether they exceed the 20 percent threshold, and ACOs could then use this information to decide whether to report quality data for the performance year. Therefore, for performance year 2018 and subsequent performance years, we proposed to determine the percentage of an ACO's assigned beneficiaries that reside in an area affected by an extreme and uncontrollable circumstance using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample. We indicated that we

could use this assignment list report regardless of the date(s) the natural disaster occurred. The assignment list report provides us with a list of beneficiaries who have received the plurality of their primary care services from ACO professionals in the ACO at a specific point in time. As this is the list that is used to determine the quality reporting sample, we believe it is appropriate to use the same list to determine how many of the ACO's beneficiaries reside in an area affected by a disaster, such that the ACO's ability to report quality data could be compromised. We proposed to revise § 425.502(f) to reflect this proposal for performance year 2018 and subsequent years.

In the Shared Savings Program IFC (82 FR 60916), we described the policies under the MIPS APM scoring standard that would apply for performance year 2017 for MIPS eligible clinicians in an ACO that did not completely report quality. The existing tracks of the Shared Savings Program (Track 1, Track 2 and Track 3), and the Track 1+ Model are all MIPS APMs under the APM scoring standard.[35] If finalized, we expect the BASIC track and ENHANCED track (based on Track 3) proposed in the August 2018 proposed rule would similarly be considered MIPS APMs under the APM scoring standard. In the August 2018 proposed rule (83 FR 41902), we noted, for purposes of the APM scoring standard, MIPS eligible clinicians in an ACO that has been affected by an extreme and uncontrollable circumstance and does not report quality for a performance year, and therefore, receives the mean ACO quality score under the Shared Savings Program, would have the MIPS quality performance category reweighted to zero percent resulting in MIPS performance category weighting of 75 percent for the Promoting Interoperability performance category and 25 percent for the Improvement Activities performance category under the APM scoring standard per our policy at § 414.1370(h)(5)(i)(B). In the event an ACO that has been affected by an extreme and uncontrollable circumstance is able to completely and accurately report all quality measures for a performance year, and therefore receives the higher of the ACO's quality performance score or the mean quality performance score under the Shared Savings Program, we would not reweight the MIPS quality performance category to zero percent under the APM scoring standard. Additionally, unless otherwise excepted, the ACO participants will receive a Promoting Interoperability (PI) (formerly called Advancing Care Information (ACI)) performance category score under the APM scoring standard based on their reporting, which could further increase their final score under MIPS.

We proposed to revise § 425.502(f) to extend the policies established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we proposed that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO's legal entity is located in such an area, we would use the following approach to calculate the ACO's quality performance score as specified in proposed revisions to paragraphs (e) and (f) of § 425.502.

- The ACO's minimum quality score would be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we would use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO's quality performance score is used, the ACO would also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO would not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we would measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality. Under this approach, the comparison would continue to be between consecutive years of quality reporting, but these years may not be consecutive calendar years.

Additionally, we proposed to address the possibility that ACOs that have a 6-month performance year (or performance period) during 2019 may be affected by extreme and uncontrollable circumstances. In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to policies for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this discussion will include a description of the applicability of policies for addressing extreme and uncontrollable circumstances.

As described in section II.A.7 of the August 2018 proposed rule, we proposed to use 12 months of data, based on the calendar year, to determine quality performance for the 6-month performance year from January 2019 through June 2019 (83 FR 41856 through 41858). We explained our belief that it is necessary to account for disasters occurring in any month(s) of CY 2019 for ACOs participating in a 6-month performance year during 2019 regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster. Therefore, for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019, affected by a disaster in any month of 2019, we would use the alternative scoring methodology specified in § 425.502(f) to determine the quality performance score for the 2019 quality reporting period, if the reporting period is not extended. For example, assume that an ACO participates in the Shared Savings Program for a 6-month performance year from January 1, 2019 through June 30, 2019, and does not continue its participation in the program for a new agreement period beginning July 1, 2019 (as proposed). Further assume that we determine that 20 percent or more of the ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the

[35] See, for example Alternative Payment Models in the Quality Payment Program as of February 2018, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Comprehensive-List-of-APMs.pdf.*

Quality Payment Program, in September 2019. The ACO's quality performance score for the 2019 reporting period would be adjusted according to the policies in § 425.502(f).

We proposed to specify the applicability of the alternative scoring methodology in § 425.502(f) for the 6-month performance year from January 1, 2019 through June 30, 2019, in the proposed new section of the regulations at § 425.609(d).

We solicited comments on the proposed policies for assessing the quality performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years, including the applicable quality data reporting period for the performance year, unless the reporting period is extended.

Comment: One commenter incorrectly stated that CMS proposed to continue to use a threshold of 25 percent to determine the applicability of the proposed alternative quality scoring policies (rather than the actual 20 percent proposed) and noted that they agreed that this threshold was reasonable. This commenter also suggested that CMS consider other percentage thresholds, such as 5 percent or 10 percent, as test cases. The same commenter also encouraged CMS to look at the percentage of an ACO's physicians and other health clinicians located in an impacted area as another means of determining which ACOs should be automatically eligible for the alternative quality scoring policy. This commenter suggested, for example, using a threshold of 50 percent of NPIs located in an impacted area, based on the practice locations listed in the Provider Enrollment, Chain, and Ownership System (PECOS).

Response: We are finalizing our proposal to continue to use 20 percent of assigned beneficiaries residing in a disaster-affected as one of the criteria for determining whether an ACO is eligible for the alternative quality scoring methodology. We will continue to monitor this criterion as we gain more experience with these policies. However, at present we believe that the 20 percent threshold, which was influenced by considerations related to ensuring a sufficient population size to allow affected ACOs to fully report on quality, remains a reasonable level. While we considered the commenter's suggestion to expand the criteria for identifying affected ACOs to include ACOs for which 50 percent or more of the NPIs billing under the ACO participant TINs are located in an impacted area, we believe that including this additional criterion would create additional operational complexity and less transparency as we do not currently include information on the location of ACO providers/suppliers in program reports.

Comment: Several commenters stated that the proposed policy of using the higher of an ACO's own quality score in the affected year or the national mean score unfairly penalizes ACOs that have had historically high quality performance. One commenter also noted that this approach could unfairly reward ACOs with historically low quality performance to the detriment of the Medicare Trust Funds. These commenters recommended that CMS should adopt an approach that considers an ACO's own quality score from one or more prior years, if available. Some of the commenters explained this approach would be similar to a policy used in Medicare Advantage.

Commenters offered various suggestions on how to implement a policy that considers an ACO's historic quality performance. A few commenters recommended that CMS use the highest of the ACO's quality score for the affected performance year, the ACO's quality score for the prior performance year (if available), or the national mean quality score. One commenter recommended following this approach for each individual quality measure. Suggestions from other commenters included: Using the higher of the ACO's average quality score for the prior two years and the national mean for ACOs in their third or subsequent year in the program and using the national average score for ACOs in their first or second year in the program; Using the higher of the affected year quality score and the prior year quality score, if one is available, and otherwise using the higher of the affected year score and the national mean score; Using the ACO's historical quality performance instead of the mean when an ACO is in its third or subsequent performance year in the program.

Several commenters also recommended that the proposed policies in this section be extended to include all ACOs affected by a natural disaster, not just those that cannot report quality data. A few commenters provided suggestive evidence that quality outcome measures such as readmission measures may be subject to immediate and significant impacts in the event of a natural disaster, which could have an adverse impact on an ACO's quality score, particularly given the non-linear nature of the program's quality scoring methodology under which an ACO receives zero points on a measure if it falls below the 30th percentile. Several commenters requested that that those ACOs whose scores on readmissions measures (ACO–8, all-cause readmissions and ACO–35, SNF readmissions) fall below the 30th percentile should be eligible to have their quality score adjusted to account for the natural disaster.

Response: We acknowledge that for some ACOs, the mean quality score could be lower, or higher, than the score those ACOs would have received in the absence of a disaster. However, we have concerns with the recommended alternatives which would potentially apply an ACO's score from the prior year or apply a score that is an average of prior year scores, particularly for ACOs in their early years of participation in the Shared Savings Program and for which the prior years may have included a higher number of pay-for-reporting measures, thus making the quality scores incomparable. Likewise, in section III.F.1.b. of this final rule we are finalizing several quality measures for use beginning in performance year 2019. These measures will be pay-for-reporting for the first 2 years of use (2019 and 2020). All else being equal, the addition of these new pay-for-reporting measures will increase ACOs' quality scores. Also, we note that ACO quality performance can vary from year to year and the fact that an ACO had a high quality score in prior years does not necessarily guarantee that the ACO would have had an above average score in the affected year in the absence of the natural disaster. Lastly, we would remind commenters that the national mean quality score includes the quality scores of 100 percent earned by ACOs in their first performance year, thus increasing the mean.

For these reasons, we are declining at this time to adopt commenters' recommendations that we consider prior year quality scores as part of determining the quality performance scores of ACOs affected by extreme and uncontrollable circumstances and are finalizing the proposed policy. We are also declining to adopt the commenter's recommendation to give special consideration to ACOs based on their performance on the ACO–8 and ACO–35 readmissions measures. We would also like to clarify that both the policy that we finalized for performance year 2017 in the Shared Savings Program IFC and the policy we are finalizing in this rule for performance year 2018 and subsequent performance years would apply to all ACOs deemed to be affected by an extreme and uncontrollable circumstance (20 percent or more of assigned beneficiaries residing in an

affected area or legal entity located in such an area), including those ACOs that were able to report quality and those for which scores on ACO–8 and ACO–35 fell below the 30th percentile. We will continue to monitor quality performance among ACOs affected by extreme and uncontrollable circumstances, and as we gain more experience will consider whether any changes to the finalized policy are warranted.

Comment: One commenter agreed with setting a disaster-affected ACO's quality score to the national mean but opposed using the mean score to calculate ''future benchmarks or subsequent year thresholds until complete and accurate reporting can be achieved.'' They noted that ''setting quality benchmarks to an artificial mean is not a valid approach to determine legitimate savings and losses.''

Response: We clarify that ACOs' quality performance scores are not used to calculate quality measure benchmarks. Rather, the quality measure benchmarks are calculating using actual ACO performance and all other available and applicable Medicare FFS data.

Comment: One commenter recommended that all affected ACOs should receive the higher of the 2018 or 2019 Star Rating for each CAHPS measure.

Response: We note that the Shared Savings Program does not provide a Star Rating to ACOs based on their CAHPS performance. Star Ratings are used for Medicare Advantage and Medicare Prescription Drug plans to provide quality and performance information to Medicare beneficiaries to assist them in choosing their health and drug services and, solely for Medicare Advantage plans, to implement the quality bonus payment adopted by Congress in the Patient Protection and Affordable Care Act. We believe that incorporating Star Ratings into the Shared Savings Program would need to be part of a larger effort that was not contemplated in the August 2018 proposed rule. In contrast, we believe our proposal of using the higher of an ACO's own calculated quality score or the mean quality score serves as a way to mitigate negative impacts for disaster-affected ACOs in manner that can be readily incorporated into the existing structure of the Shared Savings Program quality scoring methodology.

Comment: A few commenters recommended that CMS remove claims associated with disaster-impacted beneficiaries and time periods or claims with disaster payment modifier codes when calculating the numerator and denominator of the readmissions measures and other claims-based quality measures.

Response: As we describe in section V.B.2.b. of this final rule, we have examined the use of existing disaster payment modifiers during 2017 and have found their utilization to be low overall and to vary across ACOs, including those with comparably high shares of beneficiaries residing in disaster affected areas. Therefore, we have concerns that these codes would not serve as a useful means for comprehensively identifying relevant claims. We also have concerns about removing claims for beneficiaries residing in affected areas during affected time periods. In addition to adding considerable complexity, this approach could lead to the elimination of a large number of claims for some ACOs. This could lead to bias if the claims removed are systematically different from other claims for reasons apart from the natural disaster, such as because they are concentrated in a specific geographic area or time period and may also make it more difficult for CMS to provide an oversample of beneficiaries to ACOs for the CMS Web Interface sample.

Comment: One commenter requested that CMS provide additional clarity before finalizing any of the policies for extreme and uncontrollable circumstances proposed in the August 2018 proposed rule. In particular, the commenter requested that CMS provide additional clarification on how the agency would determine and announce whether the extreme and uncontrollable circumstances policies would apply or if the reporting period would be extended.

Response: We intend to make an initial determination about whether an ACO meets the criteria for being considered a disaster-affected ACO after quarter 3 assignment has been determined and before the start of the quality reporting period. We will make the final determination with respect to affected ACOs after the end of the calendar year in order to capture any additional extreme and uncontrollable circumstances that may occur in the remainder of the year or during the quality reporting period, if not extended. We will continue to use the quarter 3 assignment list as the basis for this final determination. In the event that CMS decides to extend the quality reporting period, we would provide notification to ACOs through existing communication channels such as the Shared Savings Program newsletter or an email blast. We also note that if an ACO is determined to be an affected ACO as a result of an extreme or uncontrollable circumstance during the performance year, the alternative quality scoring methodology would apply, regardless of whether the quality reporting period is extended.

Comment: One commenter recommended that CMS adopt the same period as any Declaration of Emergency by the Secretary when determining the applicable time period for an extreme and uncontrollable circumstance instead of an alternative period selected by CMS that may not be as well-aligned with the reality of health services instability for areas under a declaration of emergency. Another commenter encouraged CMS to be transparent regarding the criteria used to determine the applicable time period and to work closely with Medicare Administrative Contractors and the Federal Emergency Management Agency to communicate these policies to ACOs.

Response: We are finalizing our proposals for extreme and uncontrollable circumstances, including our proposal that CMS will have the sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred. Although we are not adopting fixed criteria for determining the applicable time periods, we note that for performance year 2017 we used the time periods associated with public health emergencies declared by the Secretary and listed on the CMS Emergency Response and Recovery website (now renamed the Emergency Preparedness & Response Operations website at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/EPRO-Home.html*). We anticipate continuing this practice, which we believe to be transparent, going forward. Furthermore, for events for which the public health emergency declaration spans calendar years, we intend to treat the portion of the period falling within each year as if it were a separate event for purposes of identifying ACOs eligible for the alternative quality scoring methodology and for computing any adjustment to shared losses.

Comment: One commenter expressed concerns about what they described as CMS' ''one-size-fits-all'' approach for determining the time period during which an ACO would be subject to the extreme and uncontrollable circumstances policies. They encouraged CMS to allow ACOs an opportunity to request relief from shared losses and negative quality adjustments over a longer period of time, up to a full performance year, to be evaluated by CMS on a case-by-case basis. The commenter noted that the impact of a disaster occurring early in the year may have a different impact

than one occurring later in the year and there may be long-lasting effects, which should not have counted against affected ACOs. They stated that the hardship exemption, which would be approved by CMS on a case-by-case basis, would have limited effect on the Trust Funds, but would be important for the integrity of the program by establishing a formal process for ACOs to request an exemption based on extenuating circumstances.

Response: We have elected to adopt automatic policies to address extreme and uncontrollable circumstances in lieu of hardship requests that must be considered on a case-by-case basis in order to increase certainty and reduce administrative burden for both ACOs and CMS. We will continue to monitor the impact of the policies that we are finalizing in this rule, and as we gain more experience, if warranted, we will propose additional modifications through future notice and comment rulemaking.

After considering the comments received, we are finalizing our proposals to extend the policies for determining the quality scores for ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we are revising §§ 425.502(e) and 425.502(f) to state that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year, if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, or that the ACO's legal entity is located in such an area, we will use the following approach to calculate the ACO's quality performance score:

- The ACO's minimum quality score will be set to equal the mean quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we will use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO's quality performance score is used, the ACO will also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO will not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we will measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality.

We clarify that if an ACO reports quality data in a year in which it is affected by an extreme and uncontrollable circumstance, but receives the national mean quality score, we will use the ACO's own quality performance score to determine quality improvement bonus points in the following year. For example, if an ACO reported quality data in years 1, 2, and 3 of an agreement period, but received the national mean quality score in year 2 as the result of an extreme or uncontrollable circumstance, we would determine quality improvement bonus points for year 3 by comparing the ACO's year 3 quality score with its year 2 score. If the ACO received the mean score in year 2 because it did not report quality, we would compare year 3 with year 1 to determine the bonus points for year 3.

We also want to clarify one point regarding the interaction between this alternative quality scoring methodology and MIPS. As we noted above, the MIPS quality performance category is reweighted to zero if a disaster-affected ACO receives the mean quality score under the Shared Savings Program's extreme and uncontrollable circumstance policy, because it did not or could not report quality data at the ACO (APM Entity) level, regardless of whether or not any of the ACOs participant TINs reported quality outside the ACO. This reweighting under MIPS results in MIPS performance category weighting of 75 percent for the PI performance category and 25 percent for IA performance category. If, for any reason, the PI performance category also is reweighted to zero, which could be more likely when there is a disaster, there would be only one performance category triggering the policy under which the ACO in question would receive a neutral (threshold) MIPS score, as per § 414.1380(c) (see discussion at 83 FR 53778). If any of the ACO's participant TINs do report PI, then the TIN or TINs' PI performance category scores will be used to score the ACO under the MIPS scoring standard, the PI performance category will not be reweighted, and the policy to assign a neutral (threshold) MIPS score will not be triggered.

(b) Mitigating Shared Losses for ACOs Participating in a Performance-Based Risk Track

In the Shared Savings Program IFC (82 FR 60916) we modified the payment methodology for performance year 2017 for performance-based risk tracks established under the authority of section 1899(i) of the Act, to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during 2017. Under this approach, we reduced the ACO's shared losses, if any, determined to be owed for performance year 2017 under the existing methodology for calculating shared losses in the Shared Savings Program regulations at 42 CFR part 425 subpart G by an amount determined by multiplying the shared losses by two factors: (1) The percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who resided in an area affected by an extreme and uncontrollable circumstance. For performance year 2017, we determined the percentage of the ACO's performance year assigned beneficiary population that was affected by the disaster based on the final list of beneficiaries assigned to the ACO for the performance year. For example, assume that an ACO was determined to owe shared losses of $100,000 for performance year 2017, a disaster was declared for October through December during the performance year, and 25 percent of the ACO's assigned beneficiaries resided in the disaster area. In this scenario, we would have adjusted the ACO's shared losses in the following manner: $\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750$. The policies for performance year 2017 are specified in paragraph (i) in § 425.606 for ACOs under Track 2 and § 425.610 for ACOs under Track 3.

In the August 2018 proposed rule (83 FR 41903), we stated our belief that it would be appropriate to continue to apply these policies in performance year 2018 and subsequent years to address stakeholders' concerns that ACOs participating under a performance-based risk track could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given

the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we believe that ACOs participating in performance-based risk tracks might reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track. The approach we adopted for performance year 2017 in the Shared Savings Program IFC, and which we proposed to continue for performance year 2018 and subsequent years, balances the need to offer relief to affected ACOs with the need to continue to hold those ACOs accountable for losses incurred during the months in which there was no applicable disaster declaration and for the portion of their final assigned beneficiary population that was outside the area affected by the disaster. In the August 2018 proposed rule, we explained our belief that, consistent with the policy adopted for performance year 2017 in the Shared Savings Program IFC, it would be appropriate to continue to use the final assignment list report for the performance year for purposes of this calculation. This final assignment list report would be available at the time we conduct final reconciliation and provides the most complete information regarding the extent to which an ACO's assigned beneficiary population was affected by a disaster.

Additionally, we proposed to also address the possibility that ACOs that have a 6-month performance year during 2019 may be affected by extreme and uncontrollable circumstances. In this final rule, we are addressing the proposals specific to the 6-month performance year from January 1, 2019 through June 30, 2019. In a forthcoming final rule, we anticipate discussing comments received on the proposals related to policies for the 6-month performance year from July 1, 2019 through December 31, 2019, and the performance period from January 1, 2019 through June 30, 2019 for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We anticipate this discussion will include a description of the applicability of policies for determining shared losses for ACOs affected by extreme and uncontrollable circumstances.

As described in section II.A.7. of the August 2018 proposed rule (83 FR 41849 through 41853) and the proposed provision at § 425.609, we proposed to use 12 months of expenditure data, based on the calendar year, to perform financial reconciliation for the 6-month performance year from January 1, 2019 through June 30, 2019. Accordingly, for ACOs participating in a 6-month performance year during the first half of 2019, we believed it would be necessary to account for disasters occurring in any month(s) of CY 2019, regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster.

For ACOs with a 6-month performance year that are affected by an extreme or uncontrollable circumstance during CY 2019, we proposed to first determine shared losses for the ACO over the full calendar year, adjust the shared losses for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year according to the methodology proposed under § 425.609. For example, assume that: A disaster was declared for October 2019 through December 2019; an ACO is being reconciled for its participation during the performance year from January 1, 2019 through June 30, 2019; the ACO is determined to have shared losses of $100,000 for CY 2019; and 25 percent of the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750$, then we would multiply these losses by the portion of the year the ACO participated $= \$93{,}750 \times 0.5 = \$46{,}875$.

Therefore, we proposed to amend §§ 425.606(i) and 425.610(i) to extend the policies regarding extreme and uncontrollable circumstances that were established for performance year 2017 to performance year 2018 and subsequent years. In addition, we proposed to include a provision at § 425.609(d) to provide that the policies on extreme and uncontrollable circumstances would apply to the determination of shared losses for ACOs participating in a 6-month performance year during 2019.

In the August 2018 proposed rule (83 FR 41904), we noted that to the extent that our proposal to extend the policies adopted in the Shared Savings Program IFC to 2018 and subsequent performance years constitutes a proposal to change the payment methodology for 2018 after the start of the performance year, we believe that consistent with section 1871(e)(1)(A)(ii) of the Act, and for the reasons discussed in section II.E.4 of the August 2018 proposed rule (83 FR 41899 through 41906), it would be contrary to the public interest not to propose to establish a policy under which we would have the authority to adjust the shared losses calculated for ACOs in Track 2 and Track 3 for performance year 2018 to reflect the impact of any extreme or uncontrollable circumstances that may occur during the year.

We also explained that these proposed policies would not change the status of those payment models that meet the criteria to be Advanced APMs under the Quality Payment Program (see § 414.1415). Our proposed policies would reduce the amount of shared losses owed by ACOs affected by a disaster, but the overall financial risk under the payment model would not change and participating ACOs would still remain at risk for an amount of shared losses in excess of the Advanced APM generally applicable nominal amount standard. Additionally, these policies would not prevent an eligible clinician from satisfying the requirements to become a QP for purposes of the APM Incentive Payment (available for payment years through 2024) or higher physician fee schedule updates (for payment years beginning in 2026) under the Quality Payment Program.

We also emphasized that all ACOs would continue to be entitled to share in any savings they may achieve for a performance year. ACOs in all tracks of the program will continue to receive shared savings payments, if any, as determined under subpart G of the regulations. The calculation of savings and the determination of shared savings payment amounts for a performance year would not be affected by the proposed policies to address extreme and uncontrollable circumstances, except that the quality performance score for an affected ACO may be adjusted as described in section II.E.4 of the proposed rule.

We solicited comments on the proposed policies for assessing the financial performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years.

Comment: Several commenters noted that ACOs are likely to experience increased expenditures as the result of a natural disaster. One commenter noted that studies have shown that natural disasters materially increase Medicare costs per beneficiary. A few other commenters noted that costs can increase because of the impact of the disaster on beneficiaries' health, safety and anxiety causing increased utilization of services but also because waivers effected during declared Public

Health Emergencies relax Medicare payment rules allowing more services to be covered than usual. Another commenter stated that an ACO may experience expenditure increases because its assigned beneficiaries migrate to areas with higher FFS payment rates in search of health care services in the wake of a natural disaster. This commenter noted that ACOs based in Puerto Rico could be significantly affected given that after a natural disaster many beneficiaries migrate to the U.S. mainland where the FFS payment rates are substantially higher than on the island.

Several commenters shared the opinion that the proposed policy of adjusting shared losses adequately addresses the situation of ACOs that would have had shared losses in the absence of a natural disaster, but had higher shared losses as the result of the disaster. However, they expressed concern that the policy does not provide relief to ACOs that receive a smaller shared savings payment as a result of the disaster or ACOs for which an expenditure increase resulting from a disaster causes the ACO to fall short of its MSR (and thus miss out on shared savings entirely) or to exceed its MLR (and thus owe shared losses when it otherwise would not have had shared losses).

A few commenters recommended addressing this issue by modifying the update that is applied to an ACO's benchmark for a performance year that is affected by an extreme and uncontrollable circumstance. For example, these commenters recommended that CMS apply a growth rate that is the higher of the national growth rate for assignable beneficiaries or the regional growth rate for assignable beneficiaries (excluding an ACO's own assigned beneficiaries). They suggested that their recommendation should be used instead of the ''current policy'' for accounting for the impact of disasters on performance year expenditures, which they believed relies on the use of natural disaster payment modifiers. A few other commenters recommended that CMS use a blend of national and regional expenditure growth rates to update the benchmark as proposed in the August 2018 rule in ''normal times'' but use a purely regional growth rate in the event of an extreme and uncontrollable circumstance. The same commenters also suggested that CMS remove claims associated with disaster-affected beneficiaries during the relevant time periods or claims with a natural disaster payment modifier code, pending changes to improve these codes, when calculating performance or benchmark year expenditures. It was unclear, however, whether they meant for these claims adjustments to be made instead of or in addition to their recommended changes to the update factors applied to the historical benchmark.

Several commenters raised concerns about the existing natural disaster modifier codes and whether, in their current form, they could be used to try to capture the negative impact on an ACO's performance. They noted that some health care providers may not be aware of the existence of such codes and that the codes may not be used properly due to lack of training and competing priorities during an emergency event. They also noted that the existing codes do not capture instances of ''unsafe place of discharge'', which they believe is a common reason for lengths of stay to be increased during a disaster and recommended that CMS expand existing modifier codes or add a new code to cover this circumstance. A few commenters recommended providing proper education on the use of such codes, which would allow these codes to serve as a more accurate means for identifying the impacts of natural disasters. Another commenter recommended that CMS allow an additional 6 to 12 months for providers to submit such codes to be considered in expenditure calculations.

Response: We are finalizing our proposed approach to mitigate shared losses for ACOs affected by extreme and uncontrollable circumstances without modification in this final rule. We acknowledge commenters' concerns regarding the potential impact of extreme and uncontrollable circumstances on the financial performance of ACOs that do not owe shared losses and we appreciate the commenters' recommendations for how to mitigate these impacts. However, because we did not propose to make any adjustments under these circumstances, these recommendations are outside the scope of this rulemaking. We will continue to monitor the financial performance of ACOs affected by extreme and uncontrollable circumstances, and as we gain more experience will consider whether any changes to our policies for mitigating the effects of extreme and uncontrollable circumstances are warranted.

Furthermore, we note that although we considered the use of natural disaster payment modifiers in developing the original extreme and uncontrollable circumstances policy for performance year 2017, we did not adopt a policy that used such codes in the Shared Savings Program IFC, nor did we propose in the August 2018 proposed rule to use such codes to adjust benchmark or performance year expenditure calculations for performance year 2018 or subsequent years. We have examined the existing natural disaster payment modifiers (specifically the ''DR'' condition code used on institutional claims and the ''CR'' modifier code used on Part B institutional and non-institutional claims) in 2017 claims for ACO assigned beneficiaries. We found that these codes were not widely or consistently used and that there appears to be variation in their use among ACOs. For example, among 69 ACOs with 90 percent or more of assigned beneficiaries residing in a disaster affected area, we found that only 0.01 percent of institutional claims and only 0.0006 percent of non-institutional claims included such a code. Among this same group of ACOs, the total number of claims (institutional or non-institutional) containing one of these codes ranged from 0 to 155 with a mean of 14 and a median of 8. In a separate analysis, we found that claims completion rates were comparable in disaster-affected and non-affected years which suggests that the low levels of modifier usage are not necessarily due to delayed claim submission. Based on these analyses, as well as the comments offered in response to the August 2018 proposed rule, we also have concerns that these codes would not serve as a useful means for comprehensively identifying relevant claims.

As we described in the August 2018 proposed rule, and have recounted in this final rule, we have some concerns about removing claims for affected beneficiaries and time periods from benchmark year expenditure calculations. As we develop additional experience, we may revisit this policy and, if warranted, propose modifications to performance or benchmark year expenditure calculations for ACOs affected by extreme and uncontrollable circumstances through further notice and comment rulemaking.

We also note that, although the policies regarding extreme and uncontrollable circumstances we are finalizing in this final rule do not include an explicit adjustment to the shared savings payment of a disaster-affected ACO, our alternative methodology for quality scoring can indirectly increase an ACO's shared savings payment. In performance year 2017, 62 of 117 disaster-affected ACOs received the national mean quality score, as it was higher than the score the

ACO would have received in the absence of the policy.

After considering the comments received, we are finalizing our proposal to extend the policy for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances established for performance year 2017 to performance year 2018 and subsequent performance years. We are revising §§ 425.606(i) and 425.610(i) to indicate that we will reduce the amount of shared losses calculated for the performance year by an amount determined by multiplying (1) the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. We are also finalizing our proposal, through a new provision at § 425.609(d), to adjust shared losses for ACOs with a 6-month performance year from January 1, 2019 through June 30, 2019. For ACOs in a 6-month performance year we will first determine shared losses for the ACO over the full calendar year, reduce the ACO's shared losses for the calendar year for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year.

(c) Determination of Historical Benchmarks for ACOs in Affected Areas

In the Shared Savings Program IFC, we sought comment on how to address the impact of extreme and uncontrollable circumstances on the expenditures for an ACO's assigned beneficiary population for purposes of determining the benchmark (82 FR 60917). As we explained in the Shared Savings Program IFC (82 FR 60913), the impact of disasters on an ACO's financial performance could be unpredictable as a result of changes in utilization and cost of services furnished to the Medicare beneficiaries it serves. In some cases, ACO participants might be unable to coordinate care because of migration of patient populations leaving the impacted areas. On the other hand, patient populations remaining in impacted areas might receive fewer services and have lower overall costs to the extent that healthcare providers are unable to reopen their offices because they lack power and water or have limited access to fuel for operating alternate power generators. Significant changes in costs incurred, whether increased or decreased, as a result of an extreme or uncontrollable circumstance may impact the benchmark determined for the ACO's subsequent agreement period in the Shared Savings Program, as performance years of the current agreement period become the historical benchmark years for the subsequent agreement period. An increase in expenditures for a particular calendar year would result in a higher benchmark value when the same calendar year is used to determine the ACO's historical benchmark, and in calculating adjustments to the rebased benchmark based on regional FFS expenditures. Likewise, a decrease in expenditures for a particular calendar year would result in a lower benchmark value when the same calendar year is used to determine the ACO's historical benchmark.

While considering options for adjusting ACOs' historical benchmarks to account for disasters occurring during a benchmark year, we considered the effect that the proposed regional factors, that are discussed in section II.D.3. of the August 2018 proposed rule (83 FR 41886 through 41891), might have on the historical benchmarks for ACOs located in a disaster area. After review, we explained that we believe that when regional factors are applied to an ACO's historical benchmark, the regional factors would inherently adjust for variations in expenditures from year to year, and thus would also adjust for regional variations in expenditures related to extreme and uncontrollable circumstances. For example, assume that an ACO experienced a reduction in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, also assume expenditures returned to their previously higher level in 2018 and this ACO subsequently renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset (rebased), the expenditures for 2017 (now a historical benchmark year) would be subject to a higher regional trend factor because expenditures increased back to the expected level in 2018, which would increase the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark increased even further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark. In contrast, consider an ACO that experienced an increase in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, assume expenditures returned to their previously lower level in 2018 and this ACO renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset, the expenditures for 2017 would be subject to a lower regional trend factor because expenditures decreased back to the expected level in 2018, which would decrease the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark decreased further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark.

Our expectation that the proposed regional factors that would be used to establish an ACO's historical benchmark would also adjust for variations in expenditures related to extreme and uncontrollable circumstances was supported by a preliminary analysis of data for areas that were affected by the disasters that occurred in performance year 2017. Our analysis of the data showed that, as a result of the disasters in these areas, expenditure trends for the performance year appeared below projections. For these areas, the expenditures began to increase after the disaster incident period ended, but expenditures were still below expectations for the year. Based on the expenditure trends beginning to return to expected levels after the disaster period, it would be reasonable to expect that expenditures would continue to increase to expected levels in 2018. This difference between the lower than expected levels of expenditures in 2017 and a return to expected expenditures in 2018, would result in a higher regional trend factor being applied to 2017 expenditures when they are used to determine an ACO's historical benchmark. Although our analysis for the proposed rule was performed using the proposed regional factors, we expect that our existing benchmarking methodology at § 425.603, which also incorporates regional factors in the determination of an ACO's historical benchmark for its second or subsequent agreement period beginning in 2017 or later years, would have a similar result.

In the August 2018 proposed rule (83 FR 41905), in considering whether it might be necessary to make an additional adjustment to ACOs' historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances, we considered an approach where we would adjust the historical benchmark by reducing the weight of expenditures for beneficiaries who resided in a disaster area during a

disaster period and placing a correspondingly larger weight on expenditures for beneficiaries residing outside the disaster area during the disaster period. Such an approach would be expected to proportionally increase the historical benchmark for ACOs that experienced a decrease in expenditures, and conversely proportionally decrease the historical benchmark for ACOs that experienced an increase in expenditures for their assigned beneficiaries who were impacted by a disaster. Under this approach, for each of the historical benchmark years, we would identify each ACO's assigned beneficiaries who had resided in a disaster area during a disaster period. The portion of expenditures for these assigned beneficiaries that was impacted by the disaster would be removed from the applicable historical benchmark year(s). The removal of these expenditures from the historical benchmark year(s) would allow the historical benchmark calculations to include only expenditures that were not impacted by the disaster. We believe this methodology for calculating benchmark expenditures would adjust for expenditure increases or decreases that may occur as a result of impacts related to a disaster.

We noted that if we were to implement such an adjustment to the historical benchmark, we believed it would be appropriate to avoid making minor historical benchmark adjustments for an ACO that was not significantly affected by a disaster by establishing a minimum threshold for the percentage of an ACO's beneficiaries located in a disaster area. Based on data from 2017, quarter 3, over 80 percent of ACOs had less than 50 percent of their assigned beneficiaries residing in disaster counties, with over 75 percent having less than 10 percent of their assigned beneficiaries residing in disaster counties. Based on this data, we noted our belief that a minimum threshold of 50 percent of assigned beneficiaries residing in disaster counties could be an appropriate threshold for the adjustment to historical benchmarks because historical benchmarks are calculated based on the ACO's entire assigned beneficiary population in each benchmark year, rather than a sample as is used for quality reporting.

However, we were concerned that this methodology for calculating an adjustment might not be as accurate as the inherent adjustment that would result from applying regional factors when resetting the benchmark and may impact other expected expenditure variations occurring in the impacted areas. For example, if an additional disaster adjustment were to be applied, it might have unintended impacts when expenditure truncation is applied, it might inappropriately weight and not account for expected variations in expenditures between areas that were and were not impacted by the disaster, and it might compound effects that have already been offset by the regional adjustment. In addition, the expenditures, as adjusted, may not be representative of the ACO's actual performance and aggregate assigned beneficiary population during the benchmark period.

In summary, we noted our belief that the regional factors that we had proposed to apply as part of the methodology for determining an ACO's historical benchmark would reduce the expenditures in a historical benchmark year when they are greater than expected (relative to other historical benchmark years) as a result of a disaster and conversely increase expenditures in a historical benchmark year when they are below the expected amount. For these reasons, we believed that the proposal in section II.D.3. of the August 2018 proposed rule (83 FR 41887 through 41888) to apply regional factors when determining ACOs' historical benchmarks, starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years, would be sufficient to address any changes in expenditures during an ACO's historical benchmark years as a result of extreme and uncontrollable circumstances, and an additional adjustment, such as the method discussed previously in this section would not appear to be necessary. However, we noted that we would continue to evaluate the impact of the 2017 disasters on ACOs' assigned beneficiary expenditures, and that we intended to continue to consider whether it might be appropriate to make an additional adjustment to the historical benchmark to account for expenditures that may have increased or decreased in a historical benchmark year as a result of an extreme or uncontrollable circumstance.

We solicited comments on these issues, including whether it is necessary to adjust ACOs' historical benchmarks to account for extreme and uncontrollable circumstances that might occur during a benchmark year, and appropriate methods for making such benchmark adjustments. We also noted that the proposal in section II.D.3. of the August 2018 proposed rule to apply regional factors to determine ACOs' historical benchmarks would apply starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years and would therefore have no effect on benchmarks for ACOs in a first agreement period starting before July 1, 2019 (see 83 FR 41887). Accordingly, we solicited comments on whether and how an adjustment should be made for ACOs whose benchmarks do not reflect regional factors. We also invited comments on any additional areas where relief may be helpful or other ways to mitigate unexpected issues that may arise in the event of an extreme and uncontrollable circumstance.

Comment: A few commenters noted that expenditure increases in a performance year due to a natural disaster could lead to unjustly high benchmark year expenditures in an ACO's subsequent agreement period which could create vulnerabilities for the Trust Funds. As described in the prior section V.B.2.d.(2) of this final rule, we received a few comments recommending modifications to the update that is applied to an ACO's benchmark for a performance year that is affected by an extreme and uncontrollable circumstance. Another commenter suggested removing claims from benchmark and performance year expenditures that have a disaster modifier code or are associated with a beneficiary residing a disaster-affected area during an affected time period.

Response: As discussed in the prior section V.B.2.d.(2) of this final rule, we intend to further consider commenters' recommendations that we address the financial impacts of extreme and uncontrollable circumstances through the update that is applied to the historical benchmark and how this approach could mitigate potential negative impacts to ACOs or to the Medicare Trust Funds for the performance year in which a disaster occurs, performance years for which there was a disaster in one or more of the benchmark years, or cases where an ACO was affected by disasters in both the benchmark period and the performance year.

As described in the prior section V.B.2.d.(2) of this final rule, we have concerns about commenters' recommendation to exclude claims with a natural disaster modifier code, or claims associated with disaster affected beneficiaries and time periods from benchmark or performance year expenditures. As we develop additional experience, we may revisit this policy and, if warranted, propose modifications to our methodology for calculating performance year or benchmark year expenditures through further notice and comment rulemaking.

Comment: One commenter opposed using regional factors as currently calculated by CMS to address concerns about the effect of extreme and uncontrollable circumstances on ACOs' historical benchmarks. This commenter disagreed with CMS' current approach, which includes ACO assigned beneficiaries when calculating regional expenditures. They stated that ''[A]bsent a reform that addresses the underlying issue with the regional adjustment factor, applying it to ACOs in a region recovering from an extreme or uncontrollable circumstance will perpetuate the flaws.''

Response: We continue to believe that the use of regional factors in establishing and updating the benchmark will provide an inherent adjustment for regional variations in expenditures related to extreme and uncontrollable circumstances. As the commenter notes, and under the June 2016 final rule, regional expenditure calculations in the Shared Savings Program are based on all assignable beneficiaries in an ACO's regional service area including ACO assigned beneficiaries. We have detailed in that earlier rule our reasons for not excluding assigned beneficiaries from these calculations (see 81 FR 37960). Furthermore, we do not believe that inclusion of an ACO's assigned beneficiaries would reduce the effectiveness of regional factors to inherently adjust for regional variations in expenditures related to extreme and uncontrollable circumstances as we have no reason to believe that such an event would have a differential impact on expenditures for assigned beneficiaries relative to expenditures for assignable beneficiaries that are not assigned to an ACO.

After considering comments we received on the determination of historical benchmarks for ACOs in areas affected by extreme and uncontrollable circumstances, we are not making any changes to the benchmarking methodology to address such events at this time. We will continue to monitor the impact of extreme and uncontrollable circumstances on benchmark expenditures and, if applicable, the extent to which any impact is mitigated by the use of regional factors in establishing and updating the benchmark. If warranted, we will propose additional modifications to our benchmarking methodology to address the effects of extreme and uncontrollable circumstances through future notice and comment rulemaking.

e. Program Data and Quality Measures

In section II.E.5. of the August 2018 proposed rule (41906 through 41908), we solicited comments on possible changes to the quality measure set and modifications to program data shared with ACOs to support CMS' Meaningful Measures initiative and respond to the nation's opioid misuse epidemic. As part of the Meaningful Measures initiative, the agency's efforts are focused on updating quality measures, reducing regulatory burden, and promoting innovation (see CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html*). Under the Meaningful Measures initiative, we are working towards assessing performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. When we developed the quality reporting requirements under the Shared Savings Program, we considered the quality reporting requirements under other initiatives, such as the Physician Quality Reporting System (PQRS) and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have not only updated the quality measure set to reduce reporting burden, but also to focus on more meaningful outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS Final Rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. Currently, more than half of the 31 Shared Savings Program quality measures are outcome-based, including—

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience;
- Outcome measures supporting care coordination and effective communication, such as unplanned admission and readmission measures; and
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes and control of high blood pressure.

As we explained in the August 2018 proposed rule (83 FR 41906), it is important that the quality reporting requirements under the Shared Savings Program align with the reporting requirements under other Medicare initiatives and those used by other payers in order to minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting. We sought comment, including recommendations and input on meaningful measures, on how we may be able to further advance the quality measure set for ACO reporting, consistent with the requirement under section 1899(b)(3)(C) of the Act that the Secretary seek to improve the quality of care furnished by ACOs by specifying higher standards, new measures, or both.

One particular area of focus by the Department of Health and Human Services is the opioid misuse epidemic. The Centers for Disease Control and Prevention (CDC) reports that the number of people experiencing chronic pain lasting more than 3 months is estimated to include 11 percent of the adult population. According to a 2016 CDC publication, 2 million Americans had opioid use disorder (OUD) associated with prescription opioids in 2014 (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*). Since the implementation of Medicare Part D in 2006 to cover prescription medications, the Medicare program has become the largest payer for prescription opioids in the United States (Zhou et al., 2016; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4955937/*). Safe and effective opioid prescribing for older adults is of particular importance because misuse and abuse of opioids can lead to increased adverse events in this population (for example, increased falls, fractures, hospitalization, ER visits, mortality), especially given the high prevalence of polypharmacy in the elderly. Polypharmacy is the simultaneous use of multiple drugs by a single patient, for one or more conditions, which increases the risk of adverse events. For example, a study by MedPAC found that some beneficiaries

who use opioids fill more than 50 prescriptions among 10 drug classes annually (*http://www.medpac.gov/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf?sfvrsn=0,* MedPAC, 2015).

As part of a multifaceted response to address the growing problem of overuse and abuse of opioids in the Part D program, CMS adopted a policy in 2013 requiring Medicare Part D plan sponsors to implement enhanced drug utilization review. Between 2011 through 2014, there was a 26 percent decrease or 7,500 fewer Medicare Part D beneficiaries identified as potential opioid over-utilizers which may be due, at least in part, to these new policies. On January 5, 2017, CMS released its Opioid Misuse Strategy. This document outlines CMS' strategy and the array of actions underway to address the national opioid misuse epidemic and is available at *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.*

We aim to align our policies under the Shared Savings Program with the priorities identified in the Opioid Misuse Strategy and the Department of Health and Human Services Strategy to Combat Opioid Abuse, Misuse, and Overdose [36] and to help ACOs and their participating providers and suppliers in responding to and managing opioid use, and are therefore considering several actions to improve alignment. Specifically, as we described in the August 2018 proposed rule, we are considering what information regarding opioid use, including information developed using aggregate Medicare Part D data, could be shared with ACOs. We are also considering the addition of one or more measures specific to opioid use to the ACO quality measures set. The potential benefits of such policies would be to focus ACOs on the appropriate use of opioids for their assigned beneficiaries and support their opioid misuse prevention efforts.

First, we are considering what information, including what aggregated Medicare Part D data, could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. We recognize the importance of available and emerging resources regarding the opioid epidemic at the federal, state, and local level, and intend to work with our federal partners to make relevant resources available in a timely manner to support ACOs' goals and activities. We will also continue to share information with ACOs highlighting Federal opioid initiatives, such as the CDC Guideline for Prescribing Opioids for Chronic Pain (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*), which reviews the CDC's recommended approach to opioid prescribing, and the Surgeon General's report on Substance Use and Addiction, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, (*https://addiction.surgeongeneral.gov/*) which focuses on educating and mobilizing prescribers to take action to end the opioid epidemic by improving prescribing practices, informing patients about the risks of and resources for opioid addiction, and encouraging health care professionals to take a pledge to end the opioid crisis. We also intend to continue to highlight information about the opioid crisis and innovations for opioid treatment and prevention strategies in ACO communications and webinars by including topics such as innovative uses of health IT for opioid use disorder treatment and specifically for electronic clinical decision support consistent with the CDC guidelines, as available.

Although we recognize that not all beneficiaries assigned to Shared Savings Program ACOs have Part D coverage, we believe a sufficient number do have Part D coverage to make aggregate Part D data regarding opioid use helpful for the ACOs. As an example, we have found the following information for performance year 2016:

- Approximately 70 percent of beneficiaries assigned to ACOs participating in the Shared Savings Program had continuous Part D coverage.
- For assigned beneficiaries with continuous Part D enrollment, almost 37 percent had at least one opioid prescription. This percentage ranged from 10.6 percent to 58.3 percent across ACOs.
- The mean number of opioid medications filled per assigned beneficiary (with continuous Part D coverage) varied across ACOs, ranging from 0.3 to 4.5 prescriptions filled, with an average of 2.1 prescriptions filled.
- The number of opioid prescriptions filled for each assigned beneficiary with at least one opioid prescription filled varied across ACOs and ranged from 2.6 to 8.4 prescriptions, with an average of 5.5 opioid prescriptions filled.

ACOs currently receive, as part of the monthly claims and claims line feed data, Part D prescription drug event (PDE) data on prescribed opioids for their assigned beneficiaries who have not opted out of data sharing. We encourage ACOs to use this beneficiary-level data in their care delivery practices.

In the August 2018 proposed rule (83 FR 41907), we sought suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. The aim would be for ACOs to utilize this additional information to improve population health management for assigned beneficiaries, including prevention, identifying anomalies, and coordinating care. The type of aggregate data should be highly relevant for a population-based program at the national level and have demonstrated value in quality improvement initiatives. We noted that we are particularly interested in high impact aggregate data that would reflect gaps in quality of care, patient safety, multiple aspects of care, and drivers of cost. We aim to provide aggregate data that have validity for longitudinal analysis to enable both ACOs and the Shared Savings Program to trend performance across time and monitor for changes. Aggregate data on both processes and outcomes are appropriate, provided that the data are readily available. Types of aggregate data that we have begun to consider, based on the information available from prescription drug event records for assigned beneficiaries enrolled in Medicare Part D, include filled prescriptions for opioids (percentage of the ACO's assigned beneficiaries with any opioid prescription, number of opioid prescriptions per opioid user), number of beneficiaries with a concurrent prescription of opioids and benzodiazepines; and number of beneficiaries with opioid prescriptions above a certain daily Morphine Equivalent Dosage threshold. We also sought comments on measures that could be added to the quality measure set for the purpose of addressing the opioid epidemic and addiction, more generally. We sought comment on measures related to various aspects of opioid use, such as prevention, pain management, or opioid use disorder treatment, and on measures related to addiction. In particular, we noted that we were considering the following relevant NQF-endorsed measures, with emphasis on Medicare beneficiaries with Part D coverage who are 18 years or older without cancer or enrolled in hospice:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries

[36] *https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf.*

18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer.

- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

In addition, we sought input on potential measures for which data are readily available, such as measures that might be appropriately calculated using Part D data, and that capture performance on outcomes of appropriate opioid management. We requested that comments on measures that are not already NQF endorsed include descriptions of reliability, validity, benchmarking, the population in which the measure was tested, along with the data source that was used, and information on whether the measure is endorsed and by what organization. We recognized that measures of the various aspects of opioid use may involve concepts related to integrated, coordinated, and collaborative care, including as applicable for co-occurring and/or chronic conditions, as well as measures that reflect the impact of interventions on patient outcomes, including direct and indirect patient outcome measures. We also sought comment on opioid-related measures that would support effective measurement alignment of substance use disorders across programs, settings, and varying interventions.

Comment: A majority of commenters supported CMS' focus on burden reduction stating that they are encouraged by the administration's efforts to reduce reporting burden for healthcare providers. However, one commenter cautioned that although decreasing burden is a laudable goal, removing process measures could unfairly impact the quality scores of healthcare providers who care for vulnerable patients exposed to the harshest social determinants of health. Several commenters suggested that CMS strive toward a core measure set that identifies and harmonizes measures across multiple CMS programs, so that incentives and goals are aligned across healthcare providers and care settings.

Several commenters supported the agency's Meaningful Measures Initiative stating that CMS should not only consider whether a measure is a process measure, but also whether the measure is considered a low-value process measure, before removing it from the Shared Savings Program quality measure set. In addition, these commenters supported CMS' move toward the use of outcome measures, as the emphasis on improved health outcomes is an appropriate focus and goal.

Several commenters suggested future potential refinements to the Shared Savings Program measure set. One commenter urged CMS to better align the Shared Savings Program with Medicare Advantage, suggesting that there should be fewer measures that are included in a roadmap for implementation in both programs, because the different measures and the differing standards for compliance that are currently used cause confusion and require the use of limited provider and staff resources. In addition, this commenter stated that with a roadmap of measures, organizations would be able to focus their energies on achieving these metrics in a systematic and deliberate fashion.

Another commenter expressed concern with the timing and burden of quality measurement and payment, suggesting that we streamline quality efforts to include ten specific outcome measures that have a social and public health impact and offering a financial incentive in connection with each measure to encourage physicians to drive, fund, and sustain continued quality efforts.

A few commenters suggested that CMS should focus on the prevention, treatment, and management of behavioral health. They stated that in the absence of effective behavioral health assessment tools, the vast majority of people with mental health conditions go unidentified in primary care settings, which in most cases leads to non-adherent patients and higher total medical costs. In addition, they stated that behavioral health is central to the prevention, treatment, and management of the preventable manifestations of diseases and health conditions. They suggested that CMS consider including broader measures that would encourage behavioral health and medical providers to work collaboratively to provide coordinated care.

Several commenters suggested that CMS consider developing a quality measure set that would evaluate the breadth of chronic conditions common in the patient population assigned to Shared Savings Program ACOs and use appropriate outcome measures to ensure assigned beneficiaries are receiving the necessary care. They noted that the proposed Shared Savings Program quality measure set discussed in section III.F.1.c. of the CY 2019 PFS proposed rule (83 FR 35876 through 35878) does not include measures related to respiratory conditions, like chronic obstructive pulmonary disease or asthma, diabetes, or additional conditions like heart failure. They encouraged CMS to include measures that evaluate the quality of care for these conditions, such as, measures focused on the delivery of comprehensive lower extremity exams for diabetic patients, and rates of complications such as amputation. They stated that greater emphasis on management of chronic conditions is necessary to promote quality and improve patient outcomes. Another commenter suggested CMS should increase the number of claims-based measures in the Shared Savings Program measure set and provide ACOs with user-friendly, actionable reports that detail the ACO-specific data used to calculate specific measure performance. One commenter suggested that CMS consider quality measures that reinforce shared decision making, as part of treatment plans that align with the individual's goals as this is a foundational component of high-quality patient-centered care.

Response: We thank the commenters for their thoughtful input on the quality measures used to assess the performance of ACOs under the Shared Savings Program. As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback in the development of our proposals.

Comment: The majority of commenters that addressed the potential inclusion of measures related to opioid use in the Shared Savings Program quality measure set were supportive of this effort. A few commenters noted that continued support and recognition for integration of EHRs and electronic sharing of health information, would promote improved communication between healthcare providers, which may help curb opioid abuse and addiction.

Several commenters supported CMS' efforts to consider the possible addition of opioid use measures to the Shared Savings Program quality measure set in future program years, but some commenters recommended that CMS work with the measure developer and NQF to reduce the dosage threshold of two of the measures discussed in the August 2018 proposed rule to 90 MME per day to align with the CDC guidelines for Prescribing Opioids for Chronic Pain. Another commenter agreed that promoting the measurement of opioid use and overuse, monitoring, and education through quality reporting is an important step in understanding and addressing the opioid crisis. A few commenters recommended that CMS utilize the Prescription Drug Monitoring Program (PDMP) Query measure, as most states have implemented PDMPs, and the PDMP Query measure is a reasonable step to improve and measure quality in opioid prescribing.

Another commenter stated that in general they support CMS' considering the addition of opioid use measures to the Shared Savings Program measure set; however, they expressed their belief that opioid dosage measures are of low-value to the program because, ''. . . since the issuance of Centers for Disease Control (CDC) and Prevention guidelines, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time.'' This commenter noted that implementing a quality measure that could force a health provider to abruptly reduce or discontinue this medication regimen could have extreme adverse outcomes such as depression, loss of function, or even suicide. The commenter suggested CMS consider quality measures other than dosage measures when determining the most appropriate metrics to help address and respond to the opioid crisis.

One commenter expressed concern with the specific opioid related measures on which CMS sought comment for potential inclusion in the Shared Savings Program quality measure set. The commenter stated that quality measurement needs to focus on utilization of preventive strategies, such as screening and treatment for substance abuse, as well as pain management. This commenter disagreed with the potential inclusion of *NQF #2940: Use of Opioids at Higher Dosage in Persons Without Cancer* because a measure that focuses only on daily dose and duration of therapy involving prescription opioid analgesics, on its own is not a good indication of quality patient care. In addition, they expressed concerns with the potential inclusion of *NQF #2950: Use of Opioids from Multiple Providers in Persons Without Cancer* and *NQF #2951: Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer* in the Shared Savings Program measure set, as these measures were developed with the intention of determining the quality of care provided by prescription drug health plans and because of the lack of information on the feasibility of ACOs' collecting and reporting pharmacy claims data.

Another commenter noted that the three opioid measures CMS suggested for inclusion in the Shared Savings Program measure set are appropriately focused on the right patient population and address the major risks associated with opioid misuse—high dosages and multiple prescriptions. However, the commenter urged CMS to conduct testing to ensure the measures provide accurate, reliable data at the ACO level, as they are currently endorsed at the health plan level not the ACO level. The commenter suggested that the measures should be reported on a voluntary or pay-for-reporting basis rather than as pay-for-performance measures for the first few years after they are added to the measure set.

Another commenter expressed concern that including measures that are so specific will distract ACOs from focusing on what works for them and their assigned beneficiary population. As an alternative, the commenter suggested CMS provide webinars, education, tools, and data for ACOs to incorporate into their current structure for care management and patient engagement. Several commenters recommended that CMS provide aggregated data to ACOs on opioid use, but they also urged CMS to go further and provide aggregated beneficiary data on the use of all prescribed medications and their related diagnoses. Similarly, another commenter encouraged CMS to continue to add more real-time data to the quarterly quality reports so providers can leverage this data to improve patient care, address social inequities in health, correct inefficiencies to drive down costs, and help to address the nation's opioid epidemic and other pressing health crises.

Response: We thank the commenters for their thoughtful input on the possible addition of measures related to opioid use to the quality measure set for the Shared Savings Program. As we plan for future updates and changes to the Shared Savings Program quality measure set, we will consider this feedback from commenters before making any proposals with respect to the addition of opioid use measures.

f. Promoting Interoperability

Consistent with the call in the 21st Century Cures Act for interoperable access, exchange, and use of health information, the final rule entitled, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (2015 Edition final rule) (80 FR 62601) under 45 CFR part 170 [37] focused on health IT certification criteria that support patient care, patient participation in care delivery, and electronic exchange of interoperable health information. The 2015 Edition final rule, which was issued on October 16, 2015, aimed to improve interoperability by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information and to facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface capabilities. These policies are relevant to assessing the use of CEHRT under the Quality Payment Program, Shared Savings Program, and other value based payment initiatives.

Under the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. Consistent with the statute, ACOs participating in the Shared Savings Program are required to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers and to have a written plan to encourage and promote the use of enabling technologies for improving care coordination, including the use of electronic health records and electronic exchange of health information (§ 425.112(b)(4)). Additionally, since the inception of the program in 2012, CMS has assessed the level of CEHRT use by certain clinicians in the ACO using a double-weighted quality measure (Use of Certified EHR Technology, ACO–11) as part of the quality reporting requirements for each performance year. Based on previously-finalized policies, for the 2018 performance year, we will use data derived from the Quality

[37] For more information, see *https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf.*

Payment Program's Promoting Interoperability performance category to calculate the percentage of eligible clinicians participating in an ACO who successfully meet the Advancing Care Information Performance Category Base Score for purposes of ACO–11. Because the measure is used in determining an ACO's quality score and for determining shared savings or shared losses under the Shared Savings Program, all eligible clinicians participating in Shared Savings Program ACOs must submit data for the Quality Payment Program's Advancing Care Information performance category for performance year 2018, including those eligible clinicians who are participating in Shared Savings Program tracks that have been designated as Advanced APMs and who have met the QP threshold or are otherwise not subject to the MIPS reporting requirements.

In the August 2018 proposed rule (83 FR 41908), we noted that some alternative payment models tested by the Innovation Center, require all participants to use CEHRT even though certain tracks within those Models do not meet the financial risk standard for designation as Advanced APMs. The primary rationale for this requirement is to promote CEHRT use by eligible clinicians and organizations participating in APMs by requiring them to demonstrate a strong commitment to the exchange of health information, regardless of whether they are participating in an APM that meets the criteria to be designated as an Advanced APM. Under the Quality Payment Program, an incentive payment will be made to certain Qualifying APM Participants (QPs) participating in Advanced APMs. Beginning in 2017, an eligible clinician can become a QP for the year by participating sufficiently in an Advanced APM during the QP performance period. Eligible clinicians who are QPs for a year receive a lump sum APM incentive payment for payment years from 2019 through 2024, and are excluded from the MIPS reporting requirements for the performance year and the MIPS payment adjustment for the payment year. In the CY 2017 Quality Payment Program final rule (81 FR 77408), we finalized the criteria that define an Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that, among other criteria, requires its participants to use CEHRT. In the CY 2017 Quality Payment Program final rule, we established that Advanced APMs meet this requirement if the APM either—(1) requires at least 50 percent of eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers; or (2) for the Shared Savings Program, applies a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity (§ 414.1415(a)(1)(i) and (ii)). In the CY 2017 PFS final rule, we updated the title and specifications of the EHR quality measure (ACO–11) to align with the Quality Payment Program criterion on CEHRT use in order to ensure that certain tracks under the Shared Savings Program could meet the criteria to be Advanced APMs. Specifically, we revised the ACO–11 measure to assess ACOs on the degree of CEHRT use by all eligible clinicians participating in the ACO. Performance on the measure is determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Performance Category Base Score.

In light of our additional experience with the Shared Savings Program, our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center, in the August 2018 proposed rule, we indicated that we believe it would be appropriate to amend our regulations related to CEHRT use and the eligibility requirements for ACOs to participate in the Shared Savings Program. Specifically, we proposed to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the Shared Savings Program. Additionally, we proposed that, as a condition of participation in a track, or a payment model within a track, that meets the financial risk standard to be an Advanced APM, ACOs must certify that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold required for Advanced APMs as defined under the Quality Payment Program (§ 414.1415(a)(1)(i)). In conjunction with this proposed new eligibility requirement, we proposed to retire the EHR quality measure (ACO–11) related to CEHRT use, thereby reducing reporting burden, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years. In addition, consistent with our proposal to align with the Advanced APM criterion on use of CEHRT, we proposed to apply the definition of CEHRT under the Quality Payment Program (§ 414.1305), including any subsequent updates to this definition, for purposes of the Shared Savings Program by adding a definition of ''CEHRT'' to § 425.20.

First, we proposed that for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM would have to attest and certify upon application to participate in the Shared Savings Program, and subsequently, as part of the annual certification process, that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. ACOs would be required to submit this certification in the form and manner specified by CMS.

We stated that our proposed requirement aligned with the requirements regarding CEHRT use in many alternative payment models being tested by the Innovation Center. Additionally, we noted that at the time of application, ACOs must have a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§ 425.112(b)(4)(i)(C)). Over the years, successful ACOs have impressed upon us the importance of ''hitting the ground running'' on the first day of their participation in the Shared Savings Program, rather than spending the first year or two developing their care processes. We stated our belief that requiring ACOs that are entering a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM to certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT would align with existing requirements under the Shared Saving Program and many Innovation Center alternative payment models and encourage participation by organizations that are more likely to meet the program goals. In addition, we stated that such a requirement would also promote greater emphasis on the importance of CEHRT use for care coordination. Finally, we noted that in the CY 2019 PFS proposed rule, we had proposed to increase the threshold of

CEHRT use required for APMs to meet criteria for designation as Advanced APMs under the Quality Payment Program to 75 percent (see 83 FR 35990). Given our proposed updates and modifications to the Shared Savings Program tracks in the August 2018 proposed rule, as well as the proposed changes to the requirements regarding CEHRT use under the Quality Payment Program, we explained that we believe it is important that only those ACOs that are likely to be able to meet or exceed the threshold designated for Advanced APMs should be eligible to enter and continue their participation in the Shared Savings Program. Because of this, and also our desire to align requirements across the different payment models and tracks in Shared Savings Program, as explained in more detail later in this section, we also considered whether to propose to require all Shared Savings Program ACOs, including ACOs in tracks or payment models within tracks that would not meet the financial criteria to be designated as Advanced APMs, to meet the 75 percent threshold proposed under the Quality Payment Program.

We proposed changes to the regulations at § 425.204(c) (to establish the new application requirement) and § 425.302(a)(3)(iii) (to establish the new annual certification requirement). We also proposed to add a new provision at § 425.506(f)(1) to indicate that for performance years starting on January 1, 2019, and subsequent performance years, all ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of their eligible clinicians use CEHRT to document and communicate clinical care to their patients or other health care providers. We noted that this proposal, if finalized, would not affect the previously-finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. In other words, MIPS eligible clinicians who are participating in ACOs would continue to report as usual on the Promoting Interoperability performance category. We welcomed comment on these proposed changes. We also sought comment on whether the percentage of CEHRT use should be set at a level higher than 50 percent for ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM given that average ACO performance on the Use of Certified EHR Technology measure (ACO–11) has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements,[38] suggesting that a higher threshold may be warranted now or in the future. We noted that a higher threshold percentage (such as 75 percent) would align with the proposed changes to the CEHRT use requirement under the Quality Payment Program that were included in the CY 2019 PFS proposed rule.

Further, for ACOs in tracks or models that meet the financial risk standard to be Advanced APMs under the Quality Payment Program, we proposed to align the proposed CEHRT use threshold with the criterion on use of CEHRT established for Advanced APMs under the Quality Payment Program. We noted that, although it would be ideal for all ACOs to meet the same CEHRT thresholds to be eligible for participation in the Shared Savings Program, there may be reasons why it may be desirable for ACOs in tracks or payment models within a track that do not meet the financial risk standard for Advanced APMs to have a different threshold requirement for CEHRT use than more sophisticated ACOs that are participating in tracks or payment models that qualify as Advanced APMs under the Quality Payment Program. For example, we noted that in order for an APM to meet the criteria to be an Advanced APM under the Quality Payment Program, it must currently require at least 50 percent of eligible clinicians in each participating APM entity to use CEHRT to document and communicate clinical care to their patients or other health care providers (in addition to certain other criteria). However, as previously noted, in the CY 2019 PFS proposed rule, we proposed to increase this threshold level under the Quality Payment Program to 75 percent of eligible clinicians in each participating Advanced APM entity. Therefore, for performance years starting on January 1, 2019, and subsequent performance years for Shared Savings Program tracks (or payment models within tracks) that meet the financial risk standard to be an Advanced APM, we proposed to align the CEHRT requirement with the Quality Payment Program Advanced APM CEHRT use criterion at § 414.1415(a)(1)(i). Specifically, we proposed that such ACOs would be required to certify that they meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at § 414.1415(a)(1)(i). We stated that requiring these ACOs to meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs would ensure alignment of eligibility requirements across all Shared Savings Program ACOs, while also ensuring that if the CEHRT use criterion for Advanced APMs were higher than 50 percent, those Shared Savings Program tracks (or payment models within a track) that meet the financial risk standard to be an Advanced APM would also meet the CEHRT threshold established under the Quality Payment Program. We anticipated that for performance years starting on January 1, 2019, the tracks (or payment models within tracks) that would be required to meet the CEHRT threshold designated at § 414.1415(a)(1)(i) would include Track 2, Track 3, and the Track 1+ Model, and for performance years starting on July 1, 2019, would include the proposed BASIC track, Level E, and the proposed ENHANCED track. ACOs in these tracks (or a payment model within such a track) would be required to attest and certify that the percentage of the eligible clinicians in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the level of CEHRT use specified under the Quality Payment Program regulation at § 414.1415(a)(1)(i). We noted that although this proposal might cause Shared Savings Program ACOs in different tracks (or different payment models within the same track) to be held to different requirements regarding CEHRT use, we believed it would be appropriate to ensure not only that ACOs that are still new to participation in the Shared Savings Program would not be excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT, but also that eligible clinicians in ACOs further along the risk continuum would have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program.

We proposed to add a new provision to the regulations at § 425.506(f)(2) to

[38] This estimate is based on calculations of primary care physician CEHRT use prior to the changes made to ACO–11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.

establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or a payment model within a track that meets the financial risk standard to be an Advanced APM under the Quality Payment Program. These ACOs would be required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold for CEHRT use by Advanced APMs at § 414.1415(a)(1)(i). We sought comment on this proposal. We also sought comment on whether we should apply the same standard regarding CEHRT use across all Shared Savings Program ACOs, including ACOs participating in tracks or payment models within tracks that do not meet the financial risk standard to be designated as Advanced APMs, specifically Track 1 and the proposed BASIC track, Levels A through D, or maintain the proposed 50 percent requirement for these ACOs as they gain experience on the glide path to performance-based risk.

We stated that, as a part of these proposals to require ACOs to certify that a specified percentage of their eligible clinicians use CEHRT, CMS would reserve the right to monitor, assess, and/or audit an ACO's compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§ 425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§ 425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds. Additionally, we proposed to adopt for purposes of the Shared Savings Program the same definition of ''CEHRT'' as is used under the Quality Payment Program. We proposed to amend § 425.20 to incorporate a definition of CEHRT consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition. Consistent with this proposal and to ensure alignment with the requirements regarding CEHRT use under the Quality Payment Program, we also proposed to amend § 425.20 to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program.

Additionally, we stated that if the proposal to introduce a specified threshold of CEHRT use as an eligibility requirement for participation in the Shared Savings Program is finalized, we believed this new requirement should replace the current ACO quality measure that assesses the Use of Certified EHR Technology (ACO–11). We explained that the proposed new eligibility requirement, which would be assessed through the application process and annual certification, would help to meet the goals of the program and align with the approach used in other MIPS APMs. Moreover, the proposed new requirement would render reporting on the Use of Certified EHR Technology quality measure unnecessary in order for otherwise eligible tracks (and payment models within tracks) to meet the Advanced APM criterion regarding required use of CEHRT under § 414.1415(a)(1)(i). As a result, continuing to require ACOs to report on this measure would impose undue reporting burden on eligible clinicians that meet the QP threshold and would otherwise not be required to report the Promoting Interoperability performance category for purposes of the Quality Payment Program. Therefore, we proposed to remove the Use of Certified EHR Technology measure (ACO–11) from the Shared Savings Program quality measure set, effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We proposed corresponding changes to the regulation at § 425.506. We also reiterated that the removal of the Use of Certified EHR Technology measure (ACO–11) from the quality measure set used under the Shared Savings Program, if finalized, would not affect policies under MIPS for reporting on the Promoting Interoperability performance category and scoring under the APM Scoring Standard for MIPS eligible clinicians in MIPS APMs. In other words, eligible clinicians subject to MIPS (such as eligible clinicians in the proposed BASIC track, Levels A through D, Track 1, and other MIPS eligible clinicians who are required to report on the Promoting Interoperability performance category for purposes of the Quality Payment Program) would continue to report as usual on the Promoting Interoperability performance category. However, data reported for purposes of the Promoting Interoperability performance category under MIPS would not be used to assess the ACO's quality performance under the Shared Savings Program. We welcomed public comment on the proposal to remove the quality measure on Use of Certified EHR Technology (ACO–11) from the Medicare Shared Savings Program measure set, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years.

Finally, as discussed previously in this section, in the CY 2017 Quality Payment Program final rule, CMS finalized a separate Advanced APM CEHRT use criterion that applies for the Shared Savings Program at § 414.1415(a)(1)(ii). To meet the Advanced APM CEHRT use criterion under the Shared Savings Program, a penalty or reward must be applied to an APM Entity based upon the degree of CEHRT use among its eligible clinicians. We believed that this alternative criterion was appropriate to assess the Advanced APM CEHRT use requirement under the Shared Savings Program because, at the time, a specific level of CEHRT use was not required for participation in the program (81 FR 77412).

As we explained in the August 2018 proposed rule (83 FR 41911), our proposal to impose specific CEHRT use requirements on ACOs participating in the Shared Savings Program would eliminate the need for the separate CEHRT use criterion applicable to the Shared Savings Program APMs found at § 414.1415(a)(1)(ii). We noted that if the proposal to incorporate specific requirements regarding the use of CEHRT by Shared Savings Program ACOs were finalized, ACOs seeking to participate in a Shared Savings Program track (or payment model within a track) that meets the financial risk standard to be an Advanced APM would be required to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the percentage specified in the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i). As a result, a separate CEHRT use criterion for APMs under the Shared Savings Program would no longer be necessary.

Therefore, we proposed to revise the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it would apply only for QP Performance Periods under the Quality Payment Program prior to 2019. We sought comment on this proposal.

Comment: Several commenters supported the continued recognition for integration of Electronic Medical Records (EMRs) and the sharing of health information between providers and suppliers.

Response: We thank the commenters for their support.

Comment: A majority of commenters supported our proposal to replace ACO–

11—Use of Certified EHR Technology with a requirement that ACOs certify regarding the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers. In addition, many commenters urged CMS to clarify that MIPS eligible clinician participating in Shared Savings Program ACOs would not be required to report Promoting Interoperability (PI) and would instead see PI performance category weights redistributed equally to the Quality and Improvement Activities performance categories.

Response: As noted in the August 2018 proposed rule (83 FR 41909), the proposal to replace ACO–11: Use of Certified EHR Technology with a requirement that ACOs certify regarding the level of CEHRT use by eligible clinicians in the ACO would not affect any previously finalized requirements for MIPS eligible clinicians reporting on the PI performance category under MIPS. MIPS eligible clinicians who are participating in ACO tracks that are not Advanced APMs and/or who are not QPs would continue to report as usual on the PI performance category.

Comment: Several commenters asked CMS to clarify the proposals for Promoting Interoperability in the August 2018 proposed rule, in the final rule. Specifically, the commenters requested clarification on when complete implementation of the 2015 CEHRT edition was required for ACOs participating in the Shared Savings Program, as the proposal discussed in the August 2018 proposed rule would require an ACO to attest to the percentage of eligible clinicians utilizing CEHRT at the time of application and annually thereafter. The commenters stated that a requirement that they attest to meeting the CEHRT use threshold at the time of application would negatively impact ACOs whose participants make CEHRT decisions (such as upgrades) based on a minimum consecutive 90-day reporting period as set forth by the Quality Payment Program The commenters stated that clarification of the deadline for implementation was needed so healthcare organizations could have a clear understanding of the expectations, allowing them to plan accordingly, especially for those organizations that participate in more than one regulatory program. In addition, several commenters requested that CMS clarify its operational expectations with respect to the proposed new certification requirement, so that ACOs can confirm that they are able to confidently certify with respect to the level of CEHRT use in their ACO.

Response: We understand that ACOs need to know the deadline by which they must meet the proposed new requirements regarding the use of CEHRT and have an understanding of how they would be required to demonstrate that they have met the requirement. As we explained in the August 2018 proposed rule, we believe it is appropriate to ensure that ACOs new to participation in the Shared Savings Program not be excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT. At the same time, however, we also sought to align with the CEHRT use requirements under the Quality Payment Program to ensure that eligible clinicians in ACOs further along the risk continuum would have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. While our proposal was intended to require that ACOs achieve the applicable CEHRT use threshold starting in the 2019 performance year, we understand from commenters that the requirement that ACOs certify that the percentage of eligible clinicians in the ACO that use CEHRT meets the applicable threshold at time of application could pose an operational challenge. For example, a commenter stated that, ACOs not yet operating on 2015 edition CEHRT may have implementation and cost barriers related to the upgrade of CEHRT that may place them in a non-complaint situation, given the short timeframe between the publication of the final rule and the start of performance year 2019.

Based on the comments received in response to the proposals in the August 2018 proposed rule and our desire to align with the Quality Payment Program, under which eligible clinicians must certify regarding their CEHRT use by the last day of the reporting period, we are not finalizing our proposal to require ACOs to certify at the time of application that they meet the applicable CEHRT requirements. However, we are finalizing our proposal to require ACOs to certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage during the current performance year. ACOs will be required to submit this certification in the form and manner specified by CMS for performance years starting on January 1, 2019, and all subsequent performance years. For performance years starting on January 1, 2019, the annual certification will occur in the spring of 2019 for ACOs extending their participation agreement for 6 months, and in the fall of 2019 for ACOs that have a 12-month performance year during 2019. We believe this final policy is not only responsive to commenters' concerns regarding the timing of the certification but also enables timely implementation of the requirement starting in 2019. As noted above, a majority of commenters supported our proposal to replace ACO–11—Use of Certified EHR Technology with a requirement that ACOs certify regarding the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers starting January 1, 2019. We also note that this new requirement aligns more closely with the requirements regarding CEHRT use imposed under the Next Generation ACO Model, which requires that participating ACOs certify compliance with the CEHRT use requirement in the fall of each performance year. As stated in the August 2018 proposed rule, we currently require that ACOs must have in place at the time of application a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§ 425.112(b)(4)(i)(C)). Because this policy is already in place, we believe that our decision not to finalize the proposal to require ACOs to certify with respect to their use of CEHRT at time of application to the Shared Savings Program will not undermine the policies under the program designated to promote and encourage the use of CEHRT.

Although the comments requesting clarification of our CEHRT proposals were not specific regarding the Shared Savings Program track for which they were seeking clarification, in this final rule we are clarifying the CEHRT threshold requirement for ACOs participating in an Advanced APM. Our intent at the time we proposed this policy was to preserve a minimum threshold of 50 percent CEHRT use for all ACOs in the Shared Savings Program, even if the requirement at § 414.1415(a)(1)(i) were revised through future rulemaking to be below 50 percent. However, we now recognize that this proposed ''higher of'' policy generated undue complexity. In the unlikely event that the requirement for CEHRT use at § 414.1415(a)(1)(i) were to be reduced to below 50 percent in the future, we would have the opportunity

to revisit the Shared Savings Program threshold through future rulemaking. Accordingly, we are revising the proposed regulation at § 425.506(f)(2) to remove the reference to the 50 percent threshold and to indicate that ACOs participating in a Shared Savings Program track that meets the financial risk standard to be an Advanced APM, would be required to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the percentage specified in the CEHRT use criterion for Advanced APMs under § 414.1415(a)(1)(i).

Comment: Several commenters suggested modifications to CMS' proposal to require ACOs to certify that the percentage of eligible clinicians in the ACO using CEHRT meets the applicable threshold. Several commenters suggested that CMS delay the implementation of the certification requirement attestation until performance year 2020 to avoid inadvertently penalizing Track 1 ACOs that may not have sufficient time to meet the new CEHRT requirement. Several other commenters expressed concern that meeting the 50 percent CEHRT threshold would be a hardship for ACOs in Track 1, especially ACOs composed of independent physician practices and rural practices. These commenters recommended that CMS not finalize this this new requirement, but if CMS were to finalize the 50 percent threshold, these commenters believed that CMS should extend exemptions to low-revenue ACOs or those ACOs in which the plurality of eligible clinicians qualify for a hardship exemption from the Promoting Interoperability performance category under the MIPS. Another commenter suggested that CMS require ACOs in a track (or payment model within a track) that meets the financial risk standard to be an Advanced APM to meet the 50 percent CEHRT requirement in the first performance year and then increase to 75 percent in the second performance year.

Response: We disagree with the suggestions that we delay implementation of the proposed new CEHRT use requirement or impose differential requirements for ACOs, depending on their performance year or other attributes. Since the inception of the Shared Savings Program in 2012, we have assessed the level of CEHRT use by certain clinicians in ACOs (ACO–11: Use of Certified EHR Technology) as part of the quality reporting requirements for each performance year. In the CY 2017 PFS final rule, we revised the ACO–11 measure to assess ACOs on the degree of CEHRT use by eligible clinicians participating in the ACO in order to align with the Quality Payment Program. Starting in 2017, performance on this measure has been determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Category Base Score. We believe that this experience offers a foundation on which ACOs can build and create processes that allow them to determine the percentage of eligible clinicians participating in the ACO that use CEHRT during an applicable performance year. As noted in the August 2018 proposed rule (83 FR 41909 through 41910), average ACO performance on ACO–11: Use of Certified EHR Technology has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements.[39] As a result, we do not believe it is unreasonable to expect Track 1 ACOs to meet the requirement that 50 percent or more of the eligible clinicians participating in the ACO use CEHRT beginning in the performance year starting on January 1, 2019. Furthermore, as noted above, our proposal to require ACOs to certify that they meet the applicable CEHRT threshold has no impact on the previously-finalized policy that MIPS eligible clinicians participating in ACOs will continue to report on the PI performance category. Under this policy, MIPS-eligible clinicians are required to use the 2015 version of CEHRT for purposes of reporting the promoting interoperability performance category (§ 414.1305). Accordingly, we believe our proposal to require this version to be used by eligible clinicians participating in Shared Savings Program ACOs aligns with existing requirements under the MIPS and does not impose a new requirement on ACOs. Further, we believe our decision not to finalize the requirement that ACOs certify with respect their level of CEHRT use as part of the application process, and to implement the requirement solely through the annual certification during the performance year, will allow additional time for ACOs to update any internal processes as needed in order to meet this requirement during the performance year starting on January 1, 2019. In addition, as noted above, over the years successful ACOs have provided feedback that it is important to ''hit the ground running'' on their first day of participation in the Shared Savings Program, rather than spending several years developing their care processes. Based on this feedback, as well as commenters who supported the CEHRT proposal, we believe it is important to implement the proposed CEHRT use thresholds starting January 1, 2019. We believe that the use of these thresholds to assess CEHRT use by ACOs participating in the Shared Savings Program aligns with existing requirements under the program and encourages participation by organizations that are more likely to meet the program goals.

We received no comments on our proposals to change the regulation at § 425.204(c) to establish the new application requirement and the regulation at § 425.302(a)(3)(iii) to establish the new annual certification requirement. We also received no comments on our proposal to amend § 425.20 to incorporate a definition of ''CEHRT'' consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program. In addition, we received no comments on our proposal to amend the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019. Furthermore, we received no comments on our proposal to add a new provision to the regulation at § 425.506 to establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or payment model within a track that does not meet the financial risk standard to be an Advanced APM and ACOs in a track or payment model within a track that meets the financial risk standard to be an Advanced APM.

After considering the comments received, we are finalizing with modification our proposal that for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. Specifically, we are finalizing

[39] This estimate is based on calculations of CEHRT use by primary care physicians prior to the changes made to ACO–11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.

the requirement that ACOs make this certification annually in the form and manner specified by CMS, but, for the reasons discussed above, we are not finalizing the proposal to require ACOs to make this certification at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that does not meet the financial risk standard to be an Advanced APM must certify annually that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. We reiterate that this final policy does not affect the previously finalized requirements for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. Accordingly, MIPS eligible clinicians who are participating in ACOs under a payment track that is not an Advanced APM and/or who are not QPs would continue to report as usual on the Promoting Interoperability performance category.

Similarly, after considering the comments received, we are also finalizing with modification our proposal with respect to ACOs in Shared Savings Program tracks that meet the financial risk standard to be an Advanced APM. We proposed that these ACOs would be required to certify at the time of application and annually thereafter that they meet the higher of the 50 percent threshold proposed for ACOs in a track that does not meet the financial risk to be an advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at § 414.1415(a)(1)(i).

For the reasons discussed previously, we not finalizing the requirement that ACOs certify that they meet the higher of the 50 percent threshold or the applicable threshold under the Quality Payment Program. Rather, ACOs will be required to certify only that they meet the applicable threshold established under the Quality Payment Program. In addition, as also discussed, we are not finalizing our proposal that ACOs certify that they meet the CEHRT requirement at the time of application. Accordingly, for performance years starting on January 1, 2019, and subsequent years, ACOs in a track that meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under the Quality Payment Program at § 414.1415(a)(1)(i).

We are finalizing the proposed new provision at § 425.506(f) with conforming modifications to reflect the policies we are finalizing in this final rule. As part of these modifications, we are omitting the reference to ''a payment model within a track'' because we are not addressing the proposal to create the BASIC track, with separate payment models at Levels A through E, at this time. We anticipate summarizing and responding to comments received on this proposal and other proposals related to the participation options under the Shared Savings Program in a forthcoming final rule. For the reasons discussed previously in this section, we are not finalizing the proposed changes to the regulation at § 425.204(c) to establish the new application requirement; but, we are finalizing the proposed changes to the regulation at § 425.302(a)(3)(iii) to establish the new annual certification requirement. In addition, we are finalizing our proposed amendments to § 425.20 to incorporate a definition of ''CEHRT'' consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition, and to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program. We are also finalizing our proposal to amend the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019.

As noted in the August 2018 proposed rule (83 FR 41910), CMS reserves the right to monitor, assess, and/or audit an ACO's compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§ 425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§ 425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds.

Finally, after considering the comments received in response to the proposal to remove ACO–11: Use of Certified EHR Technology measure from the Shared Savings Program quality measure set, we are finalizing our proposal effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We are also finalizing the corresponding revisions to the regulation at § 425.506 to reflect this change.

3. Applicability of Final Policies to Track 1+ Model ACOs

a. Background

In the August 2018 proposed rule (83 FR 41912), we discussed the applicability of proposed policies to Track 1+ Model ACOs. We explained that the Track 1+ Model was established under the Innovation Center's authority at section 1115A of the Act, to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. We noted that 55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning on January 1, 2018. This includes 35 ACOs that entered the model within their current agreement period (to complete the remainder of their agreement period under the model) and 20 ACOs that entered into a new 3-year agreement period under the model.

To enter the Track 1+ Model, ACOs must be approved to participate in the model and are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf*. Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with its authority under section 1115A(d)(1) of the Act, CMS has waived certain provisions of law that otherwise would be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model.

We explained that, unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under 42 CFR part 425 continue to apply. Consistent with § 425.212, Track 1+ Model ACOs are subject to all applicable regulatory changes, including but not limited to changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement, that become effective during the term of the ACO's Shared Savings Program Participation Agreement and Track 1+ Model

Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement. We noted that the terms of the Track 1+ Model Participation Agreement permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

b. Unavailability of Application Cycles for Entry Into the Track 1+ Model in 2019

In the August 2018 proposed rule (83 FR 41912 through 41913), we discussed the unavailability of application cycles for entry into the Track 1+ Model in 2019 and 2020. We explained that an ACO's opportunity to join the Track 1+ Model aligns with the Shared Savings Program's application cycle. The original design of the Track 1+ Model included 3 application cycles for ACOs to apply to enter or, if eligible and if applicable, to renew their participation in the Track 1+ Model for an agreement period start date of 2018, 2019, or 2020. The 2018 application cycle is closed, and as discussed elsewhere in the August 2018 proposed rule, 55 ACOs began participating in the Track 1+ Model on January 1, 2018. As discussed in section II.A.7 of the August 2018 proposed rule (83 FR 41847) and section V.B.1.a of this final rule, we are not offering an application cycle for a January 1, 2019 start date for new agreement periods under the Shared Savings Program. Therefore, we similarly are not offering a start date of January 1, 2019, for participation in the Track 1+ Model.

We explained that existing Track 1+ Model ACOs would be able to complete the remainder of their current agreement period in the model. Additionally, as discussed in section II.A.7.c.(1) of the August 2018 proposed rule (83 FR 41854 through 41855) and section V.B.1.c.(1) of this final rule, ACOs currently participating in the Track 1+ Model will not have the opportunity to apply to use a SNF 3-day rule waiver starting on January 1, 2019, under our decision to forgo an annual application cycle for a January 1, 2019 start date in the Shared Savings Program. We proposed that, if finalized, the next available application cycle for a SNF 3-day rule waiver would occur in advance of a July 1, 2019 start date. We will address proposals related to future application cycles in subsequent rulemaking.

c. Applicability of Proposed Policies to Track 1+ Model ACOs Through Revised Program Regulations or Revisions to Track 1+ Model Participation Agreements

In section II.F of the August 2018 proposed rule (83 FR 41913 through 41914), we provided a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs to allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model. We explained that there are two ways in which the proposed policies would become applicable to Track 1+ Model ACOs: (1) Through revisions to existing regulations that currently apply to Track 1+ Model ACOs; and (2) through revisions to the ACO's Track 1+ Model Participation Agreement.

We sought comment on these considerations, and any other issues that we may not have discussed related to the effect of the proposed policies on ACOs that entered the Track 1+ Model beginning in 2018. We note that these ACOs will complete their participation in the Track 1+ Model by no later than December 31, 2020 (for ACOs that entered the model at the start of a 3-year agreement period), or sooner in the case of ACOs that entered the model at the start of their second or third performance year within their current 3-year agreement period.

Generally, comments regarding the application of specific proposals to Track 1+ Model ACOs have been addressed as part of the discussion of comments in the relevant section of this final rule. Accordingly, in this section of this final rule, we are not repeating comments related to the applicability of the proposed policies to ACOs participating in the Track 1+ Model.

Therefore, unless specified otherwise, the changes to the program's regulations finalized in this final rule that are applicable to Shared Savings Program ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or Track 3 have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, changes to the regulations as finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or Track 3. For example, the following policies apply to Track 1+ Model ACOs:

- Revisions to voluntary alignment policies (section V.B.2.b. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Revisions to the definition of primary care services used in beneficiary assignment (section V.B.2.c. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Discontinuation of quality measure ACO–11; requirement to attest as part of the annual certification that a specified percentage of the ACO's eligible clinicians use CEHRT (section V.B.2.f. of this final rule), applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

We will also apply the following policies finalized in this final rule to Track 1+ Model ACOs through an amendment to the Track 1+ Model Participation Agreement executed by CMS and the ACO:

- Annual certification that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under § 414.1415(a)(1)(i) (section V.B.2.f. of this final rule). This certification is required to ensure the Track 1+ Model continues to meet the CEHRT criterion to qualify as an Advanced APM for purposes of the Quality Payment Program.
- For ACOs that started a first or second Shared Savings Program participation agreement on January 1, 2016, and entered the Track 1+ Model on January 1, 2018, and that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019 (as described in section V.B.1 of this final rule):

++ As described in section V.B.1.c.(3) of this final rule, the ACO should extend its repayment mechanism so that it remains in effect for 24 months after the end of the agreement period (June 30, 2021).

++ As described in section V.B.1.c.(10) of this final rule, the ACO is eligible for shared savings if the following conditions are met: The ACO completed the 6-month performance year starting on January 1, 2019; the ACO has completed all close-out procedures specified in § 425.221(a) by the deadline specified by CMS (if applicable); and the ACO has satisfied

the criteria for sharing in savings for the performance year.

++ We will determine performance for the 6-month performance year from January 1, 2019 through June 30, 2019, according to the approach specified in a new section of the regulations at § 425.609(b), applying the financial methodology for calculating shared losses specified in the ACO's Track 1+ Model Participation Agreement.

++ We will continue to share aggregate report data with the ACO for the entire CY 2019, consistent with the approach described in section V.B.1.c.(8) of this final rule, and the terms of the ACO's Track 1+ Model Participation Agreement.

• Extreme and uncontrollable circumstances policies for determining shared losses for performance years 2018 and subsequent years, consistent with the policies specified in § 425.610(i) (section V.B.2.d. of this final rule) and, for ACOs that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, in § 425.609(d) (section V.B.1.c.(5) of this final rule).

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35), we are required to publish a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

We solicited comments in the notice of proposed rulemaking that published in the July 27, 2018 **Federal Register** (83 FR 35704). For the purpose of transparency, we are republishing the discussion of the information collection requirements along with a reconciliation of the public comments we received.

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 60 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Private Sector Wages: The adjusted hourly wage is used to calculate the labor costs associated with our finalized requirements.

TABLE 60—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead costs ($/hr)	Adjusted hourly wage ($/hr)
All Occupations (for Individuals' Wages)	00–0000	24.34	n/a	n/a
Billing and Posting Clerks	43–3021	18.49	18.49	36.98
Computer Systems Analysts	15–1121	44.59	44.59	89.18
Family and General Practitioner	29–1062	100.27	100.27	200.54
Licensed Practical Nurse (LPN)	29–2061	21.98	21.98	43.96
Medical Assistant	31–9092	16.15	16.15	32.30
Medical Secretary	43–6013	17.25	17.25	34.50
Physicians	29–1060	103.22	103.22	206.44
Practice Administrator (Medical and Health Services Managers)	11–9111	53.69	53.69	107.38
Registered Nurse	29–1141	35.36	35.36	70.72

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries who elect to complete the CAHPS for MIPS survey, we believe that the burden will be addressed under All Occupations (see Table 60) at $24.34/hr since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage, we did not adjust this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Clinical Laboratory Fee Schedule (CLFS) (Section III.A. of This Final Rule)

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for clinical diagnostic laboratory test (CDLTs) under the CLFS. The CLFS final rule, titled ''Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule'' (CLFS final rule), was published in the **Federal Register** on June 23, 2016, and implemented section 1834A of the Act. Under that rule (81 FR 41036), ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' (that is, certain private payor data) collected during a ''data collection period'' for their component ''applicable laboratories.'' In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the 6-month data collection period and reported to us during the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the PFS. We refer to this component of the applicable laboratory definition as the ''majority of Medicare revenues threshold.'' The definition of applicable laboratory also includes a ''low expenditure threshold'' component, which requires an entity to receive at least $12,500 of its Medicare revenues

from the CLFS during a data collection period for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In determining payment rates under the private payor rate-based CLFS, one of our goals is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. We believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback in the proposed rule (see section III.A.3 of this final rule for a discussion of this feedback) and in the interest of facilitating our goal, we are finalizing the revision to the majority of Medicare revenues threshold component of the definition of applicable laboratory at § 414.502(3) to exclude Medicare Advantage (MA) payments under Medicare Part C from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). Specifically, this revision could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as applicable laboratories (provided they meet all other requirements for applicable laboratory status) and report data to us.

In addition, in response to stakeholder feedback (see section III.A.4 of this final rule for a discussion of this feedback) in response to the comment solicitation in the proposed rule and in the interest of obtaining as much applicable information as possible, we are finalizing a revision to the definition of applicable laboratory at § 414.502 to include a hospital that bills Medicare on the Form CMS–1450 14x Type of Bill (OMB control number: 0938–0997) and its electronic equivalent.

As such, we believe the finalized changes may result in more applicable information being reported, which we will use to set CLFS payment rates. However, with regard to the CLFS-related requirements and burden, as we noted in the proposed rule, section 1834A(h)(2) of the Act provides that the Paperwork Reduction Act in chapter 35 of title 44 of the U.S.C. shall *not* apply to information collected under section 1834A of the Act (which is the new private payor rate-based CLFS).

For a complete discussion of our finalized revisions to the definition of applicable laboratory in § 414.502 related to the majority of Medicare revenues threshold and use of the Form CMS–1450 14X TOB, we refer readers to sections III.A.4.a of this final rule.

2. ICRs Regarding Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (§ 414.94 and Section III.D. of this final rule)

Consultations: In the CY19 PFS proposed rule, we proposed to revise § 414.94(j) to allow the AUC consultation, when not performed personally by the ordering professional, to be performed by auxiliary personnel (as defined in § 410.26(a)(1)) under the direction of, and incident to, the ordering professional's services. In this final rule, we did not finalize this proposal but, instead, revised the regulation to specify that clinical staff acting under the direction of the ordering professional may perform the AUC consultation. The revised AUC consultation requirements and burden will be submitted to OMB for approval under control number 0938–1345 (CMS–10654).

General practitioners make up a large group of practitioners who order applicable imaging services and will be required to consult AUC under this program so we use ''family and general practitioner'' from the list of BLS occupation titles (see Table 60) to calculate the following cost estimates. While we proposed to modify the consultation requirement to allow auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation, in this final rule we changed this estimate from using the ''registered nurse'' occupation to using the ''medical assistant'' occupation to calculate our revised cost estimates for our final policy to allow clinical staff acting under the direction of the ordering professional to perform the AUC consultation.

To derive the burden associated with the requirements under § 414.94(j), we estimate it will take 2 minutes (0.033 hr) at $70.72/hr for auxiliary personnel in the form of a registered nurse to consult with a qualified CDSM. The Medicare Benefit Policy Manual (Pub. 100–02), Chapter 15, Section 60.2 IOM 100–02, requires that an incidental service performed by the nonphysician practitioner must have followed from a direct, personal, professional service furnished by the physician. Therefore, to estimate the percentage of consultations available to be performed incident to, we analyzed 2014 Medicare Part B claims comparing evaluation and management visits for new (CPT codes 99201, 99202, 99203, 99204, and 99205) relative to established (CPT codes 99211, 99212, 99213, 99214, 99215) patients with place of service codes 11 (physician's office). We found that approximately 10 percent of all claims incurred were for new patients. Therefore, we also estimate that 90 percent or 38,863,636 of the total consultations (43,181,818 total consultations × 0.90) will be performed by such auxiliary personnel, with the remaining 10 percent (43,181,818 × 0.10) performed by the ordering professional. In this final rule and after review of public comments (see below), we revised § 414.94(j) to allow ordering professionals to delegate the AUC consultation to clinical staff acting under the direction of the ordering professional. To reflect this change, we updated our burden estimates to reflect the final policy and revised our estimates to replace a registered nurse with medical assistant to perform the AUC consultation. In aggregate, we estimate an annual burden of 1,282,500 hours (38,863,636.2 consultations × 0.033 hr/consultation) at a cost of $41,424,750 (1,282,500 hr × $32.30/hr) or $1.07 per consultation performed by clinical staff under the direction of the ordering professional. We will continue to monitor our burden estimates and, if necessary, adjust them for more precision once the program begins.

Additionally, the CY 2018 Physician Fee Schedule final rule (82 FR 52976) explicitly discussed and provided a voluntary period for ordering professionals to begin to familiarize themselves with qualified CDSMs. During the current 18-month voluntary participation period, we estimate there may be 10,230,000 consultations based on market research from current applicants for the qualification of their CDSMs for advanced diagnostic imaging services. Based on feedback from CDSMs with experience in AUC consultation, as well as standards recommended by the Office of the National Coordinator (ONC) [40] and the Healthcare Information Management Systems Society (HIMSS),[41] we estimate it will take 2 minutes (0.033 hr) at $200.54/hr for a family and general practitioner or 2 minutes at $32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable

[40] *https://ecqi.healthit.gov/cds#quicktabs-tabs_cds3.*

[41] *http://www.himss.org/improving-outcomes-cds-practical-pearls-new-himss-guidebook.*

AUC. The inclusion of a medical assistant in this calculation is reflective of our modifications in the final rule as discussed above. As mentioned previously, we estimate that as many as 90-percent of practices could use auxiliary personnel working under the direction of the ordering professional to interact with the CDSM for AUC consultation. Consequently, we estimate a total burden of 337,590 hours (10,230,000 consultations × 0.033 hr) at a cost of $16,583,771 ([337,590 hr × 0.10 × $200.54/hr] + [337,590 hr × 0.90 × $32.30/hr]). Annually, we estimate 112,530 hours (337,590 hr/3 yr) at a cost of $5,527,924 ($16,583,771/3 yr). We are annualizing the one-time burden (by dividing our estimates by OMB's 3-year approval period) since we do not anticipate any additional burden after the 18-month voluntary participation period ends.

Beginning January 1, 2020, we anticipate 43,181,818 responses in the form of consultations based on the aforementioned market research, as well as Medicare claims data for advanced diagnostic imaging services. As noted earlier, we estimate it will take 2 minutes (0.033 hr) at $200.54/hr for a family and general practitioner or 2 minutes at $32.30/hr for a medical assistant to use a qualified CDSM to consult specified applicable AUC. In aggregate, we estimate an annual burden of 1,425,000 hours (43,181,818 consultations × 0.033 hr/consultation) at a cost of $70,001,700 ([0.1 × 1,425,000 hr × $200.54/hr] + [0.9 × 1,425,000 hr × $32.30/hr]).

Annual Reporting: Consistent with section 1834(q)(4)(B) of the Act, we finalized at § 414.94(k) the reporting requirement of AUC consultation information and in the CY 2018 PFS final rule (82 FR 52976) we estimated the burden of implementing the one-time voluntary reporting period beginning in July 2018, and will be implementing the mandatory annual reporting requirement beginning January 1, 2020. Specifically, § 414.94(k) requires Medicare claims for advanced diagnostic imaging services, paid for under an applicable payment system (as defined in § 414.94(b)) and ordered on or after January 1, 2020, to include the following information: (1) Which qualified CDSM was consulted by the ordering professional; (2) whether the service ordered would adhere to specified applicable AUC, would not adhere to specified applicable AUC, or whether specified applicable AUC was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional). The reporting requirement will not have any impact on any Medicare claim forms because the forms' currently approved data fields, instructions, and burden are not expected to change. Consequently, there is no need for review by OMB under the authority of the PRA; however, we have assessed the impact and include an analysis to this effect in the regulatory impact section of this final rule.

Significant Hardship Exception: We proposed and are finalizing revisions to § 414.94(i)(3) that provide for a significant hardship exception for ordering professionals who experience a significant hardship affecting their consultation of AUC when ordering an advanced diagnostic imaging service. The revisions establish a process whereby all ordering professionals can self-attest that they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Although this is not a certification being used as a substitute for a collection of AUC consultation information because no consultation is required by statute to take place, the significant hardship exception process consists of appending to the order for an applicable imaging service the significant hardship information for inclusion on the Medicare claim in lieu of the AUC consultation information. This imposes no burden beyond providing identifying information and attesting to the applicable information. In this regard, the use of this process is not ''information'' as defined under 5 CFR 1320.3(h), and therefore, is exempt from requirements of the PRA.

Recordkeeping: Section 1834(q)(4)(C) of the Act provides for certain exceptions to the aforementioned AUC consultation requirement; therefore we believe that some claims for advanced diagnostic imaging services will not contain AUC consultation information, such as in the case of an ordering professional with a significant hardship. However, ordering professionals will store documentation supporting the self-attestation of a significant hardship. Storage of this information could involve the use of automated, electronic, or other forms of information technology at the discretion of the ordering professional. We estimate that the average time for office clerical activities associated with this storage of information to be 10 minutes (0.167 hr) at $34.50/hr for a medical secretary to perform 6,699 recordkeeping actions, since consultation will not take place in the year when a hardship is incurred and 2016 data from the Medicare EHR Incentive Program and the first 2019 payment year MIPS eligibility and special status file suggests this estimate of those seeking hardship (OMB control number 0938–1314; CMS–10621). In aggregate we estimate an annual burden of 1,119 hours (6,699 recordkeeping activities × 0.167 hr/activity) at a cost of $38,596 (0.167 hr/activity × 6,699 recordkeeping activities × $34.50/hr). We solicited comments to inform these burden estimates.

The following is a summary of the comments we received regarding these burden estimates.

Comment: Commenters questioned the assumptions in CMS's calculations as part of the proposal to modify the AUC consultation requirement to allow auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation. These commenters suggested using the ''medical assistant'' rather than the ''registered nurse'' occupation to calculate our revised cost estimates.

Response: As stated in this rule, we have finalized a change in the consulting requirement at 414.94(j) to allow ordering professionals to delegate the consultation to clinical staff acting under the direction of the ordering professional. In aggregate, we update our proposed estimate of an annual burden of 1,282,500 hours at a cost of $90,698,400 or $2.33 per consultation to an annual burden of 1,282,500 hours (38,863,636.2 consultations × 0.033 hr/consultation) at a cost of $41,424,750 (1,282,500 hr × $32.30/hr) or $1.07 per consultation using the medical assistant occupation code 31–9092 with mean hourly wage of $16.15 and 100 percent fringe benefits.

Comment: A few commenters disagreed that the reporting requirement will not have any impact on any Medicare claim forms. These commenters observed that the electronic claim standard for the institutional provider (837i) does not capture or have a placeholder for reporting the ordering physician's NPI.

Response: We appreciate the opportunity to clarify our analysis and the distinctions between reporting AUC consultation information and standardized communications on Medicare claims forms. The X12N insurance subcommittee develops and maintains standards for healthcare administrative transactions on professional (837p), institutional (837i), and dental (837d) transactions when submitting healthcare claims for a service or encounter. The current mandated version of 837 transactions is 5010™. While we have not finalized a process for implementing the reporting requirements at § 414.94(k), we clarify that implementation of changes to the

claim form transactions would not take place outside of the existing process we described.

After considering the comments, we are updating the proposed impact estimate of consultations by ordering professionals. First, we modified our calculation of the effort by a registered nurse to the effort of a 2-minute consultation with a qualified CDSM by a medical assistant (occupation code 31–9092) with mean hourly wage of $16.15 and 100 percent fringe benefits for 90 percent of consultations (1,282,500 hours) to be $41,424,750 (1,282,500 hours × $32.30/hour). Consequently, we have updated our estimated total burden during the voluntary period to 337,590 hours (10,230,000 consultations × 0.033 hr) at a cost of $16,583,771.16 ([337,590 hr × 0.10 × $200.54/hr] + [337,590 hr × 0.90 × $32.30/hr]). Annually, this estimate represents 112,530 hours (337,590 hr/3 yr) at a cost of $5,527,923.72 ($16,583,771.16/3 yr). Additionally, we update our aggregate estimate of annual burden beginning January 1, 2020 of 1,425,000 hours (43,181,818 consultations × 0.033 hr/consultation) at a cost of $70,001,700 ([0.1 × 1,425,000 hr × $200.54/hr] + [0.9 × 1,425,000 hr × $32.30/hr]).

3. ICRs Regarding the Medicare Shared Savings Program (Part 425 and Section III.F. of This Final Rule)

Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the PRA, shall not apply to the Shared Savings Program.

4. ICRs Regarding the Physician Self-Referral Law (42 CFR Part 411 and Section III.G. of This Final Rule)

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Additionally, the statute mandates refunding any amount collected under a bill for an item or service furnished under a prohibited referral. Finally, the statute imposes reporting requirements and provides for sanctions, including civil monetary penalty provisions.

As discussed in section III.G. of this rule, we are finalizing regulatory updates to implement section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018), which added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the physician self-referral law's referral and billing prohibitions. Although we believe that the newly enacted provisions in section 1877(h)(1) of the Act are principally intended merely to codify in statute existing CMS policy and regulations with respect to compliance with the writing and signature requirements, we are finalizing revisions to our regulations at 42 CFR 411.354(e) and 411.353(g) to address any actual or perceived difference between the statutory and regulatory language, to codify in regulation our longstanding policy regarding satisfaction of the writing requirement found in many of the exceptions to the physician self-referral law, and to make the Bipartisan Budget Act of 2018 policies applicable to compensation arrangement exceptions issued using the Secretary's authority in section 1877(b)(4) of the Act. The burden associated with the writing and signature requirements is the time and effort necessary to prepare written documents and obtain signatures of the parties.

Although the writing and signature requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the writing and signature requirements will be incurred by persons during the normal course of their activities and in the absence of federal regulation. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing and signature requirements should be considered usual and customary business practices.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

5. The Quality Payment Program (Part 414 and Section III.I. of This Final Rule)

Summary: For the PRA, the Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs. The MIPS ICRs consist of registration for virtual groups; qualified registry and QCDR self-nomination; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; quality performance category data submission by Medicare Part B claims collection type, QCDR and MIPS CQM collection type, eCQM collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; reweighting applications for Promoting Interoperability and other performance categories; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants. ICRs for Advanced APMs consist of Partial Qualifying APM participant (QP) election; Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer Combination Option.

The following ICRs reflect this final rule's policies, as well as policies in the CY 2017 (81 FR 77008) and CY 2018 (82 FR 53568) Quality Payment Program final rules. In discussing each ICR, we reference the specific policies and whether they are finalized in this final rule or finalized in the CY 2017 or CY 2018 Quality Payment Program final rules. As described in this section in more detail, three ICRs (Quality: CMS Web Interface, Promoting Interoperability Performance Category: Data Submission, and Voluntary Participants Election to Opt-Out of Performance Data Display on Physician Compare) show a reduction in burden due to changes in policies that we are finalizing in this final rule. Most of the burden estimates discussed in this section are reductions in burden compared to currently approved estimates and reflect adjustments due to the use of data from the 2017 MIPS performance period or revised per-respondent burden assumptions. Finally, we added one ICR to incorporate a collection previously mentioned in the CY 2018 Quality

Payment Program final rule for which collection had not yet started: Submission of Data for All-Payer QP Determinations (82 FR 53886). See section V.B.5. of this final rule for a summary of the ICRs, the overall burden estimates, changes in burden estimates due to policies established in this final rule, and a summary of the policy and data changes affecting each ICR.

The revised requirements and burden estimates for all Quality Payment Program ICRs (except for CAHPS for MIPS and virtual groups election) will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). The revised CAHPS for MIPS ICRs will be submitted to OMB for approval under control number 0938–1222 (CMS–10450). The Virtual Groups Election is approved under OMB control number 0938–1343 (CMS–10652).

With regard to Quality Payment Program respondents, we selected BLS occupations Billing and Postal Clerks, Computer Systems Analysts, Physicians, Practice Administrator, and Licensed Practical Nurse (see Wage Estimates in section V.A. of this final rule) based on a study (Casalino et al., 2016) that collected data on the staff in physician's practices involved in the quality data submission process.[42] To calculate the cost for virtual groups to prepare their written formal agreements, we used wage estimates for Legal Support Workers, All Others.

Respondent estimates for the quality, Promoting Interoperability, and improvement activities performance categories are modeled using data from the 2017 MIPS performance period with the sole exception of 286 CMS Web Interface respondents, which is based on the number of groups who registered for using the CMS Web Interface during the 2018 MIPS performance period.

As discussed in section III.I.3.a. of this final rule, we are finalizing with modification our proposal to expand MIPS to additional clinician types starting with the 2019 MIPS performance period/2021 MIPS payment year; these new clinician types include physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals. In addition, in section III.I.3.c. of this final rule, we are finalizing the low-volume threshold in the following manner: If a MIPS eligible clinician meets or exceeds one, but not all, of the low-volume threshold criterion, including as defined by dollar amount ($90,000), beneficiary count (200), or covered professional services to Part-B enrolled individuals (minimum threshold of 200) then the clinician may elect to submit data and opt-in to MIPS. If a MIPS eligible clinician does not meet at least one of these low-volume determinations or meets at least one, but not all, of these low-volume determinations and elects not to opt-in, the clinician is not eligible and is excluded from MIPS. If the clinician is excluded and submits data, the clinician will be a voluntary reporter. These policies will expand the number of potential MIPS eligible clinicians, but we do not anticipate an incremental increase in the burden because the affected clinicians were assumed to be voluntary reporters in prior rules. In the CY 2018 Quality Payment Program final rule, clinicians who participated in 2016 PQRS, and who were not determined to be QPs based on their participation in Advanced APMs during CY 2017 and were not MIPS eligible, were assumed to be voluntary reporters in MIPS (82 FR 53908) with their burden accounted for within our estimates. Therefore, the finalized expansion in MIPS eligibility does not change the total number of respondents, but instead shifts a certain number of assumed voluntary reporters to MIPS eligible clinicians. Additionally, clinicians or groups agreeing to opt-in or voluntarily report will simply select the option of opt-in participation or to remain excluded and voluntarily report prior to submitting data; therefore, we do not believe a commensurate revision to the burden hours is necessary for any of our burden estimates. We realize that clinicians or groups in small practices who submit quality data via Medicare Part B claims do not have to log in the Quality Payment Program portal to submit data; however, we assume the clinicians or groups electing to opt-in would also submit data for the improvement activities performance category as well. Therefore, the effort to elect to opt-in is included in the burden estimate for the improvement activities performance category. We also note that third party intermediaries can be authorized to communicate this opt-in on behalf of clinicians.

Our participation estimates are reflected in Tables 64, 65, and 66 for the quality performance category, Table 77 for the Promoting Interoperability performance category, and Table 79 for the improvement activities performance category.

Due to data limitations, our burden estimates may overstate the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories. This is due to two primary reasons. First, we anticipate the number of QPs to increase because of total expected growth in Advanced APM participation. The additional QPs will be excluded from MIPS and likely not report. Second, it is difficult to predict what eligible clinicians who may report voluntarily will do in the 2019 MIPS performance period compared to the 2017 MIPS performance period and, therefore, the actual number of participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

The following is a summary of general public comments received regarding our request for comment on our information collections and our responses. We received several general comments regarding the burden of data collection associated with the Quality Payment Program.

Comment: One commenter requested CMS provide a table in the Collection of Information section of the final rule consistent with the summary table provided in previous years' final rules which summarizes annual recordkeeping and submission requirements as well as the total burden estimate for the cost of reporting to the Quality Payment Program. The commenter stated its belief that this information is important for policymakers to consider the total cost of pay-for-performance programs in light of the utility of the information collected.

Response: We have provided total burden summary information by OMB control number including the total burden estimate for the cost of reporting to the Quality Payment Program in the table notes for Table 91. For more details, please refer to the Supporting Statement A of the Paperwork Reduction Act package for each OMB control number.

Comment: One commenter noted that based on the burden estimates provided in the proposed rule as well as the additional time spent analyzing feedback data and implementing care improvements, clinicians and their staff are spending too much time and money reporting data and not enough time on patient care. Further, the commenter requested that CMS continue finalizing policies that will reduce administrative burden and make the Quality Payment

[42] Lawrence P. Casalino et al., ''US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures,'' Health Affairs, 35, no. 3 (2016): 401–406.

Program more cohesive, holistic, and simplified.

Response: We will continue refining the Quality Payment Program with the goal of reducing administrative, operational, and reporting burden while balancing the goal of improving quality of care.

After consideration of the public comments, we are not making any changes to our burden estimate methodology, but have updated the burden estimates to reflect the availability of participation data from the 2017 MIPS performance period.

Framework for Understanding the Burden of MIPS Data Submission: Because of the wide range of information collection requirements under MIPS, Table 61 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 61, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 61.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. For the 2019 MIPS performance period, the quality data submitted by Shared Savings Program ACOs, Next Generation ACOs, and other APM Entities on behalf of their participant MIPS eligible clinicians will fulfill any MIPS submission requirements for the quality performance category.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we describe that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Advanced APM participants who are determined to be Partial QPs may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844), but other than the election to participate in MIPS, we do not have data to estimate that burden.

TABLE 61—CLINICIANS OR ORGANIZATIONS SUBMITTING MIPS DATA ON BEHALF OF CLINICIANS, BY TYPE OF DATA AND CATEGORY OF CLINICIAN *

Category of clinician	Type of data submitted			
	Quality performance category	Promoting interoperability performance category	Improvement activities performance category	Other data submitted on behalf of MIPS eligible clinicians
MIPS Eligible Clinicians (not in MIPS APMs) and Other Eligible Clinicians Voluntarily Submitting Data [a].	As group or individual clinicians.	As group or individual clinicians. Clinicians who are hospital-based, ambulatory surgical center-based, non-patient facing, physician assistants, nurse practitioners, clinician nurse specialists, certified registered nurse anesthetists, physical therapists, occupational therapists, qualified speech-language pathologists, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting.	As group or individual clinicians.	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. Virtual groups must register via email.

TABLE 61—CLINICIANS OR ORGANIZATIONS SUBMITTING MIPS DATA ON BEHALF OF CLINICIANS, BY TYPE OF DATA AND CATEGORY OF CLINICIAN *—Continued

Category of clinician	Type of data submitted			
	Quality performance category	Promoting interoperability performance category	Improvement activities performance category	Other data submitted on behalf of MIPS eligible clinicians
Eligible Clinicians participating in the Shared Savings Program or Next Generation ACO Model (both MIPS APMs).	ACOs submit to the CMS Web Interface and CAHPS for ACOs on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates for this final rule because quality data submission to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA].[b]	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [Burden estimates for this final rule assume group TIN-level reporting].[c]	CMS will assign the improvement activities performance category score to each APM Entity group based on the activities involved in participation in the Shared Savings Program.[d] The burden estimates for this final rule assume no improvement activity reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity performance category score.].	Advanced APM Entities will make election for participating MIPS eligible clinicians.
Eligible Clinicians participating in Other MIPS APMs.	APM Entities submit to MIPS on behalf of their participating MIPS eligible clinicians. [These submissions are not included in burden estimates for this final rule because quality data submission for purposes of testing and evaluating Innovation Center models tested under Section 1115A of the Social Security Act (or Section 3021 of the Affordable Care Act) are not subject to the PRA].	Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].	CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM. [The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score].	Advanced APM Entities will make election for participating eligible clinicians.

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

[b] Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state the Shared Savings Program and testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

[c] Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[d] APM Entities participating in MIPS APMs do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

The policies finalized in the CY 2017 and the CY 2018 Quality Payment Program final rules and this final rule create some additional data collection requirements not listed in Table 61. These additional data collections, some of which were previously approved by OMB under the control numbers 0938–1314 (Quality Payment Program) and 0938–1222 (CAHPS for MIPS), are as follows:

Additional approved ICRs related to MIPS third-party intermediaries

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508 and 82 FR 53906 through 53908) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508 and 82 FR 53906 through 53908) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).

Additional ICRs related to the data submission and the quality performance category

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509 and 82 FR 53916 through 53917) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914).

Additional ICRs related to the Promoting Interoperability performance category

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918) (OMB 0938–1314).

Additional ICRs related to call for new MIPS measures and activities

- Nomination of improvement activities (82 FR 53922) (OMB 0938–1314).

• Call for new Promoting Interoperability measures (OMB 0938–1314).

• Call for new quality measures (OMB 0938–1314).

Additional ICRs related to MIPS

• Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925) (OMB 0938–1314).

Additional ICRs related to APMs

• Partial QP Election (81 FR 77512 through 77513 and 82 FR 53922 through 53923) (OMB 0938–1314).

• Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924) (OMB 0938–1314).

• Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924) (OMB 0938–1314).

• Submission of Data for All-Payer QP Determinations (New data collection for the 2019 performance period) (OMB 0938–1314).

6. Quality Payment Program ICRs Regarding the Virtual Group Election (§ 414.1315)

This final rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we have not made any virtual group election changes under that control number.

7. Quality Payment Program ICRs Regarding Third-Party Intermediaries (§ 414.1400)

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as one quality performance category measure, or can be used for completion of an improvement activity, can be submitted via CMS-approved survey vendors. In the CY 2018 Quality Payment Program final rule, we combined the burden for self-nomination of qualified registries and QCDRs (82 FR 53906). For this final rule, we determined that requirements for self-nomination for qualified registries were sufficiently different from QCDRs that it is necessary to estimate the two independently. The change will align the burden more closely to the requirements for QCDRs and qualified registries to self-nominate, not because of any change in policy in this final rule, but because of changes in our initial assumptions. Specifically, while the processes for self-nomination are similar, QCDRs have the option to submit QCDR measures for the quality performance category. Therefore, differences between QCDRs and registries self-nomination are associated with the preparation of QCDR measures for approval. The burden associated with qualified registry self-nomination, QCDR self-nomination, and the CAHPS for MIPS survey vendor applications follow:

Qualified Registry Self-Nomination: The requirements and burden associated with qualified registry self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Qualified registries interested in submitting MIPS data to us on their participants' behalf need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups (82 FR 53815).

In the CY 2018 Quality Payment Program final rule, previously approved qualified registries in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53815). In the same rule, qualified registries in good standing that would like to make minimal changes to their previously approved self-nomination application from the previous year, may submit these changes, and attest to no other changes from their previously approved qualified registry application for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53815). This simplified self-nomination process will begin for the 2019 MIPS performance period.

The CY 2017 Quality Payment Program final rule provided the definition of a qualified registry to be a medical registry, a maintenance of certification program operated by a specialty body of the American Board of Medical Specialties or other data intermediary that, with respect to a particular performance period, has self-nominated and successfully completed a vetting process (as specified by CMS) to demonstrate its compliance with the MIPS qualification criteria specified by CMS for that performance period (81 FR 77382).

For this final rule, we have adjusted the number of respondents (from 120 to 150) based on more recent data and a revised definition of ''respondent'' to account for self-nomination applications received but not approved. We have also adjusted our per respondent time estimate (from 10 hours to 3 hours) based on our review of the current burden estimates against the existing policy. Finally, we have provided a range of time estimates (from 10 hours to 0.5 hours) which reflect the availability of a simplified self-nomination process for previously approved qualified registries.

For the 2017 MIPS performance period, we received 138 applications for nomination to be a qualified registry and 145 applications for the 2018 MIPS performance period. In continuance of this trend for the 2019 MIPS performance period, we estimate 150 nomination applications will be received from qualified registries desiring approval to report MIPS data, an increase of 30 respondents from our currently approved estimate.

For this final rule, the burden associated with qualified registry self-nomination will vary depending on the number of existing qualified registries that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53815). The self-nomination form is submitted electronically using the web-based tool JIRA. For the 2018 MIPS performance period, 141 qualified registries were approved to submit MIPS data.

In section III.I.3.k.(3)(a) of this final rule, we have finalized our proposal to modify the definition of a QCDR to be an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This revised definition of a QCDR may result in previously approved QCDRs who no longer meet the new definition to decide to instead seek approval as qualified registries. However, we have not received any notifications of intent and do not have data to support changing our estimate of 150 qualified registries who will submit applications during the self-nomination period for the CY 2020 performance period.

In the CY 2018 Quality Payment Program final rule, we estimated the burden associated with self-nomination of a qualified registry to be 10 hours, similar to PQRS (82 FR 53907). For this final rule, we reduced our estimate to 3 hours because registries no longer provide an XML submission, calculated measure, or measure flow as part of the

self-nomination process and are not subject to a mandatory interview, which were done previously as part of the PQRS qualified registry self-nomination process, upon which the previous assumption of 10 hours was based. As described in the CY 2017 Quality Payment Program final rule, the full self-nomination process requires the submission of basic information, a description of the process the qualified registry will use for completion of a randomized audit of a subset of data prior to submission, and the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384).

For the simplified self-nomination process, we have estimated 0.5 hours per qualified registry to submit a nomination, a reduction of 9.5 hours from currently approved estimates.

As shown in Table 62, we estimate that the staff involved in the qualified registry self-nomination process will be mainly computer systems analysts or their equivalent, who have an adjusted labor cost of $89.18/hour. Assuming that the time associated with the self-nomination process ranges from a minimum of 0.5 hours (for the simplified self-nomination process) to 3 hours (for the full self-nomination process) per qualified registry, we estimate that the annual burden will range from 97.5 hours ([141 qualified registries × 0.5 hr] + [9 qualified registries × 3 hr]) to 450 hours (150 qualified registries × 3 hr) at a cost ranging from $8,695 (97.5 hr × $89.18/hr) to $40,131 (450 hr × $89.18/hr), respectively (see Table 62).

Independent of the change to our per response time estimate, the increase in the number of respondents results in an adjustment of 300 hours and $26,754 (30 registries × 10 hr × $89.18/hr). Accounting for the change in the number of qualified registries, the change in time per qualified registry to self-nominate results in an adjustment of between −1,402.5 hours and −125,075 ([(141 registries × −9.5 hr)] + [(9 registries × −7 hr)] at $89.18/hr) and −1,050 hours and −$93,639 (150 registries × −7 hr × $89.18/hr). When these two adjustments are combined, the net impact ranges between −1,102.5 (−1,402.5 + 300) and −750 (−1,050 + 300) hours and −$98,321 (−$125,075 + $26,754) and −$66,885 (−$93,639 + $26,754).

Qualified registries must comply with requirements on the submission of MIPS data to CMS. The burden associated with the qualified registry submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the qualified registry by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938–1314 (CMS–10621).

We expect that the time needed for a qualified registry to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the qualified registry and the number of applicable measures. However, we believe that qualified registries already perform many of these activities for their participants. We believe the estimates discussed earlier and shown in Table 62 represents the upper bound of registry burden, with the potential for less additional MIPS burden if the registry already provides similar data submission services.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 62—ESTIMATED BURDEN FOR QUALIFIED REGISTRY SELF-NOMINATION

	Minimum burden	Maximum burden
Number of Qualified Registry Simplified Self-Nomination Applications submitted (a)	141	0
Number of Qualified Registry Full Self-Nomination Applications submitted (b)	9	150
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Qualified Registries (e) = (a) * (c) + (b) * (d)	97.5	450
Cost Per Simplified Process Per Registry (@computer systems analyst's labor rate of $89.18/hr.) (f)	$44.59	$44.59
Cost Per Full Process Per Registry (@computer systems analyst's labor rate of $89.18/hr.) (g)	$267.54	$267.54
Total Annual Cost for Qualified Registries (h) = (a) * (f) + (b) * (g)	$8,695	$40,131

Both the minimum and maximum burden shown in Table 62 will be submitted for approval to OMB under control number 0938–1314 (CMS–10621) and reflect adjustments due to review of self-nomination process and the number of respondents. For purposes of calculating total burden associated with the final rule as shown in Table 89, only the maximum burden is used.

We received no public comments related to the burden estimates for qualified registry self-nomination. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36016 through 36018).

QCDR Self-Nomination:[43] The requirements and burden associated with QCDR self-nomination will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

QCDRs interested in submitting quality, Promoting Interoperability, and improvement activities performance category data to us on their participants' behalf will need to complete a self-nomination process to be considered qualified to submit on behalf of MIPS eligible clinicians or groups.

In the CY 2018 Quality Payment Program final rule, previously approved QCDRs in good standing (that are not on probation or disqualified) that wish to self-nominate using the simplified process can attest, in whole or in part, that their previously approved form is still accurate and applicable (82 FR 53808). Existing QCDRs in good standing that would like to make minimal changes to their previously approved self-nomination application

[43] We do not anticipate any changes in the CEHRT process for health IT vendors as we transition to MIPS. Hence, health IT vendors are not included in the burden estimates for MIPS.

from the previous year, may submit these changes, and attest to no other changes from their previously approved QCDR application, for CMS review during the self-nomination period, from September 1 to November 1 (82 FR 53808). This simplified self-nomination process will begin for the 2019 MIPS performance period.

For this final rule, the burden associated with QCDR self-nomination will vary depending on the number of existing QCDRs that will elect to use the simplified self-nomination process in lieu of the full self-nomination process as described in the CY 2018 Quality Payment Program final rule (82 FR 53808 through 53813). The self-nomination form is submitted electronically using the web-based tool JIRA. For the 2018 MIPS performance period, 150 QCDRs were approved to submit MIPS data.

For this CY 2019 Quality Payment Program final rule, we have adjusted the number of respondents (from 113 to 200) based on more recent data and a revised definition of ''respondent'' to account for self-nomination applications received but not approved. We have also adjusted the time burden estimates per respondent based on our review of the current burden estimates against the existing policy as well as provided a range of time burden estimates which reflect the availability of a simplified self-nomination process for previously approved QCDRs.

For the 2017 MIPS performance period, we received 138 self-nomination applications from QCDRs and for the 2018 MIPS performance period, we received 176 self-nomination applications. In continuance of this trend for the 2019 MIPS performance period, we estimate 200 self-nomination applications will be received from QCDRs desiring approval to report MIPS data, an increase of 87 respondents.

In section III.I.3.k.(3)(a) of this final rule, we have finalized our proposal to modify the definition of a QCDR to be an entity with clinical expertise in medicine and in quality measurement development that collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. This revised definition of a QCDR may result in previously approved QCDRs who no longer meet the new definition to decide to instead seek approval as qualified registries or collaborate with another previously approved QCDR to meet the requirements of the new definition. However, we have not received any notifications of intent and do not have data to support changing our estimate of 200 QCDRs who will submit applications during the self-nomination period for the CY 2020 performance period. In addition, we have not accounted for any costs associated with QCDRs collaborating to meet the requirements of the new definition as electing to do so would be a business decision made by individual entities which is not required or endorsed by CMS and considering the alternate path of seeking to be a qualified registry would be available for entities seeking to continue participating in MIPS.

We estimate that the self-nomination process for QCDRs to submit on behalf of MIPS eligible clinicians or groups for MIPS will involve approximately 3 hours per QCDR to submit information required at the time of self-nomination as described in the CY 2017 Quality Payment Program final rule including basic information about the QCDR, describing the process it will use for completion of a randomized audit of a subset of data prior to submission, providing a data validation plan, and providing results of the executed data validation plan by May 31 of the year following the performance period (81 FR 77383 through 77384). However, for the simplified self-nomination process, we estimate 0.5 hours per QCDR to submit this information. The aforementioned modification to the definition of a QCDR is not expected to affect the estimated time for submitting the full or simplified self-nomination. The self-nomination form is submitted electronically using the web-based tool JIRA.

In addition, QCDRs calculate their measure results. QCDRs must possess benchmarking capabilities (for QCDR measures) that compare the quality of care a MIPS eligible clinician provides with other MIPS eligible clinicians performing the same quality measures. For QCDR measures, the QCDR must provide to us, if available, data from years prior (for example, 2017 data for the 2019 MIPS performance period) before the start of the performance period. In addition, the QCDR must provide to us, if available, the entire distribution of the measure's performance broken down by deciles. As an alternative to supplying this information to us, the QCDR may post this information on their website prior to the start of the performance period, to the extent permitted by applicable privacy laws. The time it takes to perform these functions may vary depending on the sophistication of the entity, but we estimate that a QCDR will spend an additional 1 hour performing these activities per measure and assume that each QCDR will submit information for 9 QCDR measures, for a total burden of 9 hours per QCDR (1 hr per measure $\times$ 9 measures). The estimated average of 9 measures per QCDR is based on the number of QCDR measure submissions received in the 2017 and 2018 MIPS performance periods and is the same for each QCDR regardless of whether they elect to use the simplified or full self-nomination process.

In the 2017 MIPS performance period, we received over 1,000 QCDR measure submissions. In the 2018 MIPS performance period, we received over 1,400 QCDR measure submissions. For the 2019 MIPS performance period, we anticipate this trend will continue, and therefore, estimate we will receive a total of approximately 1,800 QCDR measure submissions, resulting in an average of 9 measure submissions per QCDR (1,800 measure submissions/200 QCDRs).

In the CY 2018 Quality Payment Program final rule, the burden associated with self-nomination of a QCDR was estimated to be 10 hours (82 FR 53907). For this final rule, we are increasing the burden associated with self-nomination to 12 hours. Because QCDRs are no longer required to provide an XML submission and are not subject to a mandatory interview; both of which were completed as part of the PQRS QCDR self-nomination process upon which the previous assumption of 10 hours was based, we are eliminating 1 hour from our previous burden assumption. Simultaneously, we are increasing our burden assumption by 3 hours to account for an increase in the number of QCDR measure submissions being submitted. These two adjustments result in a net increase of 2 hours per respondent from our previously approved burden estimates.

As shown in Table 63, we estimate that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor cost of $89.18/hr. Assuming that the hours per QCDR associated with the self-nomination process ranges from a minimum of 9.5 hours (for the simplified self-nomination process) to 12 hours (for the full self-nomination process), we estimate that the annual burden will range from 2,025 hours ([150 QCDRs $\times$ 9.5 hr] + [50 QCDRs $\times$ 12 hr]) to 2,400 hours (200 QCDRs $\times$ 12 hr) at a cost ranging between $180,590 (2,025 hr $\times$ $89.18/hr) and $214,032 (2,400 hr $\times$ $89.18/hr), respectively (see Table 63).

Independent of the change to our per response time estimate, the increase in the number of respondents results in an

adjustment of 870 hours and $77,587 (87 registries × 10 hr × $89.18/hr). Accounting for the change in the number of qualified registries, the change in time per QCDR to self-nominate results in an adjustment of between 25 hours and $2,230 ([150 registries × −0.5 hr] + [50 registries × 2 hr] at $89.18/hr) and 400 hours and $35,672 (200 registries × 2 hr × $89.18/hr). When these two adjustments are combined, the net impact ranges between 895 (870 + 25) hours at $79,817 ($77,587 + $2,230) and 1,270 (870 + 400) hours at $113,259 ($77,587 + $35,672).

QCDRs must comply with requirements on the submission of MIPS data to CMS. The burden associated with the QCDR submission requirements will be the time and effort associated with calculating quality measure results from the data submitted to the QCDR by its participants and submitting these results, the numerator and denominator data on quality measures, the Promoting Interoperability performance category, and improvement activities data to us on behalf of their participants. These requirements are currently approved by OMB under control number 0938–1314 (CMS–10621). We expect that the time needed for a QCDR to accomplish these tasks will vary along with the number of MIPS eligible clinicians submitting data to the QCDR and the number of applicable measures. However, we believe that QCDRs already perform many of these activities for their participants. We believe the estimate noted in this section represents the upper bound of QCDR burden, with the potential for less additional MIPS burden if the QCDR already provides similar data submission services.

We finalized in the CY 2018 Quality Payment Program final rule that QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR (82 FR 53813). However, some QCDR measure stewards charge a fee for the use of their QCDR measures. We have not accounted for QCDR measure licensing costs as part of our burden estimate due to the election to license a QCDR measure being a business decision made by individual QCDRs which is not required or endorsed by CMS for participation in MIPS.

Based on the assumptions previously discussed, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 63—ESTIMATED BURDEN FOR QCDR SELF-NOMINATION

	Minimum burden	Maximum burden
Number of QCDR Simplified Self-Nomination Applications submitted (a)	150	0
Number of QCDR Full Self-Nomination Applications submitted (b)	50	200
Total Annual Hours Per QCDR for Simplified Process (c)	9.5	9.5
Total Annual Hours Per QCDR for Full Process (d)	12	12
Total Annual Hours for QCDRs (e) = (a) * (c) + (b) * (d)	2,025	2,400
Cost Per Simplified Process Per QCDR (@computer systems analyst's labor rate of $89.18/hr.) (f)	$847.21	$847.21
Cost Per Full Process Per QCDR (@computer systems analyst's labor rate of $89.18/hr.) (g)	$1,070.16	$1,070.16
Total Annual Cost for QCDRs (h) = (a) * (f) + (b) * (g)	$180,590	$214,032

Both the minimum and maximum burden shown in Table 63 will be submitted for approval to OMB under control number 0938–1314 (CMS–10621) and reflect adjustments due to the review of self-nomination process and the number of respondents. For purposes of calculating total burden associated with the final rule as shown in Table 89, only the maximum burden will be used.

We received no public comments related to the burden estimates for QCDR self-nomination. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36018 through 36019), however we have provided additional elaboration on the updated requirements for QCDRs electing to self-nominate and our rationale for why the burden estimates do not require additional revision.

CMS-Approved CAHPS for MIPS Survey Vendors: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to CMS-approved CAHPS for MIPS survey vendors. The CMS-approved CAHPS for MIPS survey vendor requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we have not made any MIPS survey vendor changes under that control number.

8. Quality Payment Program ICRs Regarding Data Submission (§§ 414.1325 and 414.1335)

Under our current policies, two groups of clinicians will submit quality data under MIPS: Those who submit as MIPS eligible clinicians and other eligible clinicians who opt to submit data voluntarily but will not be subject to MIPS payment adjustments. Although the finalized expansion of the definition of a MIPS eligible clinician to new clinician types and the opt-in process for MIPS participation discussed in sections III.I.3.a and III.I.3.c.(6) of this final rule could affect respondent counts, all of the new potential respondents had the opportunity to participate in PQRS and as a voluntary reporter in MIPS. Therefore, consistent with our assumptions in the CY 2017 and CY 2018 Quality Payment Program final rules that PQRS participants that are not QPs will have participated in MIPS as voluntary respondents (81 FR 77501 and 82 FR 53908, respectively), we anticipate that this rule's finalized expansion of the definition of a MIPS eligible clinician will not have any incremental effect on any of our currently approved burden estimates. For the purpose of the following analyses, we assume that clinicians who participated in MIPS and who are not QPs in Advanced APMs in the 2017 MIPS performance period will continue to submit quality data in the 2019 MIPS performance period. We assume that 100 percent of APM Entities in MIPS APMs will submit quality data to CMS as required under their models. We estimate a total of 964,246 clinicians participated as individuals or groups in the 2017 MIPS performance period; this number differs from the currently approved estimate (OMB 0938–1314, CMS–10621) of 758,267 due to the availability of updated data.

As discussed in section III.I.3.h.(1)(b) of this final rule, we are replacing the term ''submission mechanism'' with the terms ''collection type'' and ''submission type.'' ''Submission mechanism'' is presently used to refer not only to the mechanism by which data is submitted, but also to certain types of measures and activities on which data are submitted to the entities submitting such data in the Quality Payment Program.

We assume that clinicians and groups will continue to submit quality data for the same collection types they used during the CY 2017 performance period. In addition, we assume that the 80 TINs that elect to form 16 virtual groups will continue to collect and submit MIPS data using the same collection and submission types as they did during the 2017 MIPS performance period, but the submission will be at the virtual group, rather than group level. Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their models. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[44] Tables 64, 65, and 66 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 64 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2019 MIPS performance period based on data from the 2017 MIPS performance period.

For the 2019 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and CMS Web Interface. At the time of the CY 2019 PFS proposed rule, participation data by submission type and user research data to inform burden assumptions was not available to estimate burden by submission type. As a result, we estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. While we have more information about MIPS submissions, for this final rule, we believe it is important to continue to estimate burden by collection type because the public was able to comment on our assumptions using this framework. As we gain more experience with the program, we may revise this approach through future rulemaking.

For the Medicare Part B claims collection type, in section III.I.3.h.(1)(b) of this rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals. We assumed in our currently approved burden analysis that any clinician that submits quality data codes to us for the Medicare Part B claims collection type is intending to do so for the Quality Payment Program. We made this assumption originally in the CY 2017 Quality Payment Program final rule to ensure that we fully accounted for any burden that may have resulted from our policies (81 FR 77501 through 77504). In some cases, however, clinicians may be submitting quality data codes not only for the Medicare Part B claims collection type, but also for MIPS CQM and QCDR collection types. Some registries and QCDRs utilize data from claims to populate their datasets when submitting on behalf of clinicians. We are not able to separate out when a clinician submits a quality data code solely for the Medicare Part B claim collection type or when a clinician is also submitting these codes for MIPS CQM or QCDR collection types. In addition, we see a large number of voluntary reporters for the Medicare Part B claims collection type. Approximately 70 percent of the 257,260 clinicians we estimate will submit quality data via Medicare Part B claims (see Table 64) are MIPS eligible clinicians while the other 30 percent are voluntary reporters which means our burden include estimates for a large number of voluntary reporters. Of these clinicians who are not scored as part of an APM, approximately 55 percent are in practices with more than 15 clinicians; however, over 91 percent of the number in practices larger than 15 clinicians are either voluntary reporters, group reporters, or are also reporting quality data through another collection type. Approximately 10,700 individual clinicians in non-small practices are both MIPS eligible and scored based only on Medicare Part B claims data and of these, 52 percent also qualify for facility-based reporting, and therefore, will not be required to submit quality data in order to receive facility-based quality and cost scores. It is unclear why many clinicians are submitting quality data via an alternate collection type, and we currently lack data to accurately estimate both the number of clinicians who will be impacted by these finalized policies and the potential behavioral response of those clinicians who will be required to switch to another collection type. As a result, we will continue using the assumption that all clinicians (except QPs) who submitted data via the Medicare Part B claims collection type in the 2017 MIPS performance period will continue to do so for MIPS in order to avoid overstating the impact of the change. We intend to update this burden estimate with additional data as it becomes available. We solicited comment on potential other assumptions for capturing the Medicare Part B claims burden, but no comments were received.

Using our revised terminology, clinicians who used a QCDR or Registry will now collect measures via QCDR or MIPS CQM collection type; clinicians who used the EHR submission type will elect the eCQM collection type, and groups that elected the CMS Web Interface for MIPS will continue to elect the CMS Web Interface for MIPS.

Table 64 shows that in the 2019 MIPS performance period, an estimated 257,260 clinicians will submit data as individuals for the Medicare Part B claims collection type; 324,693 clinicians will submit data as individuals or as part of groups for the MIPS CQM or QCDR collection types; 243,062 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 139,231 clinicians will submit as part of groups via the CMS Web Interface.

Table 64 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

[44] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their models.

TABLE 64—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 3 (excludes QPs) (a)	257,260	324,693	243,062	139,231	964,246
*Number of clinicians to collect data by collection type (as individual clinicians or groups) in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	255,228	131,133	93,867	758,267
Difference between Year 3 and Year 2 (c) = (a) − (b)	−20,779	+69,465	+111,929	+45,364	+205,979

*Currently approved by OMB under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule (82 FR 53625 through 53626), beginning with the 2019 MIPS performance period, we allowed MIPS eligible clinicians to submit data for multiple collection types for a single performance category. Therefore, we captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types. Hence, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the MIPS 2017 performance period.

Table 65 uses methods similar to those described for Table 64 to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the 2019 MIPS performance period. We estimate that approximately 257,260 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 71,439 clinicians will submit data as individuals using MIPS CQMs or QCDR collection types; and approximately 47,557 clinicians will submit data as individuals using eCQMs collection type.

TABLE 65—ESTIMATED NUMBER OF CLINICIANS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA AS INDIVIDUALS BY COLLECTION TYPE

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of Clinicians to submit data as individuals in Quality Payment Program Year 3 (excludes QPs) (a)	257,260	71,439	47,557	0	376,256
*Number of Clinicians to submit data as individuals in Quality Payment Program Year 2 (excludes QPs) (b)	278,039	104,281	52,709	0	435,029
Difference between Year 3 and Year 2 (c) = (a) − (b)	−20,779	−32,842	−5,152	0	−58,773

*Currently approved by OMB under control number 0938–1314 (CMS–10621).

To be consistent with the policy in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points. Therefore, our columns in Table 65 are not mutually exclusive.

Table 66 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2019 MIPS performance period and reflects our assumption that the formation of virtual groups will reduce burden. We assume that groups that submitted quality data as groups in the 2017 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2019 MIPS performance period. First, we estimated the number of groups or virtual groups that will collect data via each collection type during the 2019 MIPS performance period using data from the 2017 MIPS performance period. The second and third steps in Table 66 reflect our currently approved assumption that virtual groups will reduce the burden for quality data submission by reducing the number of organizations that will submit quality data on behalf of clinicians. We assume that 40 groups that previously collected on behalf of clinicians via QCDR or MIPS CQM collection types will elect to form 8 virtual groups that will collect via QCDR and MIPS CQM collection types. We assume that another 40 groups that previously collected on behalf of clinicians via eCQM collection types will elect to form another 8 virtual groups that will collect via eCQM collection types. Hence, the second step in Table 66 is to subtract out the estimated number of groups under each collection type that will elect to form virtual groups, and the third step in Table 66 is to add in the estimated number of virtual groups that will submit on behalf of clinicians for each collection type.

Specifically, we assume that 10,542 groups and virtual groups will submit data for the QCDR or MIPS CQM collection types on behalf of 253,254 clinicians; 4,304 groups and virtual groups will submit for eCQM collection types on behalf of 195,505 eligible clinicians; and 286 groups will submit data via the CMS Web Interface on behalf of 139,231 clinicians. Because we are using 2017 MIPS performance period participation data to estimate participation for the 2019 MIPS performance period, our estimates do not account for the finalized policy to allow only groups that meet the definition of a small practice to submit quality data via the Medicare Part B claims collection type. Due to a lack of

historic data identifying which clinicians in small practices would want to submit via the Medicare Part B claims collection type and elect to be measured as part of a group, we continue to assume these clinicians submitting Medicare Part B claims will participate as individuals but will review this assumption for future performance periods.

TABLE 66—ESTIMATED NUMBER OF GROUPS AND VIRTUAL GROUPS SUBMITTING QUALITY PERFORMANCE CATEGORY DATA BY COLLECTION TYPE ON BEHALF OF CLINICIANS

	Medicare Part B claims	QCDR/MIPS CQM	eCQM	CMS web interface	Total
Number of groups to collect data by collection type (on behalf of clinicians) in Quality Payment Program Year 3 (excludes QPs) (a)	0	10,574	4,336	286	15,196
Subtract out: Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (b)	0	40	40	0	80
Add in: Number of virtual groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (c)	0	8	8	0	16
Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 3 (d) = (a) − (b) + (c)	0	10,542	4,304	286	15,132
*Number of groups to collect data by collection type on behalf of clinicians in Quality Payment Program Year 2 (e)	0	2,936	1,509	296	4,741
Difference between Year 3 and Year 2 (f) = (d) − (e)	0	+7,606	+2,795	−10	+10,391

*Currently approved by OMB under control number 0938–1314 (CMS–10621).

The burden estimates associated with submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' work flows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2019 MIPS performance period, the total number of quality measures will be 257. These measures are stratified by collection type in Table 67, as well as counts of new, removed, and substantively changed measures.

TABLE 67—SUMMARY OF QUALITY MEASURES FOR THE 2019 MIPS PERFORMANCE PERIOD

Collection type	Number of measures finalized as new	Number of measures finalized for removal	Number of measures finalized with a substantive change	Number of measures remaining for CY 2019
Medicare Part B Claims Specifications	0	7	1	64
MIPS CQMs Specifications	6	21	0	233
eCQM Specifications	2	6	0	50
Survey—CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	1	4	10
Administrative Claims	0	0	0	1
Total	8	*26	5	*257

*A measure may be applicable to more than one collection type but will only be counted once in the total.

For the 2019 MIPS performance period, there is a net reduction of 18 quality measures across all collection types. We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups.

Quality Payment Program Identity Management Application Process: The requirements and burden associated with the application process will be

submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2018 Quality Payment Program final rule, the time associated with the Identity Management Application Process was described as ''Obtain Account in CMS-Specified Identity Management System'' and included in the ICR for Quality Data Submission by Clinicians and Groups: EHR Submission for a total burden of 54,218 hours (1 hr × 54,218 respondents) (82 FR 53914). After our review of the quality data submission process, we determined the burden associated with the application process (3,741 hours) should be accounted for in a separate ICR. Our per respondent burden estimate remains unchanged at 1 hour per response.

For an individual, group, or third-party to submit MIPS quality, improvement activities, or Promoting Interoperability performance category data using either the log in and upload or the log in and attest submission type or to access feedback reports, the submitter must have a CMS Enterprise Portal user account. Once the user account is created, registration is not required again for future years.

Based on the number of new TINs registered in the 2017 MIPS performance period, we estimate 3,741 eligible clinicians, groups, or third-parties will register for new accounts for the 2019 MIPS performance period. As shown in Table 68, it will take 1 hour at $89.18/hr for a computer systems analyst (or their equivalent) to obtain an account for the CMS Enterprise Portal. In aggregate, we estimate an annual burden of 3,741 hours (3,741 registrations × 1 hr/registration) at a cost of $333,622 (3,741 hr × $89.18/hr) or $89.18 per registration.

TABLE 68—ESTIMATED BURDEN FOR QUALITY PAYMENT PROGRAM IDENTITY MANAGEMENT APPLICATION PROCESS

	Burden estimate
Number of New TINs completing the Identity Management Application Process (a)	3,741
Total Hours Per Application (b)	1
Total Annual Hours for completing the Identity Management Application Process (c) = (a) * (b)	3,741
Cost Per Application @ computer systems analyst's labor rate of $89.18/hr.) (d)	$89.18
Total Annual Cost for completing the Identity Management Application Process (e) = (a) * (d)	$333,622

We received no public comments related to the burden estimates for the Identity Management Application Process. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36022 through 36023).

Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type: The requirements and burden associated with clinicians' Medicare Part B claims-based data submissions will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Table 64, based on 2017 MIPS performance period data, we assume that 257,260 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. We continue to anticipate that the Medicare Part B claims submission process for MIPS is operationally similar to the way the claims submission process functioned under the PQRS. Specifically, clinicians will need to gather the required information, select the appropriate QDCs, and include the appropriate QDCs on the Medicare Part B claims they submit for payment. Clinicians will collect QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved by OMB under control number 0938–1197. This final rule's provisions do not necessitate the revision of either form.

In this final rule, we have adjusted the number of respondents based on more recent data and adjusted our per respondent time estimates so that they correctly align with the number of required measures for which MIPS data must be submitted (6 measures) in comparison to the number of measures previously required under PQRS (9 measures).

The total estimated burden of Medicare Part B claims-based submission will vary along with the volume of Medicare Part B claims on which the submission is based. Based on our experience with PQRS, we estimate that the burden for submission of MIPS quality data will range from 0.15 to 7.2 hours per clinician, a reduction from the range of 0.22 to 10.8 hours as set out in the CY 2018 Quality Payment Program final rule (82 FR 53912). In the same rule, the 33 percent reduction in the number of measures (from 9 to 6) was erroneously omitted from our burden calculations; it is reflected in this final rule's burden estimates. The wide range of estimates for the time required for a clinician to submit quality measures via Medicare Part B claims reflects the wide variation in complexity of submission across different clinician quality measures. As shown in Table 69, we estimate that the cost of quality data submission using Medicare Part B claims will range from $13.38 (0.15 hr × $89.18/hr) to $642.10 (7.2 hr × $89.18/hr). The burden will involve becoming familiar with MIPS data submission requirements. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $107.38/hr for a practice administrator, 1 hour at $206.44/hr for a clinician, 1 hour at $43.96/hr for an LPN/medical assistant, 1 hour at $89.18/hr for a computer systems analyst, and 1 hour at $36.98/hr for a billing clerk.

The estimate for reviewing and incorporating measure specifications for the claims collection type is higher than that of QCDRs/Registries or eCQM collection types due to the more manual, and therefore, more burdensome nature of claims measures.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual burden ranges from 1,819,082 hours (7.15 hr × 254,417 clinicians) to 3,612,721 hours (14.2 hr × 254,417 clinicians). The estimated annual cost (per clinician) ranges from $712.08 ($13.38 + $322.14 + $89.18 + $43.96 + $36.98 + $206.44) to a maximum of $1,340.80 ($642.10 + $322.14 + $89.18 + $43.96 + $36.98 + $206.44). The total annual burden ranges from a minimum

of $183,189,701 (257,260 clinicians × $712.08) to a maximum of $344,934,208 (257,260 clinicians × $1,340.80).

Table 69 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

Independent of the change in the number of respondents, the change in estimated time per clinician results in a burden adjustment of between −19,463 hours at −$1,860,081 (278,039 clinicians × −0.07 hr × $89.18/hr) and −1,000,941 hours at −$89,261,641 (278,039 clinicians × −3.6 hr × $89.18/hr). Accounting for the change in the time burden per respondent, the decrease in number of respondents results in a total adjustment of between −148,713 hours at −$14,810,552 (−20,799 respondents × $712.08/respondent) and −295,346 hours at −$27,887,299 (−20,779 respondents × $1,340.80/respondent). When these two adjustments are combined, the net adjustment ranges between −168,176 (−19,463 −148,713) hours at −$16,670,633 (−$1,860,081 −$14,810,552) and −1,296,287 (−1,000,941 −295,346) hours at −$117,148,940 (−$89,261,641 −$27,887,299).

TABLE 69—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS USING THE MEDICARE PART B CLAIMS COLLECTION TYPE

	Minimum burden	Median burden	Maximum burden estimate
Number of Clinicians (a)	257,260	257,260	257,260
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
Number of Hours Practice Administrator Review Measure Specifications (c)	3	3	3
Number of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
Number of Hours LPN Review Measure Specifications (e)	1	1	1
Number of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
Number of Hours Clinician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2
Total Annual Hours (i) = (a) * (h)	1,839,409	2,070,943	3,653,092
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $89.18/hr.) (j)	$13.38	$93.64	$642.10
Cost to Review Measure Specifications (@ practice administrator's labor rate of $107.38/hr.) (k)	$322.14	$322.14	$322.14
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $89.18/hr.) (l)	$89.18	$89.18	$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of $43.96/hr.) (m)	$43.96	$43.96	$43.96
Cost to Review Measure Specifications (@ billing clerk's labor rate of $36.98/hr.) (n)	$36.98	$36.98	$36.98
Cost to Review Measure Specifications (@ physician's labor rate of $206/44/hr.) (o)	$206.44	$206.44	$206.44
Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$712.08	$792.34	$1,340.80
Total Annual Cost (q) = (a) * (p)	$183,189,701	$203,837,388	$344,934,208

We received no public comments related to the burden estimates for quality performance category: Clinicians using the Medicare Part B claims collection type. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36023 through 36024).

Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types: This final rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to this CQM and QCDR collection types. However, we have adjusted the number of respondents based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 64, 65, and 66, and based on 2017 MIPS performance period data, we assume that 324,693 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types. Of these, we expect 71,439 clinicians, as shown in Table 65, will submit as individuals and 10,542 groups, as shown in Table 66, are expected to submit on behalf of the remaining 253,254 clinicians. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS submission requirements and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $858.86. This consists of 3 hours at $89.18/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $107.38/hr for a practice administrator, 1 hour at $89.18/hr for a computer systems analyst, 1 hour at $43.96/hr for a LPN/medical assistant, 1 hour at $36.98/hr for a billing clerk, and 1 hour at $206.44/hr for a clinician to review measure specifications. Additionally, clinicians and groups will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We

estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) per clinician or group (respondent) for a cost of $7.40 (0.083 hr × $89.18/hr for a computer systems analyst).

In aggregate, we estimate an annual burden of 744,633 hours (9.083 hr/response × 81,981 groups plus clinicians submitting as individuals) at a cost of $71,016,861 (81,981 responses × $866.26/response). The decrease in number of respondents results in a total adjustment of −229,219 hours at −$21,860,937 (−25,236 respondents × $866.26/respondent). Based on these assumptions, we have estimated in Table 70 the burden for these submissions.

TABLE 70—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP) USING THE MIPS CQM/QCDR COLLECTION TYPE

	Burden estimate
Number of clinicians submitting as individuals (a)	71,439
Number of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	10,542
Number of Respondents (groups plus clinicians submitting as individuals) (c) = (a) + (b)	81,981
Hours Per Respondent to Report Quality Data (d)	3
Number of Hours Practice Administrator Review Measure Specifications (e)	2
Number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Number of Hours LPN Review Measure Specifications (g)	1
Number of Hours Billing Clerk Review Measure Specifications (h)	1
Number of Hours Clinician Review Measure Specifications (i)	1
Number of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083
Annual Hours Per Respondent (k) = (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083
Total Annual Hours (l) = (c) * (k)	744,633
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $89.18/hr.) (m)	$267.54
Cost to Review Measure Specifications (@ practice administrator's labor rate of $107.38/hr.) (n)	$214.76
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $89.18/hr.) (o)	$89.18
Cost LPN Review Measure Specifications (@ LPN's labor rate of $43.96/hr.) (p)	$43.96
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $36.98/hr.) (q)	$36.98
Cost Clinician Review Measure Specifications (@ physician's labor rate of $206.44/hr.) (r)	$206.44
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $89.18/hr.) (s)	$7.40
Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$866.26
Total Annual Cost (u) = (c) * (t)	$71,016,861

We received no public comments related to the burden estimates for quality performance category: Clinicians using the MIPS CQM/QCDR collection type. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36024 through 36025).

Quality Data Submission by Clinicians and Groups: eCQM Collection Type: This final rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the eCQM collection type. However, we have adjusted the number of respondents based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As noted in Tables 64, 65, and 66, based on 2017 MIPS performance period data, we assume that 243,062 clinicians will elect to use the eCQM collection type; 47,557 clinicians are expected to submit eCQMs as individuals; and 4,304 groups are expected to submit eCQMs on behalf of the remaining 195,505 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

In the CY 2018 Quality Payment Program final rule, the time required for users to obtain an account for the CMS Enterprise Portal was included in this Quality Data Submission by Clinicians and Groups: eCQM Collection Type ICR (82 FR 53914). However, in this final rule, we are finalizing a separate ICR for this activity (now described as the Quality Payment Program Identity Management Application Process; see Table 68) and therefore, reduce (by 1 hour) our per respondent burden estimate for this ICR commensurately. We have also adjusted the number of respondents based on more recent data.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a health IT vendor to submit the data to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to the CMS-designated clinical data warehouse or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to the CMS-designated clinical data warehouse.

We continue to estimate that it will take no more than 2 hours at $89.18/hr for a computer systems analyst to submit the actual data file. The burden

will also involve becoming familiar with MIPS submission. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $107.38/hr for a practice administrator, 1 hour at $206.44/hr for a clinician, 1 hour at $89.18/hr for a computer systems analyst, 1 hour at $43.96/hr for a LPN/medical assistant, and 1 hour at $36.98/hr for a billing clerk.

In aggregate we estimate an annual burden of 414,888 hours (8 hr × 51,861 groups and clinicians submitting as individuals) at a cost of $39,916,374 (51,861 responses × $769.68/response) (see Table 71).

Independent of the change in the number of respondents, removing the time burden associated with completing the Quality Payment Program Identity Management Application Process results in an adjustment to the total burden of −54,218 hours and −$4,835,161 (54,218 respondents × −1 hr × $89.18/hr). Accounting for the change in the per respondent time estimate, the decrease in number of respondents results in a total adjustment of −18,856 hours at −$1,814,136 (−2,357 respondents × $769.68/respondent). When these two adjustments are combined, the net adjustment is −73,074 (−54,218–18,856) hours at −$6,649,297 (−$4,835,161–$1,814,136).

TABLE 71—ESTIMATED BURDEN FOR QUALITY PERFORMANCE CATEGORY: CLINICIANS (SUBMITTING INDIVIDUALLY OR AS PART OF A GROUP) USING THE eCQM COLLECTION TYPE

	Burden estimate
Number of clinicians submitting as individuals (a)	47,557
Number of Groups submitting via EHR on behalf of individual clinicians (b)	4,304
Number of Respondents (groups and clinicians submitting as individuals) (c) = (a) + (b)	51,861
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
Number of Hours Practice Administrator Review Measure Specifications (e)	2
Number of Hours Computer Systems Analyst Review Measure Specifications (f)	1
Number of Hours LPN Review Measure Specifications (g)	1
Number of Hours Billing Clerk Review Measure Specifications (h)	1
Number of Hours Clinicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8
Total Annual Hours (k) = (c) * (j)	414,888
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $88.10/hr.) (l)	$178.36
Cost to Review Measure Specifications (@ practice administrator's labor rate of $105.16/hr.) (m)	$214.76
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $88.10/hr.) (n)	$89.18
Cost to Review Measure Specifications (@ LPN's labor rate of $43.12/hr.) (o)	$43.96
Cost to Review Measure Specifications (@ clerk's labor rate of $36.12/hr.) (p)	$36.98
Cost to D21Review Measure Specifications (@ physician's labor rate of $202.08/hr.) (q)	$206.44
Total Cost Per Respondent (r) = (l) + (m) + (n) + (o) + (p) + (q)	$769.68
Total Annual Cost (s) = (c) * (r)	$39,916,374

We received no public comments related to the burden estimates for quality performance category: Clinicians using the eCQM collection type. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36025 through 36026).

Quality Data Submission via CMS Web Interface: The finalized requirements and burden associated with CMS Web Interface data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.I.3.h.(2)(a)(iii)(A)(bb) of this rule, we are finalizing a 33 percent reduction in the number of measures (from 15 to 10 measures) for which clinicians are required to submit quality data via the CMS Web Interface. To account for the decrease in measures, we are also finalizing a decrease to our per respondent time estimate.

We assume that 286 groups will submit quality data via the CMS Web Interface based on the number of groups who registered for using the CMS Web Interface during the 2018 MIPS performance period. This is a decrease of 10 groups from the currently approved number provided in the CY 2018 Quality Payment Program final rule (82 FR 53915) due to receipt of more current data. We estimate that approximately 91,757 clinicians will submit via this method.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. In the CY 2018 Quality Payment Program final rule, we estimated that it would take, on average, 74 hours for each group to submit quality measures data via the CMS Web Interface (82 FR 53915). Of those hours, approximately half (or 37 hr) are unaffected by the number of required measures while the other half (37 hr) are affected proportionately by the number of required measures (37 hr × 33 percent reduction = 24.67 hr). Accounting for the finalized reduction in required measures, our revised estimate for the time to submit data via the CMS Web Interface for the 2019 MIPS performance period is 61.67 hours (37 hr + 24.67 hr), a reduction of 12.33 hours or approximately 18 percent of the currently approved 74 hour time estimate. Considering only the time which varies based on the number of required measures, the process of entering or uploading data requires approximately 2.74 hours of a computer systems analyst's time per measure (24.67 hr/9 measures). Our estimate for submission includes the time needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data

from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate an annual burden of 17,637 hours (286 groups × 61.67 hr) at a cost of $1,572,837 (17,637 hr × $89.18/hr).

Independent of the change in the number of respondents, the decrease in total burden resulting from the decrease in required measures is −3,650 hours at −$325,566 (296 groups × −12.33 hr × $89.18/hr). Accounting for the decrease in total time, the decrease in number of respondents results in a total adjustment of −616.7 hours at −$54,994 (−10 respondents × 61.67 hr × $89.18/hr). When these adjustments are combined, the net adjustment is −4,267 (−3,650–617) hours at −$380,560 (−$325,566–$54,994).

Based on the assumptions discussed in this section, Table 72 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 72—ESTIMATED BURDEN FOR QUALITY DATA SUBMISSION VIA THE CMS WEB INTERFACE

	Burden estimate
Number of Eligible Group Practices (a)	286
Total Annual Hours Per Group to Submit (b)	61.67
Total Annual Hours (c) = (a) * (b)	17,637
Cost Per Group to Report (@ computer systems analyst's labor rate of $89.18/hr.) (d)	$5,499
Total Annual Cost (e) = (a) * (d)	$1,572,837

We received no public comments related to the burden estimates for quality data submission via the CMS Web Interface. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect the change in the number of required measures from 9 in the proposed rule to 10 in the final rule (83 FR 36026 through 36027).

Beneficiary Responses to CAHPS for MIPS Survey: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the CAHPS for MIPS survey. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this final rule, we have adjusted the number of groups electing to report on the CAHPS for MIPS survey as well as the average number of beneficiaries per group based on more recent data.

Under MIPS, groups of 25 or more clinicians can elect to contract with a CMS-approved survey vendor and use the CAHPS for MIPS survey as one of their 6 required quality measures. Beneficiaries that choose to respond to the CAHPS for MIPS survey will experience burden.

The usual practice in estimating the burden on public respondents to surveys such as CAHPS is to assume that respondent time is valued, on average, at civilian wage rates. As explained in section V.A. of this final rule, BLS data sets out an average hourly wage for civilians in all occupations at $24.34/hr. Although most Medicare beneficiaries are retired, we believe that their time value is unlikely to depart significantly from prior earnings expense, and we have used the average hourly wage to compute our cost estimate for the beneficiaries' time.

For the 2019 MIPS performance period, we assume that 143 groups will elect to report on the CAHPS for MIPS survey, which is equal to the number of groups that have registered and have a sufficient beneficiary sample size to conduct the CAHPS for MIPS survey in the 2018 MIPS performance period; a decrease of 318 from the 461 groups currently approved by OMB. Table 73 shows the estimated annual burden for beneficiaries to participate in the CAHPS for MIPS Survey. Based on the number of complete and partially complete surveys for groups participating in CAHPS for MIPS survey administration for the 2018 MIPS performance period, we assume that an average of 273 beneficiaries will respond per group for the 2019 MIPS performance period. Therefore, the CAHPS for MIPS survey will be administered to approximately 39,039 beneficiaries per year (143 groups × an average of 273 beneficiaries per group responding). This is a decrease of 93,268 from our currently approved 132,307 beneficiary estimate.

The CAHPS for MIPS survey that will be administered in the 2019 MIPS performance period is unchanged from the survey administered in the 2018 MIPS performance period. In that regard, we continue to estimate an average administration time of 12.9 minutes (or 0.215 hr) at a pace of 4.5 items per minute for the English version of the survey. For the Spanish version, we estimate an average administration time of 15.5 minutes (assuming 20 percent more words in the Spanish translation). However, since less than 1 percent of surveys were administered in Spanish for reporting year 2016, our burden estimate reflects the time for administering the English version of the survey.

Given that we expect approximately 39,039 respondents, we estimate an annual burden of 8,393 hours (39,039 respondents × 0.215 hr/respondent) at a cost of $204,286 (8,393 hr × $24.34/hr).

The decrease in the number of beneficiaries responding to the CAHPS for MIPS survey results in an adjustment to the total time burden of −20,715 hours and −$503,556 (−93,268 beneficiaries × 0.215 hr × $24.34/hr).

TABLE 73—ESTIMATED BURDEN FOR BENEFICIARY PARTICIPATION IN CAHPS FOR MIPS SURVEY

	Burden estimate
Number of Eligible Group Practices Administering CAHPS for MIPS (a)	143
Number of Beneficiaries Per Group Responding to Survey (b)	273
Number of Total Beneficiary Respondents (c) = (a) * (b)	39,039
Number of Hours Per Beneficiary Respondent (d)	0.215
Cost (@ labor rate of $24.34/hr.) (e)	$24.34/hr
Total Annual Hours (f) = (c) * (d)	8,393
Total Annual Cost for Beneficiaries Responding to CAHPS for MIPS (g) = (c) * (e)	$204,286

We received no public comments related to the burden estimates for beneficiary participation in CAHPS for MIPS survey. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2018 MIPS performance period (83 FR 36027).

Group Registration for CMS Web Interface: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration for CMS Web Interface. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this final rule, we have adjusted the number of respondents based on more recent data and adjusted our per response time estimate based on our review of the currently approved estimates against the existing registration process.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an on-line registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 74, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $89.18/hr for a computer systems analyst (or their equivalent) to register the group. Although the registration process remains unchanged from the CY 2018 Quality Payment Program final rule, a review of the steps required for registration warranted a reduction of 0.75 hours in estimated burden per group (82 FR 53917).

We assume that approximately 67 groups will elect to use the CMS Web Interface for the first time during the 2019 MIPS performance period based on the number of new registrations received during the CY 2018 registration period; an increase of 57 compared to the number of groups currently approved by OMB under control number 0938–1314 (CMS–10621). In aggregate, we estimate a burden of 16.75 hours (67 new registrations $\times$ 0.25 hr/registration) at a cost of $1,494 (16.75 hr $\times$ $89.18/hr).

Independent of the decrease in time burden per group, the increase in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of 57 hours at $5,083 (57 groups $\times$ 1 hr $\times$ $89.18/hr). Accounting for the increase in the number of groups, the decrease in time burden per group to register results in an adjustment to the total burden of -50.25 hours at $-$4,481 (67 groups $\times$ -0.75 hrs $\times$ $89.18/hr). When these adjustments are combined, the net adjustment is 6.75 hours ($57-50.25$) at $602 ($5,083 $-$ $4,481).

TABLE 74—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CMS WEB INTERFACE

	Burden estimate
Number of New Groups Registering for CMS Web Interface (a)	67
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a) * (b)	16.75
Labor Rate to Register for CMS Web Interface @ computer systems analyst's labor rate) (d)	$89.18/hr
Total Annual Cost for CMS Web Interface Group Registration (e) = (a) * (d)	$1,494

We received no public comments related to the burden estimates for group registration for the CMS Web Interface. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36027 through 36028).

Group Registration for CAHPS for MIPS Survey: This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the group registration for the CAHPS for MIPS Survey. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1222 (CMS–10450).

In this final rule, we have adjusted our currently approved number of respondents based on more recent data and adjusted our per respondent time estimate based on our review of the current burden estimates against the existing registration process.

Under MIPS, the CAHPS for MIPS survey counts for 1 measure toward the MIPS quality performance category and, as a patient experience measure, it also fulfills the requirement to submit at least one high priority measure in the absence of an applicable outcome measure. Groups that wish to administer the CAHPS for MIPS survey must register by June of the applicable 12-month performance period, and electronically notify CMS of which vendor they have selected to administer

the survey on their behalf. For the 2019 MIPS performance period, we assume that 282 groups will enroll in the MIPS for CAHPS survey based on the number of groups which elected to register during the CY 2018 registration period; a decrease of 179 compared to the number of groups currently approved by OMB under the aforementioned control number (82 FR 53917).

As shown in Table 75, we assume that the staff involved in the group registration for CAHPS for MIPS Survey will mainly be computer systems analysts (or their equivalent) who have an average labor cost of $89.18/hr. We assume the CAHPS for MIPS Survey registration burden consists of 0.25 hours to register for the survey as well as 0.5 hours to select the CAHPS for MIPS Survey vendor that will be used and electronically notifying CMS of this selection. In this regard, the total time for CAHPS for MIPS registration is 0.75 hours. Although the registration process remains unchanged from the CY 2018 Quality Payment Program final rule, after we reviewed the steps required for registration more thoroughly, we believe that the burden was less than we had originally estimated. Therefore, we have adjusted the estimated burden from 1.5 hours to 0.75 hours per respondent.

In aggregate, we estimate an annual burden of 211.50 hours (282 groups × 0.75 hr per group) at a cost of $18,862 (211.50 hr × $89.18/hr).

Independent of the change in time per group, the decrease in the number of groups registering results is an adjustment to the total burden of −268.5 hours at −$23,945 (−179 groups × 1.5 hrs × $89.18/hr). Accounting for the decrease in the number of groups registering, the decrease in time per group to register results in an adjustment to the total burden of −211.5 hours at −$18,862 (282 groups × −0.75 hr × $89.18/hr). When these adjustments are combined, the net adjustment is −480 hours (−268.5 − 211.5) at −$42,807 (−$23,945 − $18,862).

TABLE 75—ESTIMATED BURDEN FOR GROUP REGISTRATION FOR CAHPS FOR MIPS SURVEY

	Burden estimate
# of Groups Registering for CAHPS (a)	282
Total Annual Hours for CAHPS Registration (b)	0.75
Total Annual Hours for CAHPS Registration (c) = (a) * (b)	211.5
Labor Rate to Register for CAHPS (computer systems analyst) (d)	$89.18/hr
Total Annual Cost for CAHPS Registration (e) = (a) * (d)	$18,862

We received no public comments related to the burden estimates for group registration for the CAHPS for MIPS survey. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2018 MIPS performance period (83 FR 36028 through 36029).

9. Quality Payment Program ICRs Regarding the Nomination of Quality Measures

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of quality measures. However, we have adjusted our currently approved burden estimates based on more recent data. We have also accounted for burden associated with policies that have been finalized but whose burden were erroneously excluded from our estimates. The new and adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section III.I.3.h.(2)(b)(i) of this final rule, quality measures are selected annually through a call for quality measures under consideration, with a final list of quality measures being published in the **Federal Register** by November 1 of each year. Under section 1848(q)(2)(D)(ii) of the Act, the Secretary must solicit a ''Call for Quality Measures'' each year. Specifically, the Secretary must request that eligible clinician organizations and other relevant stakeholders identify and submit quality measures to be considered for selection in the annual list of MIPS quality measures, as well as updates to the measures. Under section 1848(q)(2)(D)(ii) of the Act, eligible clinician organizations are professional organizations as defined by nationally recognized specialty boards of certification or equivalent certification boards.

As we described in the CY 2017 Quality Payment Program final rule (81 FR 77137), we will accept quality measures submissions at any time, but only measures submitted during the timeframe provided by us through the pre-rulemaking process of each year will be considered for inclusion in the annual list of MIPS quality measures for the performance period beginning 2 years after the measure is submitted. This process is consistent with the pre-rulemaking process and the annual call for measures, which are further described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rule-Making.html*.

To identify and submit a quality measure, eligible clinician organizations and other relevant stakeholders use a one-page online form that requests information on background, a gap analysis which includes evidence for the measure, reliability, validity, endorsement and a summary which includes how the proposed measure relates to the Quality Payment Program and the rationale for the measure. In addition, proposed measures must be accompanied by a completed Peer Review Journal Article form.

As shown in Table 76, we estimate that approximately 140 organizations, including clinicians, CEHRT developers, and vendors, will submit measures for the Call for Quality Measures process; an increase of 100 compared to the number of organizations currently approved by OMB. In keeping with the focus on clinicians as the primary source for recommending new quality measures, we are using practice administrators and clinician time for our burden estimates. We also estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $107.38/hr for a practice administrator to make a strategic decision to nominate and submit a measure and 0.2 hours at $206.44/hr for clinician review time.

The 0.5 hour estimate assumes that submitters will have the necessary information to complete the nomination form readily available, which we believe is a reasonable assumption. Additionally, some submitters familiar

with the process or who are submitting multiple measures may require significantly less time, while other submitters may require more if the opposite is true; on average we believe 0.5 hours is a reasonable average across all submitters.

Consistent with the CY 2017 Quality Payment Program final rule, we also estimate it will take 4 hours at $206.44/hr for a clinician (or equivalent) to complete the Peer Review Journal Article Form (81 FR 77153 through 77155). This assumes that measure information is available and testing is complete in order to have the necessary information to complete the form, which we believe is a reasonable assumption. Although the requirement for completing the Peer Review Journal Article was previously included in the CY 2017 Quality Payment Program final rule, the time required for completing the form was erroneously excluded from our burden estimates.

As shown in Table 76, in aggregate we estimate an annual burden of 630 hours (140 organizations × 4.5 hr/response) at a cost of $125,896 (140 × [(0.3 hr × $107.38/hr) + (4.2 hr × $206.44/hr)].

Independent of the change in time per organization, the change in the number of organizations nominating new quality measures results in an adjustment of 50 hours at $7,350 (100 organizations × [(0.3 hr × $107.38/hr) + (0.2 hr x $206.44/hr)]). When accounting for the change in respondents, the change in burden to nominate a quality measure results in an adjustment of 560 hours at $115,606 (140 organizations × 4 hr × $206.44/hr). When these adjustments are combined, the total adjustment is 610 hours (560 + 50) at $122,956 ($7,350 + $115,606).

TABLE 76—ESTIMATED BURDEN FOR CALL FOR QUALITY MEASURES

	Burden estimate
# of Organizations Nominating New Quality Measures (a)	140
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20
# of Hours Per Clinician to Complete Peer Review Article Form (d)	4.00
Annual Hours Per Response (e) = (b) + (c) + (d)	4.50
Total Annual Hours (f) = (a) * (e)	630
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $107.38/hr.) (g)	$32.21
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ physician's labor rate of $206.44/hr.) (h)	$867.05
Total Annual Cost Per Respondent (i) = (g) + (h)	$899.26
Total Annual Cost (j) = (a) * (i)	$125,896

We received no public comments related to the burden estimates for the Call for Quality Measures. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36029 through 36030).

10. Quality Payment Program ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

The finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

For the 2019 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. We have worked to further align the Promoting Interoperability performance category with other MIPS performance categories. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category which is not available for the quality performance category, we anticipate that most organizations will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. Hence, the following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

Reweighting Applications for Promoting Interoperability and Other Performance Categories: As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability performance category in the following circumstances: insufficient internet connectivity, extreme and uncontrollable circumstances, lack of control over the availability of CEHRT, clinicians who are in a small practice, and decertified EHR technology (81 FR 77240 through 77243 and 82 FR 53680 through 53686). In addition, as finalized in the CY 2018 Quality Payment Program final rule, MIPS eligible clinicians and groups citing extreme and uncontrollable circumstances may also apply for a reweighting of the quality, cost, and/or improvement activities performance categories (82 FR 53783 through 53785). Respondents who apply for a reweighting for any of these performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. Since we do not have data on the number of reweighting applications submitted for the 2018 MIPS performance period for this rule, we assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications. As data availability allows, we will estimate the reporting burden for each reweighting application under separate ICRs in future rulemaking.

Table 77 summarizes the burden for clinicians to apply for reweighting the

Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received for the 2017 MIPS performance period, we assume 6,041 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification. We estimate that 3,344 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 2,697 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship. In total, this represents a decrease of 34,604 from the number of respondents currently approved by OMB. In the CY 2019 PFS proposed rule, we lacked the detailed data necessary to independently estimate the number of reweighting applications submitted by clinicians in a small practice who were of an eligible clinician type and are not eligible to have the Promoting Interoperability performance category reweighted for any other reason (for example, because they are hospital-based, ASC-based, or non-patient facing), and therefore, assumed all clinicians in small practices that met these criteria would apply for reweighting of the Promoting Interoperability performance category. Data from the 2017 MIPS performance period has sufficient detail to allow for this analysis, resulting in a decrease of 78,573 from the estimate of 81,270 clinicians in a small practice cited in the CY 2019 PFS proposed rule (83 FR 36030).

The total of 6,041 respondents represents a decrease of 34,604 from the number of respondents currently approved by OMB. The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We estimate it will take 0.25 hours at $89.18/hr for a computer system analyst to submit the application. This is a reduction from the 0.5 hours estimated in the CY 2018 Quality Payment Program final rule due to a revised assessment of the application process (82 FR 53918). As shown in Table 77, in aggregate, we estimate an annual burden of 1,510.25 hours (6,041 applications × 0.25 hr/application) at a cost of $134,684 (1,510.25 hr × $89.18/hr).

Independent of the change to the number of respondents, the decrease in the amount of time to submit a reweighting application results in an adjustment of −10,161.25 hours at −$906,180 (40,645 respondents × −0.25 hr × $89.18/hr). Accounting for the decrease in time per respondent, the decrease in the number of respondents submitting reweighting applications results in an adjustment of −8,651 hours at −$771,496 (−34,604 respondents × 0.25 hr × $89.18hr). When these adjustments are combined, the total adjustment is −18,812.25 hours (−10,161.25 − 8,651) at $1,677,676 (−$906,180 − $771,496).

TABLE 77—ESTIMATED BURDEN FOR REWEIGHTING APPLICATIONS FOR PROMOTING INTEROPERABILITY AND OTHER PERFORMANCE CATEGORIES

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions (a)	3,344
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	2,697
Total Respondents Due to Hardships, Other Exceptions and Hardships for Small Practices (c)	6,041
Hours Per Applicant per application submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	1,510.25
Labor Rate for a computer systems analyst (f)	$89.18/hr
Total Annual Cost (g) = (a) * (f)	$134,684

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding reweighting applications for Promoting Interoperability and other performance categories:

Comment: One commenter noted that CMS's estimate of 15 minutes to complete and submit the Promoting Interoperability reweighting application is low and should be increased to an estimate of between 30 minutes and 1 hour.

Response: We understand that some respondents may require additional time to submit a reweighting application above the 15 minutes we estimate, but we believe this estimate is a reasonable average across all respondents as the application process requires limited basic information about the clinician or submitter, a small number of check boxes and drop-down selections, and a free text field to provide justification for the requested application. In addition, we believe increased familiarity with the process in its second year also reduces the average time across all respondents.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36030 through 36031).

Submitting Promoting Interoperability Data: In this final rule, we have adjusted the estimated number of respondents based on data from the 2017 MIPS performance period and the estimated per respondent time due to the net reduction of 3 measures (6 removed measures and 3 new measures) for which clinicians are required to submit data, which we are finalizing as discussed in section III.I.3.h.(5)(f) of this final rule.

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264), we established that eligible clinicians in MIPS APMS other than the Shared Savings Program may submit data for the Promoting Interoperability performance category as individuals or as part of a group, whereas eligible clinicians participating in the Shared Savings Program are limited to submitting data through the ACO participant TIN. In section III.I.3.h.(6)(d)(ii) of this final rule, we are finalizing our proposal to extend this flexibility to allow for both individual and group reporting by eligible clinicians participating in the Shared Savings Program.

As shown in Table 78, based on data from the 2017 MIPS performance period, we estimate that a total of 93,933 respondents consisting of 81,456 individual MIPS eligible clinicians and 12,413 groups will submit Promoting Interoperability data. Similar to the process shown in Table 66 for groups reporting via QCDR/MIPS CQM and eCQM collection types, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period. These estimates reflect that under the policies in the CY 2017 Quality Payment Program final rule and in the CY 2018 Quality Payment Program final rule, certain MIPS eligible clinicians will be eligible for automatic reweighting of the Promoting Interoperability performance category to zero percent, including MIPS eligible clinicians that are hospital-based, ambulatory surgical center-based, non-patient facing clinicians, physician assistants, nurse practitioners, clinician nurse specialists, and certified registered nurse anesthetists (81 FR 77238 through 77245 and 82 FR 53680 through 53687). As discussed in section III.I.3.h.(5)(h)(ii) of this final rule, starting with the 2021 MIPS payment year, we are finalizing a policy to automatically reweight the Promoting Interoperability performance category for clinician types new to MIPS: Physical therapists; occupational therapists; qualified speech-language pathologists or qualified audiologist; clinical psychologists; and registered dieticians or nutrition professionals. These estimates also account for the reweighting policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, including exceptions for MIPS eligible clinicians who have experienced a significant hardship (including clinicians who are in small practices), as well as exceptions due to decertification of an EHR.

Further, we assume that Shared Savings Program Track 1 ACOs will submit data at the ACO participant TIN-level, APM Entities electing the one-sided track in the CEC model will submit data at the group TIN-level, and APM Entities in the OCM (one-sided risk arrangement) will submit data at APM Entity level; these entities are included in our estimate of the number of groups submitting data. Our respondent estimate is based on existing data and does not consider policies finalized in section V of this final rule, as well as additional policies that were proposed in the August 2018 proposed rule and may be finalized in a future rule, which may change the number of Shared Saving Program ACOs that are required to submit Promoting Interoperability data for future years.[45]

TABLE 78—ESTIMATED NUMBER OF RESPONDENTS TO SUBMIT PROMOTING INTEROPERABILITY PERFORMANCE DATA ON BEHALF OF CLINICIANS

	Number of respondents
Number of individual clinicians to submit Promoting Interoperability (a)	81,456
Number of groups to submit Promoting Interoperability(b)	12,477
Subtract: Number of groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups in Quality Payment Program Year 3 (c)	80
Add in: Number of virtual groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 (d)	16
Number of groups to submit Promoting Interoperability on behalf of clinicians in Quality Payment Program Year 3 (e) = (b) − (c) + (d)	12,413
Total (f) = (a) + (e)	93,869

In the CY 2018 Quality Payment Program final rule, we estimated it takes 3 hours for a computer system analyst to collect and submit Promoting Interoperability performance category data (82 FR 53920). For this final rule, we estimate the time required to submit such data should be reduced by 20 minutes to 2.67 hours due to the reduction in the number of measures for which clinicians are required to submit data, which we are finalizing as discussed in section III.I.3.h.(5)(f) of this final rule. As shown in Table 78, the total time for an organization to submit data on the specified Promoting Interoperability objectives and measures is estimated to be 250,317 hours (93,869 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the clinician, practice manager, and computer system's analyst time required to submit quality data) at a cost of $22,323,300 (250,317 hr × $89.18/hr).

Independent of the change in the number of respondents, the reduction in estimated time to submit Promoting Interoperability data results in a decrease in burden of −72,738.33 hours at −$6,486,805 (218,215 respondents × −0.33 hr × $89.18/hr). Accounting for the decreased per respondent time, the decrease in the number of respondents

[45] *https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-17101.pdf.*

results in an adjustment to the total burden of −331,589.33 hours at −$29,571,137 (−124,346 respondents × 2.67 hrs × $89.18/hr). When these adjustments are combined, the total adjustment is −404,327.67 hours (−72,738.33 −331,589.33) at −$36,057,941 (−$6,486,805 −$29,571,137).

TABLE 79—ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION

	Burden estimate
Number of individual clinicians to submit Promoting Interoperability (a)	81,456
Number of groups to submit Promoting Interoperability (b)	12,413
Total (c) = (a) + (b)	93,869
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a) * (b)	250,317
Labor rate for a computer systems analyst to submit Promoting Interoperability data/hr.) (d)	$89.18/hr
Total Annual Cost (e) = (a) * (d)	$22,323,300

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding Promoting Interoperability Data:

Comment: One commenter noted that CMS should consider and reduce the operational burden imposed on clinicians and medical practice staff by the required measures and reporting processes associated with the Quality Payment Program specifically and all quality reporting programs in general. The commenter cited the 20 minute reduction in burden associated with the proposed reduction in Promoting Interoperability measures as evidence of its belief that reducing the number of measures is not enough to reduce the total burden on respondents. The commenter also noted its belief that frustration and clinician burnout are increased due to the documentation requirements and workflow modifications associated with quality reporting programs.

Response: We thank the commenter for its input. We recognize there is additional burden on clinicians and practice staff beyond the reporting burden estimated in the Collection of Information section of this policy which only accounts for the time required for record keeping, reporting, and third-party disclosures associated with the policy. CMS does consider the operational burden imposed on clinicians and practice staff and weighs it against the goal of improving quality of care prior to finalizing policy decisions. On balance, we believe that any potential additional burden is outweighed by increased quality and improved patient outcomes. We will continue to monitor this balance and will continue to propose efficiencies and policies that will help to further reduce burden.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36031 through 36032).

11. Quality Payment Program ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of Promoting Interoperability measures. However, we have adjusted our currently approved burden estimates based data from the 2017 MIPS performance period. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Consistent with our requests for stakeholder input on quality measures and improvement activities, we also request potential measures for the Promoting Interoperability performance category that measure patient outcomes, emphasize patient safety, support improvement activities and the quality performance category, and build on the advanced use of CEHRT using 2015 Edition standards and certification criteria. Promoting Interoperability measures may be submitted via a designated submission form that includes the measure description, measure type (if applicable), reporting requirement, and CEHRT functionality used (if applicable).

We estimate 47 organizations will submit Promoting Interoperability measures, based on the number of organizations submitting measures during the CY 2017 nomination period. This is an increase of 7 from the estimate currently approved by OMB under the aforementioned control number. We estimate it will take 0.5 hours per organization to submit an activity to us, consisting of 0.3 hours at $107.38/hr for a practice administrator to make a strategic decision to nominate that activity and submit an activity to us via email and 0.2 hours at $206.44/hr for a clinician to review the nomination. As shown in Table 80, in aggregate, we estimate an annual burden of 235 hours (47 organizations × 0.5 hr/response) at a cost of $3,455 (47 × [(0.3 h × $107.38/hr) + (0.2 hr × $206.44/hr)]. The increase in the number of respondents results in an adjustment of 3.5 hours and $514.50 (7 respondents × 0.5 hrs × $73.50 per respondent).

TABLE 80—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES

	Burden estimate
# of Organizations Nominating New Promoting Interoperability Measures (a)	47
# of Hours Per Practice Administrator to Identify and Propose Measure (b)	0.30
# of Hours Per Clinician to Identify Measure (c)	0.20

TABLE 80—ESTIMATED BURDEN FOR CALL FOR PROMOTING INTEROPERABILITY MEASURES—Continued

	Burden estimate
Annual Hours Per Respondent (d) = (b) + (c)	0.50
Total Annual Hours (e) = (a) * (d)	23.50
Cost to Identify and Submit Measure (@practice administrator's labor rate of $107.38/hr.) (f)	$32.21
Cost to Identify Improvement Measure (@physician's labor rate of $206.44/hr.) (g)	$41.29
Total Annual Cost Per Respondent (h) = (f) + (g)	$73.50
Total Annual Cost (i) = (a) * (h)	$3,455

We received no public comments related to the burden estimates for the Call for Promoting Interoperability Measures. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36032 through 36033).

12. Quality Payment Program ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the submission of Improvement Activities data. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512) and the CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922) for our previous burden estimates for improvement activities under the Quality Payment Program.

The CY 2018 Quality Payment Program final rule provides: (1) That for activities that are performed for at least a continuous 90 days during the performance period, MIPS eligible clinicians must submit a ''yes'' response for activities within the Improvement Activities Inventory (82 FR 53651); (2) that the term ''recognized'' is accepted as equivalent to the term ''certified'' when referring to the requirements for a patient-centered medical home to receive full credit for the improvement activities performance category for MIPS (82 FR 53649); and (3) that for the 2020 MIPS payment year and future years, to receive full credit as a certified or recognized patient-centered medical home or comparable specialty practice, at least 50 percent of the practice sites within the TIN must be recognized as a patient-centered medical home or comparable specialty practice (82 FR 53655).

In the CY 2017 Quality Payment Program final rule, we describe how we determine MIPS APM scores (81 FR 77185). We compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77817 through 77831). If, by our assessment, the MIPS APM does not receive the maximum improvement activities performance category score, then the APM Entity can submit additional improvement activities, although, as we noted, we anticipate that MIPS APMs in the 2019 MIPS performance period will not need to submit additional improvement activities as the models will already meet the maximum improvement activities performance category score (81 FR 77185).

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Our CY 2018 Quality Payment Program final rule burden estimates assumed that all APM Entities will receive the maximum CMS-assigned improvement activities score (82 FR 53921 through 53922).

As represented in Table 81, based on 2017 MIPS performance period data, we estimate that 125,713 clinicians will submit improvement activities as individuals during the 2019 MIPS performance period and 16,478 groups will submit improvement activities on behalf of clinicians. Similar to the process shown in Table 77 for groups submitting Promoting Interoperability data, we have adjusted the group reporting data from the 2017 MIPS performance period to account for virtual groups, as the option to submit data as a virtual group was not available until the 2018 MIPS performance period.

Our burden estimates assume there will be no improvement activities burden for MIPS APM participants. We will assign the improvement activities performance category score at the APM level. We also assume that the MIPS APM models for the 2019 MIPS performance period will qualify for the maximum improvement activities performance category score and the APM Entities will not need to submit any additional improvement activities.

TABLE 81: Estimated Numbers of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2019 MIPS performance period (a)	119,956
# of Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (b)	16,112
Subtract: # of groups to submit improvement activities on behalf of clinicians in Quality Payment Program Year 3 that will submit as virtual groups during the 2019 MIPS performance period (c)	80
Add in: # of Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (d)	16
# of Groups and Virtual Groups to submit improvement activities on behalf of clinicians during the 2019 MIPS performance period (e)	16,048
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (f) = (a) + (b) + (e)	136,004
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2018 MIPS performance period (g)	439,786
Difference between 2019 MIPS performance period and 2018 MIPS performance period (h)=(g)-(f)	-303,782

As described in section III.I.3.h.(4)(b) of this final rule, for purposes of the 2021 MIPS payment year, we have finalized § 414.1360(a)(1) to more accurately reflect the data submission process for the improvement activities performance category. In particular, instead of ''via qualified registries; EHR submission mechanisms; QCDR, CMS Web Interface; or attestation,'' as currently stated, we have revised the first sentence to state that data will be submitted ''via direct, log in and upload, and log in and attest.'' The revision will more closely align with the actual submission experience users have.

In the CY 2018 Quality Payment Program final rule, we estimated it would take 1 hour for a computer system analyst to submit data on the specified improvement activities (82 FR 53922). We are finalizing to decrease this burden estimate since the actual submission experience of the user is such that improvement activities data is submitted as part of the process for submitting quality and Promoting Interoperability data, resulting in less additional required time to submit improvement activities data. As a result, we estimate that the per response time required per individual or group is 5 minutes at $89.18/hr for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials. Additionally, as stated in the CY 2018 Quality Payment Program final rule, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to submit for the 2019 MIPS performance period (82 FR 53921).

As discussed in section III.I.3.h.(4)(d)(ii) of this final rule, we are also finalizing for CY 2019 and future years to: Add 6 new improvement activities; modify 5 existing improvement activities; and remove 1 existing improvement activity. Because MIPS eligible clinicians are still required to submit the same number of activities, we do not expect these provisions to affect our collection of information burden estimates. In addition, in order for an eligible clinician or group to receive credit for being a patient-centered medical home or comparable specialty practice, the eligible clinician or group must attest in the same manner as any other improvement activity.

As shown in Table 82, we estimate an annual burden of 11,333.7 hours (136,004 responses × 5 minutes/60) at a cost of $1,010,736 (11,333.7 hr × $89.18/hr).

Independent of the change to our per response time estimate, the decrease in the number of respondents results in an adjustment of −303,782 hours at −$27,091,279 (−303,782 respondents × 1 hr × $89.18/hr). Accounting for the change in number of respondents, the decrease in the time to submit improvement activities data results in an adjustment of −124,670.33 hours at −$11,118,100.33 (136,004 respondents × 55 minutes/60 × $89.18/hr). When these adjustments are combined, the total adjustment is −428,452.33 hours (−303,782 − 124,670.33) hours at −$38,209,379.33 (−$27,091,279 − $11,118,100.33).

TABLE 82—ESTIMATED BURDEN FOR IMPROVEMENT ACTIVITIES SUBMISSION

	Burden estimate
Total Number of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a)	136,004
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c)	11,333.7
Labor rate for a computer systems analyst to submit improvement activities (d)	$89.18/hr
Total Annual Cost (e) = (a) * (d)	$1,010,736

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding Improvement Activities Submission:

Comment: One commenter noted that CMS's estimate of 5 minutes to submit data for the Improvement Activities performance category is low and should be increased to an estimate of between 15 and 30 minutes.

Response: We thank the commenter for its input. We understand that some respondents may require additional time to submit improvement activities data above the 5 minutes we estimate, but we believe this estimate is a reasonable average across all respondents as it reflects the actual submission experience of the user. User experiences from the 2017 MIPS performance period reflect that the majority of users submit improvement activities data as part of the login and upload or direct submission types which allow multiple performance categories (*i.e.,* quality and promoting interoperability) worth of data to be submitted at once. This results in less additional required time to submit improvement activities data which consists of manually attesting that certain activities were performed. In addition, as previously stated in the CY 2018 Quality Payment Program final rule, the same improvement activity may be reported across multiple performance periods so many MIPS eligible clinicians will not have any additional information to submit for the 2019 MIPS performance period, further reducing the average time spent reporting improvement activities data across all MIPS eligible clinicians (82 FR 53921).

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. However, the burden estimates have been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36033 through 36034).

13. Quality Payment Program ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2018 Quality Payment Program final rule for our previous burden estimates for nomination of improvement activities under the Quality Payment Program (82 FR 53922). In this final rule, we have adjusted the number of respondents based on more recent data and adjusted our per response time estimate based on our review of our currently approved burden estimates against the existing process for nomination of improvement activities. As discussed in section III.I.3.h.(4)(d)(i)(A) of this final rule, we are also finalizing to adopt one new criteria and remove one existing criteria for nominating new improvement activities beginning with the CY 2019 performance period and future years. Furthermore, we have made clarifications to: (1) Considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. We believe these policy changes will not affect our currently approved burden estimates since they do not substantively impact the level of effort previously estimated to nominate an Improvement Activity.

As discussed in section III.I.3.h.(4)(d)(i)(D) of this final rule, we are finalizing changing the performance year for which the nominations will apply, such that improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in the following year. Also, as discussed in section III.I.3.h.(4)(d)(i)(D) of this final rule, we are finalizing changing the submission timeframe for the Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately four additional months for stakeholders to submit nominations. We believe these policy changes will not affect our currently approved burden estimates since we believe that the number of nominations is unlikely to change, but the quality of the nominations is likely to increase given the additional time provided.

For the 2018 MIPS performance period, we provided opportunity for stakeholders to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). The 2018 Annual Call for Activities lasted from March 2, 2017 through March 1, 2018, for which we received 72 nominations consisting of a total of 125 activities which were evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2019 Improvement Activities Inventory. Based on the number of activities being evaluated during the 2018 Annual Call for Activities (125 activities), we estimate that the total number of nominations we will receive for the 2019 Annual Call for Activities will continue to be 125, unchanged from the number of activities evaluated in CY 2018, which is a decrease from the 150 nominations currently approved by OMB.

In the CY 2018 Quality Payment Program final rule, we estimated that it takes 0.5 hours to nominate an improvement activity (82 FR 53922). As shown in Table 83, due to a review of the nomination process including the criteria required to nominate an improvement activity, we now estimate it will take 2 hours (per organization) to submit an activity to us. Of those hours, we estimate it will take 1.2 hours at $107.38/hr for a practice administrator or equivalent to make a strategic decision to nominate and submit that activity and 0.8 hours at $206.44/hr for a clinician's review. In aggregate, we estimate an annual burden of 250 hours (125 nominations × 2 hr/nomination) at a cost of $36,751 (125 × [(1.2 hr × $107.38/hr) + (0.8 hr × $206.44/hr)]).

The percentage of practice administrator and clinician labor in relation to the total is unchanged from the CY 2018 Quality Payment Program final rule (82 FR 53922).

Independent of the change to our per response time estimate, the decrease in the number of nominations results in an adjustment of −12.5 hours and −$1,837 (−25 activities × [(0.3 hr × $107.38/hr) + (0.2 hr × $206.44/hr)]). Accounting for the decrease in the number of nominated improvement activities, the increase in time per nominated improvement activity results in an adjustment of 187.5 hours and $27,563 (125 activities × [(0.9 hr × $107.38/hr) + (0.6 hr × $206.44/hr)]). When these adjustments are combined, the total adjustment is 175 hours (187.5 − 12.5) and $25,726 ($27,563 − $1,837).

TABLE 83—ESTIMATED BURDEN FOR NOMINATION OF IMPROVEMENT ACTIVITIES

	Burden estimate
Number of Organizations Nominating New Improvement Activities (a)	125
Number of Hours Per Practice Administrator to Identify and Propose Activity (b)	1.2
Number of Hours Per Clinician to Identify Activity (c)	0.8
Annual Hours Per Respondent (d) = (b) + (c)	2
Total Annual Hours (e) = (a) * (d)	250
Cost to Identify and Submit Activity (@practice administrator's labor rate of $107.38/hr.) (f)	$128.86
Cost to Identify Improvement Activity (@physician's labor rate of $206.44/hr.) (g)	$165.15
Total Annual Cost Per Respondent (h) = (f) + (g)	$294.01
Total Annual Cost (i) = (a) * (h)	$36,751

The following is a summary of the public comments received on the Quality Payment Program ICRs regarding Improvement Activities Submission:

Comment: One commenter noted that the burden estimate of 2 hours for nomination of Improvement Activities is low due to the time needed by clinicians and their staff to assess a need in their practice situation, formulate a creative solution, and determine how they would implement it in their practice in addition to documenting and submitting the improvement activity to CMS.

Response: We recognize there is additional burden on respondents associated with development of a new improvement activity beyond the reporting burden estimated in the Collection of Information section of this policy which only accounts for the time required for record keeping, reporting, and third-party disclosures associated with the policy. We understand that some respondents may require additional time above the 2 hours we estimate for completing the process for nominating an improvement activity, but given that we do not include development of an improvement activity in our burden estimate, we believe this estimate is a reasonable average across all respondents based on our review of the nomination process, the information required to complete the nomination form, and the criteria required to nominate an improvement activity.

After consideration of public comments, we are making no changes to our estimates as a result of public comments received. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36034 through 36035).

14. Quality Payment Program ICRs Regarding CMS Study on Factors Associated With Reporting Quality Measures

During each performance year, eligible clinicians are recruited to participate in the CMS study on the burden associated with reporting quality measures. Eligible clinicians who are interested in participating can sign up whereby an adequate sample size is then selected by CMS from this group of potential participants. This study is ongoing, and participants are recruited on a yearly basis. Current participants can sign up when the study year ends.

Section 1848(s)(7) of the Act, as added by section 102 of the MACRA (Pub. L. 114–10) states that Chapter 35 of title 44, United States Code, shall not apply to the collection of information for the development of quality measures. Consequently, we are not setting out such burden since the study shall inform us (and our contractors) on the root causes of clinicians' performance measure data collection and data submission burdens and challenges that hinders accurate and timely quality measurement activities. We refer readers to the discussion of this policy in section VII.F.7 of this final rule.

15. Quality Payment Program ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the provisions of this final rule do not result in the need to add or revise or delete any claims data fields. Therefore, we do not anticipate any new or additional submission requirements and/or burden for MIPS eligible clinicians resulting from the cost performance category.

We received no public comments related to burden for the cost performance category.

16. Quality Payment Program ICRs Regarding Partial QP Elections (§ 414.1430)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to QP elections. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

APM Entities may face a data submission burden under MIPS related to Partial QP elections. Advanced APM participants will be notified about their QP or Partial QP status as soon as possible after each QP determination. Where Partial QP status is earned at the APM Entity level, the burden of Partial QP election will be incurred by a representative of the participating APM Entity. Where Partial QP status is earned at the eligible clinician level, the burden of Partial QP election will be incurred by the eligible clinician. For the purposes of this burden estimate, we assume that all MIPS eligible clinicians determined to be Partial QPs will participate in MIPS.

Based on our predictive QP analysis for the 2019 QP performance period, we estimate that 6 APM Entities and 75 eligible clinicians will make the election to participate as a Partial QP in MIPS (see Table 84), an increase of 64 from the 17 elections currently approved by OMB under the aforementioned control number. We estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate

an annual burden of 20.25 hours (81 respondents × .25 hr/election) at a cost of $1,805.90 (20.25 hours × $89.18/hr). The increase in the number of Partial QP elections results in an adjustment of 16 hours and $1,431 (64 elections × 0.25 hrs × $89.18/hr).

TABLE 84—ESTIMATED BURDEN FOR PARTIAL QP ELECTION

	Burden estimate
Number of respondents making Partial QP election (6 APM Entities, 75 eligible clinicians) (a)	81
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25 hours
Total Annual Hours (c) = (a) * (b)	20.25 hours
Labor rate for computer systems analyst (d)	$89.18/hr
Total Annual Cost (d) = (c) * (d)	$1,805.90

We received no public comments related to the burden estimates for Partial QP Election. The burden estimates have not been updated from the CY 2019 PFS proposed rule (83 FR 36036).

17. Quality Payment Program ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1440) and Eligible Clinician Initiated Process (§ 414.1445)

As indicated below, the finalized requirements and burden discussed under this section will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Payer Initiated Process (§ 414.1440): This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the Payer Initiated Process. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advance notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the 2018 CY Quality Payment Program final rule established a payer-initiated process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53844). The payer-initiated process for Other Payer Advanced APM determinations began in CY 2018 for Medicaid, Medicare Health Plans, and payers participating in CMS multi-payer models. Payers seeking to submit payment arrangement information for Other Payer Advanced APM determination through the payer-initiated process are required to complete a Payer Initiated Submission Form, instructions for which is available at *https://qpp.cms.gov/*. Determinations made in 2018 are applicable for the Quality Payment Program Year 3.

Also in the CY 2018 Quality Payment Program final rule we established our intent to finalize that the remaining other payers, including commercial and other private payers, may request that we determine whether other payer arrangements are Other Payer Advanced APMs starting prior to the 2020 QP performance period and each performance period thereafter (82 FR 53867). As a result, in this final rule, we finalized our proposal to eliminate the Payer Initiated Process that is specifically for CMS Multi-Payer Models. We believe that payers aligned with CMS Multi-Payer Models can submit their arrangements through the Payer Initiated Process for Remaining Other Payers in section III.I.4.e.(4)(c) of this final rule, or through the Medicaid or Medicare Health Plan payment arrangement submission processes.

As shown in Table 85, we estimate that in 2019 for the 2020 QP performance period 215 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (15 Medicaid payers, 100 Medicare Advantage Organizations, and 100 remaining other payers), a decrease of 85 from the 300 total requests currently approved by OMB under the aforementioned control number. We estimate it will take 10 hours at $89.18/hr for a computer system analyst per arrangement submission. In aggregate, we estimate an annual burden of 2,150 hours (215 submissions × 10 hr/submission) at a cost of $191,737 (2,150 hr × $89.18/hr). The decrease in the number of payer-initiated requests results in an adjustment of −850 hours and −$75,803 (−85 requests × 10 hr × $89.18/hr).

TABLE 85—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS

	Burden estimate
Number of other payer payment arrangements (15 Medicaid, 100 Medicare Advantage Organizations, 100 remaining other payers) (a)	215
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	2,150
Labor rate for a computer systems analyst (d)	$89.18/hr

TABLE 85—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM IDENTIFICATION DETERMINATIONS: PAYER-INITIATED PROCESS—Continued

	Burden estimate
Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	$191,737

We received no public comments related to the burden estimates for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process. The burden estimates have been updated from the CY 2019 PFS proposed rule to reflect updated respondent estimates (83 FR 36036 through 36037).

Eligible Clinician Initiated Process (§ 414.1445): This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the Eligible Clinician Initiated Process. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning in Quality Payment Program Year 3, the All-Payer Combination Option will be an available pathway to QP status for eligible clinicians participating sufficiently in Advanced APMs and Other Payer Advanced APMs. The All-Payer Combination Option allows for eligible clinicians to achieve QP status through their participation in both Advanced APMs and Other Payer Advanced APMs. In order to include an eligible clinician's participation in Other Payer Advanced APMs in their QP threshold score, we will need to determine if certain payment arrangements with other payers meet the criteria to be Other Payer Advanced APMs. To provide eligible clinicians with advanced notice prior to the start of a given performance period, and to allow other payers to be involved prospectively in the process, the CY 2018 Quality Payment Program final rule provided a payer-initiated identification process for identifying payment arrangements that qualify as Other Payer Advanced APMs (82 FR 53854). In the same rule, under the Eligible Clinician Initiated Process, APM Entities and eligible clinicians participating in other payer arrangements will have an opportunity to request that we determine for the year whether those other payer arrangements are Other Payer Advanced APMs (82 FR 53857—53858). However, to appropriately implement the statutory requirement to exclude from the All Payer Combination Option QP threshold calculations certain Title XIX payments and patients, we determined it will be problematic to allow APM Entities and eligible clinicians to request determinations for Title XIX payment arrangements after the conclusion of the QP performance period because any late-identified Medicaid APM or Medicaid Medical Home Model that meets the Other Payer Advanced APM criteria could unexpectedly affect QP threshold calculations for every other clinician in that state (or county). Thus, the CY 2018 Quality Payment Program final rule provided that APM Entities and eligible clinicians may request determinations for any Medicaid payment arrangements in which they are participating at an earlier point, prior to the start of a given QP performance period (82 FR 53858). This will allow all clinicians in a given state or county to know before the beginning of the performance period whether their Title XIX payments and patients will be excluded from the all-payer calculations that are used for QP determinations for the year under the All-Payer Combination Option. This Medicaid specific eligible clinician-initiated determination process for Other Payer Advanced APMs also began in CY 2018, and determinations made in 2018 are applicable for the Quality Payment Program Year 3. Eligible clinicians or APM Entities seeking to submit payment arrangement information for Other Payer Advanced APM determination through the Eligible Clinician-Initiated process are required to complete an Eligible Clinician Initiated Submission Form, instructions for which is available at *https://qpp.cms.gov/*.

As shown in Table 86, we estimate that 150 other payer arrangements will be submitted by APM Entities and eligible Other Payer Advanced APM determinations, an increase of 75 from the 75 total requests currently approved by OMB under the aforementioned control number.

We estimate it will take 10 hours at $89.18/hr for a computer system analyst per arrangement submission to submit this data. In aggregate, we estimate an annual burden of 1,500 hours (150 submissions × 10 hr/submission) at a cost of $133,770 (1,500 hr × $89.18/hr). The increase in the number of clinician-initiated requests results in an adjustment of 750 hours and $66,885 (75 requests × 10 hr × $89.18/hr).

TABLE 86—ESTIMATED BURDEN FOR OTHER PAYER ADVANCED APM DETERMINATIONS: ELIGIBLE CLINICIAN INITIATED PROCESS

	Burden estimate
Number of other payer payment arrangements from APM Entities and eligible clinicians	150
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	1,500
Labor rate for a computer systems analyst (d)	$89.18/hr
Estimated Total Annual Cost for Other Payer Advanced APM determinations (e) = (a) * (d)	$133,770

We received no public comments related to the burden estimates for Other Payer Advanced APM Identification Determinations: Eligible Clinician Initiated Process. The burden estimates have not been updated from the CY

2019 PFS proposed rule (83 FR 36037 through 36038).

Submission of Data for QP Determinations under the All-Payer Combination Option (§ 414.1440): The following reflects the burden associated with the first year of data collection resulting from policies set out in the CY 2018 Quality Payment Program final rule. Because no collection of data was required prior to the CY 2019 performance period, the requirements and burden were not submitted to OMB for approval. However, by virtue of this rulemaking, the requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

The CY 2017 Quality Payment Program final rule provided that either APM Entities or individual eligible clinicians must submit by a date and in a manner determined by us: (1) Payment arrangement information necessary to assess whether each other payer arrangement is an Other Payer Advanced APM, including information on financial risk arrangements, use of CEHRT, and payment tied to quality measures; (2) for each payment arrangement, the amounts of payments for services furnished through the arrangement, the total payments from the payer, the numbers of patients furnished any service through the arrangement (that is, patients for whom the eligible clinician is at risk if actual expenditures exceed expected expenditures), and (3) the total number of patients furnished any service through the arrangement (81 FR 77480). The rule also specified that if we do not receive sufficient information to complete our evaluation of another payer arrangement and to make QP determinations for an eligible clinician using the All-Payer Combination Option, we will not assess the eligible clinicians under the All-Payer Combination Option (81 FR 77480).

In the CY 2018 Quality Payment Program final rule, we explained that in order for us to make QP determinations under the All-Payer Combination Option using either the payment amount or patient count method, we will need to receive all of the payment amount and patient count information: (1) Attributable to the eligible clinician or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician during the QP performance period (82 FR 53885). We also finalized that eligible clinicians and APM Entities will not need to submit Medicare payment or patient information for QP determinations under the All-Payer Combination Option (82 FR 53885).

The CY 2018 Quality Payment Program final rule noted that we will need this payment amount and patient count information for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31 (82 FR 53885). We noted that the timing may be challenging for APM Entities or eligible clinicians to submit information for the August 31 snapshot date. If we receive information for either the March 31 or June 30 snapshots, but not the August 31 snapshot, we will use that information to make QP determinations under the All-Payer Combination Option. This payment amount and patient count information is to be submitted in a way that allows us to distinguish information from January 1 through March 31, January 1 through June 30, and January 1 through August 31 so that we can make QP determinations based on the two finalized snapshot dates (82 FR 30203 through 30204).

The CY 2018 Quality Payment Program final rule specified that APM Entities or eligible clinicians must submit all of the required information about the Other Payer Advanced APMs in which they participate, including those for which there is a pending request for an Other Payer Advanced APM determination, as well as the payment amount and patient count information sufficient for us to make QP determinations by December 1 of the calendar year that is 2 years to prior to the payment year, which we refer to as the QP Determination Submission Deadline (82 FR 53886).

In section III.I.4.e.(5)(b) of this final rule, we are finalizing the addition of a third alternative to allow QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights to the TIN participate in a single (the same) APM Entity. This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for which all clinicians who have reassigned billing rights to the TIN participating in a single APM Entity. To make QP determinations under the All-Payer Combination Option at the TIN level as finalized using either the payment amount or patient count method, we will need to receive, by December 1 of the calendar year that is 2 years to prior to the payment year, all of the payment amount and patient count information: (1) Attributable to the eligible clinician, TIN, or APM Entity through every Other Payer Advanced APM; and (2) for all other payments or patients, except from excluded payers, made or attributed to the eligible clinician(s) during the QP performance period for the periods January 1 through March 31, January 1 through June 30, and January 1 through August 31.

As shown in Table 87, we assume that 4 APM Entities, 225 TINs, and 80 eligible clinicians will submit data for QP determinations under the All-Payer Combination Option in 2019. We estimate it will take the APM Entity representative, TIN representative, or eligible clinician 5 hours at $107.38/hr for a practice administrator to complete this submission. In aggregate, we estimate an annual burden of 1,545 hours (309 respondents × 5 hr) at a cost of $165,902 (1,545 hr × $107.38/hr).

TABLE 87—ESTIMATED BURDEN FOR THE SUBMISSION OF DATA FOR ALL-PAYER QP DETERMINATIONS

	Burden estimate
# of APM Entities submitting data for All-Payer QP Determinations (a)	4
# of TINs submitting data for All-Payer QP Determinations (b)	225
# of eligible submitting data for All-Payer QP Determinations (c)	80
Hours Per respondent QP Determinations (d)	5
Total Hours (g) = [(a) * (d)] + [(b) * (d)] + [(c) * (d)]	1,545
Labor rate for a Practice Administrator ($107.38) (h)	$107.38/hr
Total Annual Cost for Submission of Data for All-Payer QP Determinations (i) = (g) * (h)	$165,902

We received no public comments related to the burden estimates for the Submission of Data for All-Payer QP Determinations. The burden estimates have been updated from the CY 2019 PFS proposed rule to reflect updated respondent estimates (83 FR 36038 through 36039).

18. Quality Payment Program ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule does not include any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we have adjusted our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 11,617 (10 percent × 116,174 voluntary MIPS participants), a decrease of 10,783 from the total respondents currently approved by OMB under the aforementioned control number due to the reduction in voluntary participation in MIPS overall. As we discussed earlier in this section of the final rule, voluntary respondents are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements discussed in section III.I.3.a. of this final rule, but have elected to submit data to MIPS. In implementing the finalized opt-in policy, we estimate that 33 percent of clinicians that exceed 1 of the low-volume criteria, but not all 3, will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter. This logic was also applied in the regulatory impact analysis of this rule. Table 88 shows that for these voluntary participants, we estimate it will take 0.25 hours at $89.18/hr for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,904.25 hours (11,617 requests × 0.25 hr/request) at a cost of $259,001 (2,904.25 hr × $89.18/hr).

The decrease in the number of respondents due to policies finalized in this rule results in a decrease of −2,695.75 hours (−10,783 respondents × 0.25 hr) and −$240,407 (−2,695.75 hours × $89.18/hr).

TABLE 88—ESTIMATED BURDEN FOR VOLUNTARY PARTICIPANTS TO ELECT OPT OUT OF PERFORMANCE DATA DISPLAY ON PHYSICIAN COMPARE

	Burden estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	11,617
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours for Opt-out Requester (c) = (a) * (b)	2,904.25
Labor rate for a computer systems analyst (d)	$89.18/hr
Total Annual Cost for Opt-out Requests (e) = (a) * (d)	$259,001

We received no public comments related to the burden estimates for voluntary participants to elect to opt out of performance data display on Physician Compare. However, the burden estimates have not been updated from the CY 2019 PFS proposed rule to reflect availability of data from the 2017 MIPS performance period (83 FR 36039).

19. Summary of Annual Quality Payment Program Burden Estimates

Table 89 summarizes this final rule's burden estimates for the Quality Payment Program. To understand the burden implications of the policies finalized in this rule, we have also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2018 Quality Payment Program final rule into the 2019 MIPS performance period. Our baseline burden estimates reflect the recent availability of data sources to more accurately reflect the number of the respondents for the quality, Promoting Interoperability, and improvement activities performance categories and the number of organizations exempt from the Promoting Interoperability performance category.

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TABLE 89: Summary of Finalized Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Respondents	Finalized Respondents	Change in Respondents	Currently Approved Total Burden Hours	Finalized Total Burden Hours	Change in Total Burden Hours
ICRs Under OMB Control Number 0938-1314 (CMS-10621)						
§414.1400 Registry self- nomination*	120	150	30	1,200	450	-750
§414.1400 QCDR self-nomination*	113	200	87	1,130	2,400	1,270
§§414.1325 and 414.1335 CMS Enterprise Portal User Account Registration	0	3,741	3,741	0	3,741	3,741
§§414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type	278,039	257,260	-20,779	4,949,094	3,653,092	-1,296,002
§§414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type	107,217	81,981	-25,236	973,852	744,633	-229,219
§§414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type	54,218	51,861	-2,357	487,962	414,888	-73,074
§414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface	296	286	-10	21,904	17,636.7	-4,267.3
§§414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface	10	67	57	10	16.75	6.75
(Quality Performance Category) Call for Quality Measures	40	140	100	20	630	610
§414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories	40,645	6,041	-34,604	20,323	1,510	-18,813
§§414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission	218,215	93,869	-124,346	654,645	250,317	-404,328
(Promoting Interoperability Performance Category) Call for Promoting Interoperability Measures	40	47	7	20	23.5	3.5
§414.1360 (Improvement Activities Performance Category) Data Submission	439,786	136,004	-303,782	439,786	11,334	-428,452
§414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities	150	125	-25	75	250	175
§414.1430 Partial Qualifying APM Participant (QP) Election	17	81	64	4.25	20.25	16
§414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	300	215	-85	3,000	2,150	-850
§414.1445 Other Payer Advanced APM Identification: Eligible Clinician Initiated Process	75	150	75	750	1,500	750
§414.1440 Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option	0	309	309	0	1,545	1,545
§414.1395 (Physician Compare) Opt Out for Voluntary Participants	22,400	11,617	-10,783	5,600	2,904.25	-2,695.75
Subtotal	*1,161,681*	*644,144*	*-517,537*	*7,559,375*	*5,109,042*	*-2,350,334*
ICRs Under OMB Control Number 0938-1222 (CMS-10450)						
§§414.1325 and 414.1335 (CAHPS for MIPS Survey) Beneficiary Participation	132,307	39,039	-93,268	29,108	8,393	-20,715
§§414.1325 and 414.1335 (CAHPS for MIPS Survey) Group Registration	461	282	-179	691.5	211.5	-480
Subtotal	*132,768*	*39,321*	*-93,447*	*29,799.5*	*8,605*	*-21,195*
TOTAL	**1,294,449**	**683,465**	**-610,984**	**7,589,175**	**5,117,646**	**-2,371,529**

*These two ICRs were combined in a single ICR in the CY 2018 Quality Payment Program final rule (82 FR 53906 through 53907).

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Table 90 provides the reasons for changes in the estimated burden for information collections in this final rule. We have divided the reasons for

our change in burden into those related to new policies and those related to changes in the baseline burden of continued Quality Payment Program Year 2 policies that reflect updated data and methods.

TABLE 90—REASONS FOR CHANGE IN BURDEN COMPARED TO THE CURRENTLY APPROVED CY 2018 INFORMATION COLLECTION BURDENS

Table in collection of information	Changes in burden due to finalized Year 3 policies	Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data*)
Table 62: Qualified Registry Self-Nomination.	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in a decrease in estimated time needed to complete simplified self-nomination (−9.5 hr. computer system analyst time) and full self-nomination (−7 hr. computer system analyst time). *Increase in the number of respondents as the number of qualified registries enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of qualified registries being approved.*
Table 63: QCDR Self-Nomination	None	After a review of the self-nomination process, we determined it is more accurate to separately assess the burden of Qualified Registry and QCDR self-nomination rather than aggregate them in the same ICR. Review of self-nomination process resulted in an increase in estimated time needed to complete simplified self-nomination (−0.5 hr. computer system analyst time) and full self-nomination (+2 hr. computer system analyst time). *Increase in the number of respondents as the number of QCDRs enrolling increases and the basis for estimating the number of respondents is updated to reflect the number of self-nomination applications received in place of the number of QCDRs being approved.*
Table 68: Quality Payment Program Identity Management Application Process.	None	*Decreased number of respondents due to updates to the identity management system being used for data submission in the 2018 MIPS performance period; only new respondents submitting quality data using the CMS Enterprise Portal need to create a new account, versus system where all respondents submitting via EHR needed to register for user account annually.*
Table 69: Quality Performance Category Medicare Part B Claims Collection Type.	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.* Correction to estimate to account for reduced number of required measures compared to PQRS (6 in MIPS; 9 in PQRS) reduced estimated time to submit data.
Table 70: Quality Performance Category QCDR/MIPS CQM Collection Type.	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.*
Table 71: Quality Performance Category eCQM Collection Type.	None	*Decreased number of respondents due to updated data from 2017 MIPS performance period.*
Table 72: Quality Performance Category CMS Web Interface.	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (−12.33 hrs computer system analyst time).	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elected to submit data using the CMS Web Interface.*
Table 73: Beneficiary Responses to CAHPS for MIPS Survey.	None	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elect to have vendors administer the CAHPS for MIPS survey and fewer beneficiaries per group respond to the survey, on average.*
Table 74: Registration for CMS Web Interface.	None	*Increase in the number of respondents due to updated data from the 2018 MIPS performance period as more groups register to submit data using the CMS Web Interface.* Review of registration process resulted in decrease in estimated time to register. (−0.75 hr. computer system analyst time).
Table 75: Registration for CAHPS for MIPS Survey.	None	*Decrease in the number of respondents due to updated data from the 2018 MIPS performance period as fewer eligible group practices elect to have vendors administer the CAHPS for MIPS survey.* Review of registration process resulted in decrease in estimated time to register. (−0.75 hr. computer system analyst time).
Table 76: Call for Quality Measures	None	*Increase in the number of new quality measures being nominated.* Inclusion of time required to complete Peer Review Journal Article Form resulted in increase in time to nominate a quality measure. This was a requirement in the CY 2017 Quality Payment Program final rule (81 FR 77153 through 77155) but was not included in burden estimates. (+4 hrs Physician time).
Table 77: Reweighting Applications for Promoting Interoperability and Other Performance Categories.	None	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.* Review of application process resulted in decrease in estimated time to apply (−0.25 hr computer system analyst time).
Table 79: Promoting Interoperability Performance Category Data Submission.	Decrease in number of required measures resulted in reduction in estimated time needed to submit data (−.33 hr computer system analyst time).	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*
Table 80: Call for Promoting Interoperability Measures.	None	*Increase in the number of new Promoting Interoperability measures being nominated.*
Table 82: Improvement Activities Submission.	None	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*

TABLE 90—REASONS FOR CHANGE IN BURDEN COMPARED TO THE CURRENTLY APPROVED CY 2018 INFORMATION COLLECTION BURDENS—Continued

Table in collection of information	Changes in burden due to finalized Year 3 policies	Changes to "baseline" of burden continued Year 2 policy (*italics are changes in number of respondents' due to updated data*)
		Review of submission process resulted in decrease in estimated to submit (−0.92 hr computer system analyst time).
Table 83: Nomination of Improvement Activities.	None	Review of nomination process resulted in increase in estimated time to nominate a new improvement activity (+0.9 hrs Practice Administrator time; +0.6 hrs Physician time).
Table 84: Partial QP Election	None	*Increase in the number of respondents due to additional APM Entities and eligible clinicians electing to participate as a Partial QP in MIPS.*
Table 85: Other Payer Advanced APM Identification: Other Payer Initiated Process.	None	*Decrease in the number of anticipated other payer arrangements submitted for identification as Other Payer Advanced APMs.*
Table 86: Other Payer Advanced APM Identification: Eligible Clinician Initiated Process.	None	*Increase in the number of anticipated other payer arrangements submitted by APM Entities and eligible clinicians for identification as Other Payer Advanced APMs.*
Table 87: Submission of Data for All-Payer QP Determinations under the All-Payer Combination Option.	Reflects new policy in this final rule.	None.
Table 88: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare.	*Decrease in the number of respondents due to updated data from 2017 MIPS performance period.*	None.

C. Summary of Annual Burden Estimates for Finalized Requirements

TABLE 91—ANNUAL REQUIREMENTS AND BURDEN

Regulation section(s) under Title 42 of the CFR	OMB control No. ***	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($/hr)	Total cost ($) *
§ 414.94(j) (AUC consultations) Voluntary period.	0938–1345	10,230,000	3,410,000	0.033 (2 min)	112,530	Varies	5,527,924
§ 414.94(j) (AUC consultations) Beginning Jan 1, 2020.	0938–1345	586,386	43,181,818	0.033 (2 min)	1,425,000	Varies	70,001,700
§ 414.94 (AUC recordkeeping)	0938–1345	586,386	6,699	0.167 (10 min)	1,119	34.50	38,596
Quality Payment Program (See Subtotal Under Table 89).	0938–1314	(**)	(517,537)	varies	(2,450,334)	varies	(221,510,118)
Quality Payment Program (See Subtotal Under Table 89).	0938–1222	(93,447)	(93,447)	varies	(21,195)	varies	(546,362)
Total		10,722,939	45,987,533	Varies	(932,880)	Varies	(146,488,260)

* For the PRA, this rule will not impose any non-labor costs.

** We are unable to accurately calculate a total number of respondents for the Quality Payment Program. In many cases, individuals, groups, and entities have responded to multiple data collections and there is no unified way to identify unique respondents.

*** OMB and CMS' PRA package ID numbers: OMB 0938–1345 (CMS–10654), OMB 0938–1314 (CMS–10621), and OMB 0938–1222 (CMS–10450).

**** For OMB 0938–1314 (CMS–10621), the estimated total number of respondents across all ICRs for the CY 2019 performance period is 644,144 while estimated total burden hours are 5,109,042 at a cost of $482,416,597. (CMS–10450), the estimated total number of respondents across all ICRs for the CY 2019 performance period is 39,336 while estimated total burden hours are 8,755 at a cost of $236,525. For OMB 0938–1343 (CMS–10652), the estimated total number of respondents across all ICRs for the CY 2019 performance period is 16 while estimated total burden hours are 160 at a cost of $13,506.

VII. Regulatory Impact Analysis

A. Statement of Need

This final rule makes payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and section 2001(a) of the SUPPORT for Patients and Communities Act of 2018. This final rule also makes changes to payment policy and other related policies for Medicare Part B.

This final rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed regulatory impact analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to section 1834(q) of the Act and, to the extent feasible, maximize net benefits.

This final rule also makes payment and policy changes under the Medicare PFS and makes required statutory changes under the MACRA, as amended by section 51003 of the Bipartisan Budget Act of 2018.

The new policies for CY 2019 are detailed throughout this final rule. For example, the policies associated with modernizing Medicare physician payment by recognizing communication technology-based services are described in section II.D. of this final rule, while the policies associated with E/M visits are described in section II.I. of this final rule. Several policies addressing the use of innovative technology that enables remote services will expand access to care and create more opportunities for patients to access more personalized care management, as well as connect with their physicians more quickly. These policies support access to care using telecommunications technology by paying clinicians for virtual check-ins (brief, non-face-to-face appointments via communications technology), paying clinicians for evaluation of patient-submitted photos or videos, and

expanding Medicare-covered telehealth services to include prolonged preventive services.

Several policies in the final rule will also give physicians more time to spend with their patients, especially those with complex needs, rather than on paperwork. Specifically, there are provisions that simplify certain documentation requirements for E/M visits, which make up about 40 percent of allowed charges under the PFS and consume much of clinicians' time; reduce supervision requirements for radiologist assistants during diagnostic test services; and remove burdensome and overly complex functional reporting requirements for outpatient therapy. In addition, section VII.H. of this final rule, the RIA, details the economic effect of these policies on Medicare providers and beneficiaries.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS policies included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

For example, the effects of changes to payment rates for practitioners, other providers, and suppliers are discussed in VII.C. of this final rule. Alternative options considered to the payment rates are discussed generally in section VII.F. of this final rule.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and non-physician practitioners in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is considered an E.O. 13771 deregulatory action because it is expected to result in regulatory cost savings. The estimated impact would be $71 million in cost savings in 2019, $3.986 billion in costs in 2020, $387 million in cost savings in 2021, $450 million cost savings in 2022, and $557 million in cost savings in 2023 and thereafter. Annualizing these costs and cost savings in perpetuity and discounting at 7 percent back to 2016, we estimated that this rule would generate $190 million in annualized net cost savings for E.O. 13771 accounting purposes. Details on the estimated cost savings of this rule can be found in the following analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, we are implementing a variety of changes to our regulations, payments, or payment policies to ensure that our payment

systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provided information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2018 with payment rates for CY 2019 using CY 2017 Medicare utilization. The payment impacts in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). Section 101(a) of the MACRA repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for CY 2015 and beyond. The update adjustment factor for CY 2019, as required by section 53106 of the Bipartisan Budget Act of 2018, is 0.25 percent before applying other adjustments.

To calculate the CF for this year, we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimated the CY 2019 PFS CF to be 36.0391 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) and the 0.25 percent update adjustment factor specified under section 1848(d)(18) of the Act. We estimate the CY 2019 anesthesia CF to be 22.2730, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 92—CALCULATION OF THE FINAL CY 2019 PFS CONVERSION FACTOR

CY 2018 Conversion Factor		35.9996
Statutory Update Factor	0.25 percent (1.0025)	
CY 2019 RVU Budget Neutrality Adjustment	−0.14 percent (0.9986)	
CY 2019 Conversion Factor		36.0391

TABLE 93—CALCULATION OF THE FINAL CY 2019 ANESTHESIA CONVERSION FACTOR

CY 2018 National Average Anesthesia Conversion Factor		22.1887
Statutory Update Factor	0.25 percent (1.0025)	
CY 2019 RVU Budget Neutrality Adjustment	−0.14 percent (0.9986)	
CY 2019 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment.	0.27 percent (1.0027)	
CY 2019 Conversion Factor		22.2730

Table 94 shows the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 94 (CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 94.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2017 utilization and CY 2018 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2019 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2019 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2019 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2019 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 94—CY 2019 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	0	−1	0	−1
Anesthesiology	1,982	0	0	0	0
Audiologist	68	0	1	0	1
Cardiac Surgery	293	0	0	0	0
Cardiology	6,616	0	0	0	0
Chiropractor	754	0	−1	0	−1
Clinical Psychologist	776	0	3	0	3
Clinical Social Worker	728	0	3	0	2
Colon and Rectal Surgery	166	0	1	0	1
Critical Care	342	0	−1	0	−1
Dermatology	3,489	0	1	0	1
Diagnostic Testing Facility	734	0	−5	0	−5
Emergency Medicine	3,121	0	0	0	0
Endocrinology	482	0	0	0	0
Family Practice	6,207	0	0	0	0
Gastroenterology	1,754	0	0	0	0
General Practice	428	0	0	0	0
General Surgery	2,090	0	0	0	0
Geriatrics	197	0	0	0	0
Hand Surgery	214	0	0	0	0
Hematology/Oncology	1,741	0	−1	0	−1
Independent Laboratory	646	0	−2	0	−2
Infectious Disease	649	0	0	0	−1
Internal Medicine	10,766	0	0	0	0
Interventional Pain Mgmt	868	0	1	0	1
Interventional Radiology	384	1	1	0	2
Multispecialty Clinic/Other Phys	149	0	0	0	0
Nephrology	2,188	0	0	0	0
Neurology	1,529	0	0	0	0
Neurosurgery	802	0	0	0	0
Nuclear Medicine	50	0	−1	0	−1
Nurse Anes/Anes Asst	1,242	0	0	0	0
Nurse Practitioner	4,060	0	0	0	0
Obstetrics/Gynecology	637	0	0	0	0
Ophthalmology	5,451	0	−1	0	−1
Optometry	1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	67	0	0	0	0
Orthopedic Surgery	3,741	0	0	0	0
Other	31	0	4	0	4
Otolarngology	1,222	0	0	0	0
Pathology	1,165	0	−1	0	−2
Pediatrics	61	0	0	0	0
Physical Medicine	1,107	0	0	0	0
Physical/Occupational Therapy	3,950	0	−1	0	−1
Physician Assistant	2,438	0	0	0	0
Plastic Surgery	376	0	0	0	0
Podiatry	1,974	0	2	0	2
Portable X-Ray Supplier	99	0	1	0	1
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,714	0	0	0	0
Radiation Oncology and Radiation Therapy Centers	1,765	0	0	0	−1
Radiology	4,907	0	0	0	0
Rheumatology	541	0	0	0	0
Thoracic Surgery	357	0	0	0	0
Urology	1,738	0	1	0	1
Vascular Surgery	1,141	0	2	0	2
Total	92,733	0	0	0	0

*Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2019 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including clinical psychologists, vascular surgery, interventional radiology, and podiatry, reflect increases relative to other physician specialties. These increases can largely be attributed to finalized increases in

value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC) and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the implementation of new payment policies associated with communication technology-based services.

The estimated impacts for several specialties, including diagnostic testing facilities, independent labs, pathology, and ophthalmology, reflect decreases in payments relative to payment to other physician specialties. These decreases can largely be attributed to revaluation of individual procedures reviewed by the AMA's committee and CMS, decreased payments as a result of finalized updates to supply and equipment pricing, and continued implementation of previously finalized code-level reductions that are being phased-in over several years. We note that the estimated impacts for many specialties differ significantly relative to the estimates included in the proposed rule. These changes reflect changes between the proposed and final policies based on our consideration of public comments. We note that the most significant of these changes relates to the various elements of the proposed changes in coding and payment for office/outpatient E/M visits, none of which are being finalized for CY 2019. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 2 percent reduction for CY 2019 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 94), including comments received in response to the proposed rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 94 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 94 displays the estimated CY 2019 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2019 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

c. Estimated Impacts of Implementing the Payment and Coding Changes for Office/Outpatient E/M Services for CY 2021

Although we are not finalizing changes to E/M coding and payment for CY 2019, we are finalizing certain changes for CY 2021. We provide the following impact estimate only for illustrative purposes. Table 95 illustrates the estimated specialty level impacts associated with implementing our finalized policies for E/M coding and payment in CY 2019, rather than delaying until CY 2021. Table 24C shows the estimated impacts of adopting single payment rates for new and established patient E/M visit levels 2–4 (with the rates determined using input values that reflect the weighted average of 2018 inputs for codes describing those visit levels), keeping separate rates for new and established patient E/M visit level 5 (with the rates determined using the 2018 input values for level 5 visits), and adopting add-on codes with equal rates to adjust for the inherent visit complexity of primary care and non-procedural specialty care (with the rates determined using the input values from the proposed rule for the non-procedural specialty care complexity code).

TABLE 95—ESTIMATED SPECIALTY LEVEL IMPACTS OF FINAL E/M PAYMENT AND CODING POLICIES IF IMPLEMENTED FOR 2019

Specialty	Allowed charges (mil)	Impact of work RVU changes %	Impact of PE RVU changes %	Impact of MP RVU changes %	Combined impact %
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	0	0	0	0
Anesthesiology	1,981	−1	0	0	−2
Audiologist	68	−1	1	0	0
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	−1	−1	0	−2
Chiropractor	754	−1	0	0	−1
Clinical Psychologist	776	−1	1	0	0
Clinical Social Worker	728	−2	2	0	0
Colon and Rectal Surgery	166	0	1	0	0
Critical Care	342	−2	−1	0	−3
Dermatology	3,486	1	3	0	4
Diagnostic Testing Facility	733	0	−5	0	−5
Emergency Medicine	$3,121	−2	−1	0	−2
Endocrinology	482	−1	−1	0	−2
Family Practice	6,208	1	1	0	2
Gastroenterology	1,757	−2	−1	0	−3
General Practice	429	2	1	0	3
General Surgery	2,093	0	0	0	−1

TABLE 95—ESTIMATED SPECIALTY LEVEL IMPACTS OF FINAL E/M PAYMENT AND CODING POLICIES IF IMPLEMENTED FOR 2019—Continued

Specialty	Allowed charges (mil)	Impact of work RVU changes %	Impact of PE RVU changes %	Impact of MP RVU changes %	Combined impact %
(A)	(B)	(C)	(D)	(E)	(F)
Geriatrics	197	−1	−1	0	−1
Hand Surgery	214	1	1	0	3
Hematology/Oncology	1,741	0	−1	0	0
Independent Laboratory	646	−1	3	0	3
Infectious Disease	649	−1	−1	0	−1
Internal Medicine	10,767	0	0	0	0
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−2	0	−2
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	−1	0	−2
Neurology	1,529	−1	0	0	−1
Neurosurgery	804	−1	−1	0	−1
Nuclear Medicine	50	−1	−1	0	−3
Nurse Anes/Anes Asst	1,242	−2	0	0	−2
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	5
Ophthalmology	5,448	−1	−2	0	−3
Optometry	$1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	68	0	0	0	1
Orthopedic Surgery	3,743	0	1	0	1
Other	31	−1	3	0	2
Otolarngology	1,210	3	3	0	5
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−2	0	−3
Physician Assistant	2,457	2	1	0	4
Plastic Surgery	377	0	0	0	1
Podiatry	1,974	4	6	0	10
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	3	2	0	5
Pulmonary Disease	1,715	−1	−1	0	−2
Radiation Oncology and Radiation Therapy Centers	1,766	−1	−1	0	−1
Radiology	4,911	−1	−1	0	−2
Rheumatology	541	0	−1	0	−1
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	4
Vascular Surgery	1,148	0	−2	0	−2
Total	92,771	0	0	0	0

Under our finalized policies, specialties that disproportionately report lower level visits, such as podiatry, and specialties that report office/outpatient visits in conjunction with minor procedures, such as dermatology, would see significant increases. Specialties that predominantly furnish higher level visits would have their negative redistribution significantly mitigated by the maintenance of the level 5 visit and the add-on codes for inherent visit complexity for primary and non-procedural specialty care.

We note that our original proposal was developed more generally to maintain overall RVUs within the codes describing office/outpatient visits, but, after consideration of public comments, we are not finalizing several elements of those proposals, including and especially the multiple procedure payment reduction. As a result, implementation with the values and policies as altered, would require off-setting reductions in overall PFS payments. Following our current methodology, these reductions, required by statute, would be applied through a budget neutrality adjustment in the PFS CF, consistent with our established methodology. As a result of such an adjustment, specialties that do not furnish office/outpatient visits generally would see overall reductions in payment of approximately 2.0 percent, as generally reflected in the Table 95. Given that overall payment for the office/outpatient E/M codes would increase, and because these services are reported by most specialities, the overall changes for most specialties are generally offsetting. However, for physician specialties and suppliers that do not report office/outpatient E/M services, the reduction would be approximately −2.0 percent.

As discussed in section II.H., of this final rule, based on the statements by commenters that the medical community, through the CPT process, has committed itself to considering revisions to the office/outpatient visit codes and given the history of collaboration between CMS and the medical community, we expect to consider any possible changes in CPT coding, as well as recommendations regarding valuation for services, from the RUC and other stakeholders, through our annual rulemaking process, between now and implementation for

CY 2021. We note that any potential coding changes, and recommendations in overall valuation for new or existing codes, could have significant impact on the actual change in overall RVUs for office/outpatient visits relative to the rest of the PFS. Given the various factors that will be considered by the variety of stakeholders involved in the CPT and RUC processes, we do not believe we can estimate with any degree of certainty what the impact of potential changes might be. We also, note, however, that any changes in coding and payment for these services would be subject to notice and comment rulemaking.

With regard to the documentation policies we are finalizing for CY 2021, our intent is to allow clinicians a choice in how levels 2 through 5 visits are documented—using current framework, MDM or time. Assuming the current code set for E/M office/outpatient visits is maintained for CY 2021, when a level 2 through 4 visit (which comprises the majority of visits currently furnished) is documented using the current framework or MDM, documentation will be simplified by applying a minimum level 2 documentation standard to level 2 through 4 visits. When a level 2 through 4 visit is documented using time, practitioners should report the appropriate code based on the time defined as typical under the CPT code descriptors for office/outpatient E/M visits. Practitioners will be required to document that the visit was medically necessary and the billing practitioner spent at least the amount of time included in the CPT as typical face-to-face with the patient. The extended visit code can be reported with a level 2 through 4 visit when the time of the overall visit is between 34 and 69 minutes (for established patients) and between 38 and 89 minutes (for new patients) of face-to-face time with the billing practitioner. (See section II.I. of this final rule. For example, a level 2 through 4 extended visit will require the billing practitioner to spend and document that he or she spent at least 35 minutes face-to-face with the patient. We are also finalizing a policy to require minimal documentation to support reporting of the add-on codes that we are finalizing for use with the level 2 through 4 visit codes. These add-on codes are to reflect the inherent complexity in E/M services for primary care, and for other non-procedural specialty care, and for extended visits).

For level 5 E/M visits, again assuming the current code set remains in place for CY 2021, we will allow the visit to be documented using the current framework, MDM or time. When documenting using MDM, the current definition of level 5 MDM will apply. When documenting a level 5 visit using time, we will require the billing practitioner to document that they spent at least the typical time for the reported level 5 CPT code, face-to-face with the patient (currently 40 minutes for an established patient and 60 minutes for a new patient). The add-on codes that we are finalizing for use with the level 2 through 4 visits (the inherent complexity add-on codes for primary care and other non-procedural specialty care and extended visits) will not be reportable with level 5 visits. We note that the current coding for prolonged visits would continue to be reportable with level 5 visits.

As discussed elsewhere in this section of the final rule, we estimate this approach would lead to significant burden reduction for practitioners, while allowing preparatory time and time for potential refinement over the next few years as we take into account any feedback from stakeholders on these changes, as well as any potential revisions to the E/M code set.

D. Effect of Changes Related to Telehealth

As discussed in section II.D. of this final rule, we are adding two new codes, HCPCS codes G0513 and G0514, to the list of Medicare telehealth services. Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the proposed additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, for services already on the list, they are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. This addition was responsive to longstanding stakeholder interest in expanding Medicare payment for telehealth services. The restrictions placed on Medicare telehealth by the statute limit the magnitude of utilization; however, we believe there is value in allowing physicians and patients the greatest flexibility when appropriate.

E. Effect of Changes to Payment to Provider-Based Departments (PBDs) of Hospitals Paid Under the PFS

As discussed in section II.G. of this final rule, we are finalizing a PFS Relativity Adjuster of 40 percent for CY 2019, meaning that nonexcepted items and services furnished by nonexcepted off-campus PBDs will be paid under the PFS at a rate that is 40 percent of the OPPS rate. In finalizing our policy to maintain the PFS Relativity Adjuster at 40 percent, we updated our analysis to include a full year of claims data. We estimated site-specific PFS rates for the technical component of a service for the entire range of HCPCS codes furnished in nonexcepted off campus PBDs. Next we compared the sum of the site-specific payment rates under the PFS, weighted by OPPS claims volume, to the sum of payment rates under the OPPS, also weighted by OPPS claims volume. This calculation resulted in a relative rate of approximately 40 percent, supporting our policy to maintain the PFS Relativity Adjuster at 40 percent. We are finalizing the PFS Relativity Adjuster of 40 percent, as proposed. There will be no additional savings for CY 2019 relative to CY 2018 because we are maintaining the current PFS Relativity Adjuster of 40 percent, which was finalized for CY 2018.

F. Other Provisions of the Final Regulation

1. Part B Drugs: Application of an Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments

In section II.M. of this final rule, we finalized the following policy: Effective January 1, 2019, Wholesale Acquisition Cost (WAC)-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3 percent add-on in place of the 6 percent add-on that is currently being used. We also will permit Medicare Administrative Contractors (MACs) to use an add-on percentage of up to 3 percent for WAC-based payments for new drugs.

We anticipate that the reduction to the add-on payment made for a subset of Part B drugs will result in savings to the Medicare program. The 3 percent add-on is consistent with MedPAC's analysis and recommendations, as well as discounts observed by MedPAC in their June 2017 Report to the Congress. We have also considered how CMS' experience with WAC-based pricing for recently marketed new drugs and biologicals compares to MedPAC's findings. Although the number of new drugs that are priced using WAC is very limited, the average difference between WAC and Average Sales Price (ASP)-based payment limits for a group of 3 recently approved drugs and biologicals that appeared on the ASP Drug Pricing Files (including one biosimilar biological product) was 9.0 percent. Excluding the biosimilar biological product results in a difference of 3.5 percent. The difference was determined by comparing a partial quarter WAC-based payment amount determined

under section 1847A(c)(4) of the Act to the next quarter's ASP-based payment amount. These findings are in general agreement with MedPAC's findings.

Although we are able to provide examples of the relative differences between ASP and WAC based payment limits, and we anticipate some savings from the change in policy, we cannot estimate the magnitude of savings over time because we cannot determine how many new drugs and biologicals subject to partial quarter pricing will appear on the ASP Drug Pricing files in the future or how many Part B claims for these products will be paid. This limitation also applies to contractor-priced drugs and biologicals that have HCPCS codes and are in their first quarter of sales. Finally, the claims volume for contractor-priced drugs and biologicals that are billed using miscellaneous or Not Otherwise Classified codes, such as J3490 and J3590, cannot be quantified. We would like to note that for the three drugs discussed in the preceding paragraph, Medicare Part B payments for individual doses of each drug range from approximately $3,000 to $10,000. The payment changes finalized in this rule would result in a little less than $100 to $300 savings in Medicare allowed charges for each dose.

Although we cannot estimate the overall savings to the Medicare Program or to beneficiaries, we would like to note that this change in policy is likely to decrease copayments for individual beneficiaries who are prescribed new drugs. Given that launch prices for single doses for some new drugs may range from tens to hundreds of thousands of dollars, a 3 percentage point reduction in the total payment allowance will reduce a patient's 20 percent Medicare Part B copayment. This reduction can result in savings to an individual beneficiary and can help Medicare beneficiaries particularly those without supplementary insurance, afford to pay for new drugs by reducing out of pocket expenses.

The 3 percent add-on is expected to reduce the difference between acquisition cost and certain WAC-based Part B drug payments. Based on MedPAC's June 2017 Report to Congress, and for reasons discussed in section II.M. of this rule, we do not anticipate that this change will result in payments amounts that are below acquisition cost or that the new policy will impair providers or patients' access to Part B drugs.

2. Changes to the Regulations Associated With the Ambulance Fee Schedule

As discussed in section III B.2. of this final rule, section 50203(a) of the Bipartisan Budget Act of 2018 amended section 1834(l)(12)(A) and (l)(13)(A) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2022. The ambulance extender provisions are enacted through legislation that is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there were no policy proposals associated with these legislative provisions or associated impact in this rule. We are finalizing our proposal without modification to revise the dates in § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory requirements.

In addition, as discussed in section III.B.3. of this final rule, section 53108 of the BBA amended section 1834(l)(15) of the Act to increase the payment reduction from 10 percent to 23 percent effective for ambulance services furnished on or after October 1, 2018 consisting of non-emergency basic life support services involving transports of an individual with end stage renal disease for renal dialysis services furnished other than on an emergency basis by a provider of services or a renal dialysis facility. The 10 percent reduction applies for such ambulance services furnished during the period beginning on October 1, 2013 and ending on September 30, 2018.

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate decrease and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there were no policy proposals associated with these legislative provisions or associated impact in this rule. We are finalizing our proposal without modification to revise § 414.610(c)(8) to conform the regulations to this self-implementing statutory requirement.

3. Clinical Laboratory Fee Schedule: Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory

As discussed in section III. A. of this final rule, section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the Clinical Laboratory Fee Schedule (CLFS). The CLFS final rule titled, Medicare Clinical Diagnostic Laboratory Tests Payment System final rule, published in the **Federal Register** on June 23, 2016, implemented section 1834A of the Act. Under the CLFS final rule (81 FR 41036), ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' (that is, certain private payor data) collected during a ''data collection period'' for their component ''applicable laboratories.'' In general, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the 6-month data collection period and reported to us during the 3-month data reporting period, and is equal to the weighted median of the private payor rates for the CDLT.

An applicable laboratory is defined at § 414.502, in part, as an entity that is a laboratory (as defined under the Clinical Laboratory Improvement Amendments (CLIA) definition at § 493.2) that bills Medicare Part B under its own National Provider Identifier (NPI). In addition, an applicable laboratory is an entity that receives more than 50 percent of its Medicare revenues during a data collection period from the CLFS and/or the PFS. We refer to this component of the applicable laboratory definition as the ''majority of Medicare revenues threshold.'' The definition of applicable laboratory also includes a ''low expenditure threshold'' component which requires an entity to receive at least $12,500 of its Medicare revenues from the CLFS during a data collection period, for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).

In determining payment rates under the private payor rate-based CLFS, one of our objectives is to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities. We believe it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a CDLT, and minimizing the reporting burden for entities. In response to stakeholder feedback and in the interest of facilitating this objective, we are finalizing the revision to the majority of

Medicare revenues threshold component in the third paragraph of the definition of applicable laboratory at § 414.502 to exclude Medicare Advantage (MA) payments under Medicare Part C from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). We believe this change would increase the opportunity for laboratories with a significant Medicare Part C revenue component to meet the majority of Medicare revenues threshold and qualify as an applicable laboratory (provided all other requirements for applicable laboratory status are met). We believe this will result in a broader representation of the laboratory industry reporting applicable information from which to determine payment rates under the CLFS. For a complete discussion of this revision to the majority of Medicare revenues threshold component of the definition of applicable laboratory under the Medicare CLFS, we refer readers to section III A. of this final rule.

Therefore, in response to stakeholder feedback and in the interest of obtaining as much applicable information as possible, we are finalizing the revision of the definition of applicable laboratory at § 414.502 to include a hospital laboratory that bills Medicare on the Form CMS–1450 14x bill type and its electronic equivalent. For a complete discussion of this revision to the definition of applicable laboratory under the Medicare CLFS, we refer readers to section III.A. of this final rule.

a. Estimation of Increased Reporting

To estimate the potential impact of excluding MA plan payments from total Medicare revenues (that is, the denominator of the low expenditure threshold) on the number of laboratories meeting the majority of Medicare revenues threshold, using CY 2017 Medicare claims data, we compared the number of billing NPIs that would have met the majority of Medicare revenues threshold with MA plan revenues included in total Medicare revenues (which is the current requirement) versus the number of billing NPIs that would meet the majority of Medicare revenues threshold had MA plan payments been *excluded* from total Medicare revenues. We found that excluding MA plan payments from total Medicare revenues increased the level of laboratories meeting the majority of Medicare revenues threshold by approximately 49 percent. In other words, we estimate that excluding MA plan payments from total Medicare revenues (the denominator) of the majority of Medicare revenues threshold, and keeping the numerator constant (that is revenues from only the CLFS and or PFS) yields an increase of 49 percent in the number of laboratories meeting the majority of Medicare revenues threshold.

Our summary analysis of data reporting from the initial data reporting period under the Medicare CLFS private payor rate-based payment system, indicates that we received applicable information from 1,942 applicable laboratories and they reported over 4.9 million records. Applying the projected 49 percent increase to the number of applicable laboratories from the first data reporting period (1,942 × 1.49) yields an estimated 2,893 laboratories that would meet the majority of Medicare revenues threshold, which reflects an additional 951 laboratories. Provided all other requirements for applicable laboratory status are met (including the low expenditure threshold of receiving at least $12,500 in CLFS revenues during a data collection period) a laboratory would report applicable information for the next data reporting period.

To determine the estimated reporting burden for an applicable laboratory, we looked at the distribution of reported records that occurred for the first data reporting period. The average number of records reported for an applicable laboratory for the first data reporting period was 2,573. The largest amount of records reported for an applicable laboratory was 457,585 while the smallest amount reported was 1 record. A summary of the distribution of reported records from the first data collection period is illustrated in the Table 96.

TABLE 96—SUMMARY OF RECORDS REPORTED FOR FIRST DATA REPORTING PERIOD

[By applicable laboratory]

Total records	Average records	Min records	Max records	Percentile distribution of records				
				10th	25th	50th	75th	90th
4,995,877	2,573	1	457,585	23	79	294	1,345	4,884

Presuming that all of the additional laboratories that are projected to meet the majority of Medicare revenues threshold, that is approximately 951, also meet all of the criteria necessary to receive applicable laboratory status, as defined at § 414.502, they would be an applicable laboratory and report applicable information for the next data reporting period, January 1, 2020 through March 31, 2020. Using the mid-point of the percentile distribution of reported records from the initial data reporting period, that is approximately 300 records reported per applicable laboratory (50th percentile for the first data reporting period was 294), we estimate an additional 285,300 records would be reported for the next data reporting period (951 laboratories × 300 records per laboratory = 285,300). This represents an increase in data reporting of about 5 percent over the number of records reported for the initial data reporting period (285,300 additional records/4,995,877 = 0.05). In other words, using the approximate mid-point of reported records for the first data reporting period, we estimate that our proposed change to the majority of Medicare revenues threshold would increase the total amount of records reported by approximately 5 percent. As illustrated in Table 96, the number of records reported varies greatly, depending on the volume of services performed by a given laboratory. Laboratories with larger test volumes, for instance at the 90th percentile, should expect to report more records as compared to the midpoint used for this analysis. Laboratories with smaller test volume, for instance at the 10th percentile, should expect to report fewer records as compared to the midpoint.

We estimate that the inclusion of 14X type of bills would yield an increase of 39 percent in the total number of laboratories meeting the majority of Medicare revenues threshold. Applying the projected 39 percent increase to the number of applicable laboratories from the first data reporting period (1,942 × 1.39) yielded an estimated 2,699 laboratories that would meet the majority of Medicare revenues threshold, which reflects approximately

757 additional laboratories. Provided all other required criteria for applicable laboratory status are met (including the low expenditure threshold of receiving at least $12,500 in CLFS revenues during a data collection period) a laboratory would report applicable information for the next data reporting period. Using the mid-point of the percentile distribution of reported records from the initial data reporting period, that is approximately 300 records reported per applicable laboratory (50th percentile for the first data reporting period was 294), we estimated an additional 221,100 records would be reported for the next data reporting period (757 laboratories × 300 records per laboratory = 227,100). This represents an increase in data reporting of about 5 percent over the number of records reported for the initial data reporting period (227,100 additional records/4,995,877 = 0.05).

b. Minimal Impact Expected on CLFS Rates

We note that there would only be an associated Medicare cost or savings to the extent that the additional applicable laboratories are paid at a higher or lower private payor rate, as compared to other laboratories that reported previously, and only to the extent that the volume of services performed by these ''additional'' applicable laboratories is significant enough to make an impact on the weighted median of private payor rates. We have no reason to believe that increasing the level of participation, either by excluding MA plan payments from total Medicare revenues or including laboratories that bill Medicare Part B on the Form CMS–1450 14x bill type would result in a measurable cost difference under the CLFS. Given that the largest laboratories with the highest test volumes, by definition, dominate the weighted median of private payor rates, and that the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we do not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates because of the reasons stated above. However, we believe that this proposal responds directly to stakeholder concerns regarding the number of applicable laboratories reporting applicable information for the initial data reporting period. Therefore, in an effort to increase the number of laboratories qualifying for applicable laboratory status, we are finalizing a change to the majority of Medicare revenues threshold so that laboratories furnishing tests to a significant level of Medicare Part C enrollees may qualify as applicable laboratories and report data to us. In addition, as part of the same effort to increase the number of laboratories qualifying for applicable laboratory status, we are finalizing a change in the definition of applicable laboratory to include an entity that bills Medicare Part B on the Form CMS–1450 14x bill type. We note that other laboratory types, such as independent laboratories and physician office laboratories, are required under the current definition of an applicable laboratory to determine applicable laboratory status and must report applicable information. The use of Form CMS–1450 14x TOB to define an applicable laboratory would assist hospital outreach laboratories to comply with their obligation to assess applicable laboratory status for any outreach laboratories and report applicable information if they meet the requirements to be an applicable laboratory. As such, the hospital could use the revenues from the CLFS and PFS as the numerator compared to the total revenues for the 14X TOB to determine applicable laboratory status. Alternatively, a hospital could get an NPI for its outreach laboratory.

Comment: One commenter disagreed with our using the number of laboratories reporting applicable information during the first data reporting period as a baseline for estimating the number of additional laboratories that would report applicable information as a result of excluding MA plan payments under Part C from total Medicare revenues. The commenter stated that because the OIG estimated that 5 percent of all laboratories paid under Medicare Part B, or about 12,500 laboratories, would qualify as applicable laboratories and would be required to report applicable information to CMS. The commenter stated that because the OIG's estimate is far greater than the number of laboratories that actually reported (that is 1,942), we should not have used the number of laboratories reporting applicable information during the first data reporting period as a baseline.

Response: We believe that it is more appropriate to use the actual reporting levels (1,942 laboratories) from the initial data reporting period as a baseline for projecting increased data reporting under our final policy rather than an estimation of laboratories determined as applicable. We acknowledge that the OIG estimated that 5 percent of all laboratories paid under Medicare Part B, or about 12,500 laboratories, would qualify as applicable laboratories. It is important to note that individual laboratories determine whether they meet the requirements to be an applicable laboratory and that neither OIG nor CMS had the benefit of experience with collecting private payor data before those estimates were made. We believe that using the actual number of laboratories that reported is the more reliable method to develop our estimates of future potential applicable laboratories. We believe that it is would be inappropriate here to estimate future changes using an estimate as a baseline when there is actual experience (for example, number of reporters) that can base used as a baseline.

4. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 1834(q)(2) of the Act, as added by section 218(b) of the PAMA, established a program to promote the use of AUC for applicable imaging services furnished in an applicable setting. The CY 2016 PFS final rule with comment period established an evidence-based process and transparency requirements for the development of AUC and stated that the AUC development process requirements, as well as the application process that organizations must comply with to become qualified provider-led entities (PLEs) did not impact CY 2016 physician payments under the PFS (80 FR 71362). The CY 2017 PFS final rule identified the requirements clinical decision support mechanisms (CDSMs) must meet for qualification and stated that the CDSM requirements, as well as the application process that CDSM developers must comply with for their mechanisms to be specified as qualified under this program, did not impact CY 2017 physician payments under the PFS (81 FR 80546). The CY 2018 PFS final rule established the effective date of January 1, 2020, on which the AUC consulting and reporting requirements will begin, and extended the voluntary consulting and reporting period to 18 months. Therefore, we stated these proposals did not impact CY 2018 physician payments under the PFS (82 FR 53349) and noted we would provide an impact statement when applicable in future rulemaking.

This final rule modifies the Medicare AUC Program and addresses the impacts related to the actions taken by ordering professionals who order advanced diagnostic imaging services and those who furnish the advanced diagnostic imaging services, including the professional and technical portions of the services. We finalized a modification to the AUC consultation requirement for ordering professionals

specified in our regulation at § 414.94(j) to allow clinical staff under the direction of the ordering professional to perform the AUC consultation; therefore, this analysis estimates the impact of AUC consultations. We also clarified the requirement that reporting AUC consultation information across claims for both the furnishing professional and furnishing facility is required in § 414.94(k), and this analysis estimates the impact of the statutorily required reporting AUC consultation information. In addition, we modified the significant hardship exceptions in § 414.94(i) as proposed, therefore this analysis estimates the impact of a self-attestation process for ordering professionals. We also estimated the further reaching impacts of the AUC program in the detailed analysis that follows, assuming that some ordering professionals will voluntarily choose to purchase a qualified CDSM integrated within their existing electronic health record (EHR) and others may voluntarily choose to purchase an EHR system in order to obtain an integrated qualified CDSM. We believe that in the beginning of this program due to the additional action required on the part of the ordering professional, it may take longer for a Medicare beneficiary to obtain an order for an advanced diagnostic imaging service, and therefore, we have calculated an estimated impact to Medicare beneficiaries.

This final rule includes a discussion of the proposed options along with the final policy to report the required claims-based AUC consultation information in the form of G-codes and HCPCS modifiers. We estimated the impact to use existing coding methods (G-codes and HCPCS modifiers) to report that information. Finally, we measured the estimated impact on furnishing professionals and facilities of the finalized proposal to include independent diagnostic testing facilities (IDTFs) as an applicable setting in § 414.94(b). While the AUC consultation and reporting requirements of this program are effective beginning January 1, 2020 with an educational and operations testing period, we attempt in this analysis to identify areas of potential qualitative benefits to both Medicare beneficiaries and the Medicare program.

a. Impact of Required AUC Consultations by Ordering Professionals

In this final rule, we modified the AUC program largely in response to public comments and recommendations as we believe these modifications are also important in minimizing burden of the AUC program on ordering professionals, furnishing professionals, and facilities. Specifically, we included a proposal regarding who, other than the ordering professional, may conduct the AUC consultation through a qualified CDSM and still meet the requirements of our regulations. In the CY 2018 PFS final rule (82 FR 53349), we based our estimate for the AUC consultation requirement on the 2 minute effort of a family and general practitioner resulting in an annual burden of 1,425,000 hours (43,181,818 consultations (Part B analytics 2014 claims data) × 0.033 hr/consultation) at a cost of $275,139,000.

An important difference from last year's analysis is that this year's analysis includes estimates for non-physician practitioners that order advanced diagnostic imaging services. For the purposes of this analysis, we assumed that orders for advanced diagnostic imaging services will be placed by ordering professionals that are non-physician practitioners in the same percent as the numbers of non-physician practitioners are relative to the total number of non-institutional providers. Therefore, this analysis assumed that 40 percent of all advanced diagnostic imaging services will be ordered by non-physician practitioners. While non-physician practitioners may not order advanced diagnostic imaging services in the same proportion as their numbers, we did not have other data to use for this estimate. We specifically solicited comment and data on alternative assumptions about the number of non-physician practitioners who order advanced imaging services. We did not receive comments on this aspect of our estimate.

In addition, we had proposed, but did not finalize, that auxiliary personnel may perform the AUC consultation when under the direction of, and incident to, the ordering professional's services. We finalized that the AUC consultation task may be delegated by the ordering professional to clinical staff under the direction of the ordering professional. The final estimate below, after taking into account public comments, is applicable given the change in policy from proposed rule to final rule. In the CY 2019 PFS proposed rule, we estimated that the majority, or as many as 90 percent, of practices will employ the use of auxiliary personnel, working under the direction of the ordering professional, to interact with the CDSM for AUC consultation for advanced diagnostic imaging orders. We also considered leaving the policy unchanged, and smaller modifications to that could expand who performs the consultation to a single type of non-physician practitioner. We originally proposed this modification because we believed it maximized burden reduction effort as illustrated in the following updated estimate of consultation burden.

To estimate the burden of this proposed policy, we calculated the effort of a 2-minute consultation with a qualified CDSM by a registered nurse (occupation code 29–1141) with mean hourly wage of $35.36 and 100 percent fringe benefits to be $2.33/consultation ($35.36/hour × 2 × 0.033 hour). If 90 percent of AUC consultations (1,282,500 hours) are performed by auxiliary personnel as proposed then annually the burden estimate would be $90,698,400 (1,282,500 hours × $70.72/hour) to consult. We acknowledged that some AUC consultations will be performed by the ordering professional, therefore the remaining total annual burden we estimated was $28,576,950 for the consultation requirement as it was proposed. As a result of these assumptions and calculations, we estimated a reduction in the burden of the statutorily required AUC consultation burden from $275,139,000 (as fully discussed in the CY 2018 PFS final rule) to $122,508,675, which resulted in a net burden reduction of $152,630,325.

The following is a summary of the comments we received on the proposed estimated impact of consultations by ordering professionals.

Comment: In general, several commenters found CMS' proposed estimate of the burden of the Medicare AUC program to be sensible. A few commenters disagreed with the proposed burden estimate of 2 minutes to consult a qualified CDSM. One commenter suggested the time was too short and noted that the Medicare Imaging Demonstration Evaluation Report to Congress [46] indicated 3.3 additional minutes to order an advanced diagnostic imaging service, while another commenter questioned whether the estimate of burden included calculations for the time and effort of the ordering professional to look up the CDSM username and password, wait for web pages to load, conduct the AUC consultation, and record the results. Additionally, a few commenters stated that more complex clinical situations will require additional time to perform an AUC consultation, as well as consultations involving new patients with new clinical scenarios. In contrast, a few other commenters suggested that

[46] Timbie JW, Hussey PS, Burgette L, et al. Medicare imaging demonstration evaluation report for the report to congress. April 2014. RR–706–CMMS.

the 2 minute estimate to perform AUC consultation overestimated the time and effort, stating that accessing one no fee website for a qualified CDSM to perform an AUC consultation takes a healthcare provider less than 50 seconds.

Response: Based on the average of two estimates provided ([3.3 min + 0.8 min]/2 = 2.1 min), we continue to believe that 2 minutes is a reasonable estimate of the time and effort to consult one of the currently qualified clinical decision support mechanisms available under this program. We will continue to supplement these estimates with published evidence as the AUC consultation and reporting requirements are implemented beginning January 1, 2020.

Comment: A few commenters agreed with our estimates that as many as 90 percent of practices would use other personnel working under the direction of the ordering professional to interact with the CDSM. One commenter noted that most family physicians and general practitioners would not employ a registered nurse for the purpose of AUC consultation and instead would rely upon a licensed practical nurse or medical assistant. The commenter also noted that we are likely overestimating the costs in question because if CMS anticipates a registered nurse is needed, then such a professional would be cost prohibitive for most family medicine practices.

Response: As a result of the finalized policy at § 414.94(j) and after reading the public comments, we have updated our estimate to account for the $16.15 mean hourly wage and fringe benefits of a medical assistant (BLS #31–9092) to perform the AUC consultation. If 90 percent of consultations (1,282,500 hours) are performed by such an individual then annually the burden estimate would be $41,424,750 (1,282,500 hours × $32.30/hour) to consult.

Comment: One commenter suggested that not all clinical situations will require the ordering professional to consult a CDSM and report the AUC adherence, but rather noted that first the ordering professional must determine if the patient's clinical scenario is within a priority clinical area. Additionally, one commenter stated that additional time and effort should be considered to estimate the interaction that will likely be required between the ordering professional and auxiliary personnel to complete the AUC consultation within the CDSM. Finally, one commenter suggested that CMS also estimate the time and effort for the furnishing professional to perform the AUC consultation on behalf of the ordering professional.

Response: We remind all commenters that an AUC consultation must take place for any applicable imaging service furnished in an applicable setting and paid for under an applicable payment system, regardless of whether the patient's clinical scenario falls within a priority clinical area. Therefore, we believe that there is not additional time and effort needed to make this determination as it does not change the estimation of burden for the AUC consultation requirement at § 414.94(j). As a result of the finalized policy at § 414.94(j), the furnishing professional cannot perform the AUC consultation on behalf of the ordering professional; therefore, we did not include this additional estimate. When the consultation and reporting requirements are implemented beginning January 1, 2020, we may have data to support additional time for other supportive consultations, such as that between clinical staff and the ordering professional. However, at this time we have no experience or data to suggest the type or time of these interactions, and did not receive estimates or experience from commenters to suggest the level of effort required to change this AUC consultation burden estimate further.

Comment: A few commenters requested that CMS consider situations where multiple consultations occur for the same advanced diagnostic imaging service for the same Medicare beneficiary, such as in the case of obtaining a second opinion. One commenter expected that the estimate of burden would include calculations for the time and effort required of the ordering professional to consult more than one CDSM. Another commenter noted situations resulting in the Medicare beneficiary being unable to receive an order during the encounter and forced to return to the practice such as in the case of technical issues with a CDSM. Finally, one commenter asked that CMS consider an assumption that some ordering professionals will decide not to use a qualified CDSM and instead refer the patient to a specialist for AUC consultation.

Response: If we can consider that a patient is referred to a specialist in lieu of receiving an order from their general practitioner, then we recognize that no second consultation would occur and that a specialist acting as an ordering professional may choose to delegate the AUC consultation to another individual such as someone on their clinical staff. If there are technical difficulties that result in a significant hardship for the ordering professional to consult specified applicable AUC, then no consultation is required and no additional time and effort to perform the consultation would take place. While multiple consultations may take place, such as in the case of consulting more than one CDSM, it is not a requirement. We will continue to look for published evidence on these experiences after the AUC consultation and reporting requirements are implemented beginning January 1, 2020.

Comment: A few commenters noted that additional costs should be considered on the part of the ordering professional and/or personnel under their supervision. One commenter asked that CMS consider the time and effort to educate ordering professionals and auxiliary personnel on how to use a CDSM.

Response: We agree with the commenter that we unintentionally excluded the time and effort to undertake educational training activities related to performing an AUC consultation. As a result we have included the time and effort of a general practitioner (occupation code 29–1062) with mean hourly wage of $100.27 plus 100-percent to account for fringe benefits to attend a one-time, 1.0 hour training. The hour is representative of training incurred by physicians for a single topic as part of the process of maintaining credentials. Some physicians may not need to undertake educational training activities related to this program. Others may undertake training activities in lieu of an alternative continuing education training resulting in no net increase to their training costs. If all 579,687 ordering professionals subject to this program attend a one-time, 1.0 hour training, then we estimate the total burden to be $116,250,431 ($100.27 × 2 × 1.0 hour × 579,687). We recognize that some ordering professionals may be specialists with higher mean hourly wage and other ordering professionals are not physicians (for example, nurse practitioners, physician assistants) with lower mean hourly wage, however without any additional evidence or specific estimates from commenters, we could not inform this burden estimate further.

After considering the comments, we are updating the proposed impact estimate of consultations by ordering professionals. First, we modified our calculation of the effort by a registered nurse to the effort of a 2-minute consultation with a qualified CDSM by a medical assistant (occupation code 31–9092) with mean hourly wage of $16.15 and 100 percent fringe benefits

for 90 percent of consultations (1,282,500 hours) to be $41,424,750 (1,282,500 hours × $32.30/hour). We acknowledged that some AUC consultations will not be performed by these individuals, therefore the remaining total annual burden we estimate is $28,576,950 (142,500 hours × $200.54/hour) for this proposed consultation requirement. As a result of these assumptions and calculations, we estimated a reduction in burden of the statutorily required consultation from cost of $275,139,000 to $70,001,700, which results in a net burden reduction of $205,137,300.

In section VII.G. of this RIA, Alternatives Considered, we provide a detailed estimate of the burden of an ordering professional voluntarily choosing to consult a second, free CDSM for 300,717 services annually. If 90 percent of those consultations (300,717 services × 90 percent × 0.033 hr/service) for 8,931.285 total hours were performed by a medical assistant at a rate of $32.30/hour for a total of $288,480.50 (8,931.285 × $32.30/hour) and 10 percent of consultations (300,717 services × 10 percent × 0.033 hr/service) for 992.376 total hours were performed by the ordering professional at a rate of $200.54/hour for a total of $199,011.08 then annually the burden estimate would be 9,923.661 total hours (8,931.285 hours + 992.376 hours) and $487,491.58 ($288,480.50 + $199,011.08) to perform the second consultation.

We also estimated the burden of this one-time effort to undertake educational training activities related to the impact of consultations by ordering professionals. As a result we have included the time and effort of a general practitioner (occupation code 29–1062) with mean hourly wage of $100.27 plus 100-percent to account for fringe benefits to attend a one-time, 1.0 hour training. Based on our proposed estimate in section VII.F.4.b. of this RIA, if 579,687 ordering professionals are subject to this program, and all attend training for the same amount of time, then we estimate the total one-time burden of education and training to be $116,250,431 ($200.54/hr × 1.0 hour × 579,687). Since not all physicians would undertake educational training activities, this estimate should be considered an upper bound.

b. Impact of Significant Hardship Exceptions for Ordering Professionals

We previously identified significant hardship exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services (81 FR 80170). Our original intention was to design the AUC hardship exception process in alignment with the EHR Incentive Program and then the MIPS ACI performance category (now Promoting Interoperability). However, in this final rule, we modified the significant hardship exception criteria under § 414.94(i)(3) to be specific to the Medicare AUC program and independent of other Medicare programs both in policy and process. Specifically, we finalized the policy that all ordering professionals self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order. Since the Medicare EHR Incentive Program has ended and we are unable to continue referring to a regulation that is no longer in effect, we did not consider leaving this policy unchanged. We also considered using a significant hardship application submission process. However, we believe that the self-attestation process maximizes burden reduction effort as illustrated in the following updated estimate of ordering professionals subject to an AUC consultation burden.

To estimate the impact of our modification and create a hardship exception specific to this program we attempted to identify how many ordering professionals would be subject to this program.

Medicare non-institutional Part B claims for the first 6 months of 2014 shows that for claims for an advanced diagnostic imaging service that listed an NPI for the ordering/referring provider, up to 90-percent of claims include only 18 different provider specialties. These specialties include: Emergency Medicine; Internal Medicine; Family Practice; Cardiology; Hematology/Oncology; Orthopedic Surgery; Neurology; Urology; Physician Assistant; Nurse Practitioner; Pulmonary Disease; General Surgery; Neurosurgery; Medical Oncology; Gastroenterology; Radiation Oncology; Otolaryngology; and Diagnostic Radiology. We then used CMS data that served to create Table II.8 of the 2014 Medicare Statistics Book and were able to identify how many practitioners in each of those specialties were participating in Medicare program. Table II.8 of the 2014 Medicare Statistics Book combines many of these specialties into higher level groupings and displays the total number of practitioners participating in the Medicare program. However, we used more granular information that identifies the number of practitioners participating in the Medicare program by an individual specialty rather than higher level groupings (table available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/Downloads/PROVIDERS/2016_CPS_MDCR_PROVIDERS_6.pdf*). For example, Table II.8 of the 2014 Medicare Statistics Book combines all surgeons into one category whereas we used detailed information for the individual surgical specialties of general surgery and orthopedic surgery for this estimate.

Using this more specific data for the 18 specialties, we estimate the count of practitioners that will be ordering professionals under the AUC program to be 586,386. There are limitations as we do not have data on the actual number of practitioners who order advanced diagnostic imaging services because information about the ordering professional is not currently required to be included on the Medicare claim form for advanced diagnostic imaging services.

In the absence of data on the breadth of professionals who would be required to consult AUC, we assumed that all professionals in the specialties listed earlier could potentially be subject to these requirements because some professionals within a specialty may order these imaging services. We specifically requested comments and data on the numbers of professionals in the specialties that actually order advanced imaging services. We did not receive comments on this estimate.

With respect to the significant hardship exceptions, based on 2016 data from the Medicare EHR Incentive Program and the 2019 payment year MIPS eligibility and special status file, we estimated that 6,699 respondents in the form of eligible clinicians, groups, or virtual groups will submit a request for a reweighting to zero for the advancing care information performance category due to extreme and uncontrollable circumstances or as a result of a decertification of an EHR. For the purposes of this analysis, we cautiously estimated that each of the 6,699 respondents represents a unique ordering professional and that all respondents who experience extreme and uncontrollable circumstances or have an EHR that is decertified are ordering professionals who would self-attest to a significant hardship exception under the AUC program. Nevertheless, we have used this information to update our estimate that there are 579,687 ordering professionals subject to this program.

We believe that the proposed significant hardship exception at

§ 414.94(i) would further reduce the burden of this program as finalized for four reasons. First, due to the availability of a significant hardship exception there will likely be fewer ordering professionals consulting specified applicable AUC. Second, the self-attestation process is a less burdensome proposal when compared to the alternative of a hardship application process that may have both regulatory impact and information collection requirements. We estimate the impact of a significant hardship exception application in section VII.G. of this RIA, Alternatives Considered.

Third, any application or case-by-case determination would necessitate immediate infrastructure development by CMS directly or through one or more MACs, which adds burden and impact to this program. Finally, the proposed self-attestation process requires no verification on the part of the furnishing professional or facility required to report AUC consultation information on the Medicare claim, thus minimizing burden for both ordering professionals, furnishing professionals and facilities. While some of the efficiencies gained from a self-attestation process are qualitative in nature and difficult to measure, such as the streamlined reporting, we believe that relative to other regulatory approaches this proposal uses a least burdensome approach.

We recognize that ordering professionals would store documentation supporting the self-attestation of a significant hardship. Storage of this information could involve the use of automated, electronic, or other forms of information technology at the discretion of the ordering professional. We estimated that the average time for office clerical activities associated with this task to be 10 minutes. To estimate the burden of this storage, we expected that a Bureau of Labor Statistics (BLS) occupation title 43–6013 Medical Secretary with a mean hourly rate of $17.25 and 100-percent fringe benefits would result in a calculated effort of 10 minutes of clerical work to be $5.76 ($17.25/hour × 2 × 0.167 hour). If 6,699 separate ordering professionals require that a Medical Secretary perform the same clerical activity on an annual basis, then this equates to a cost of approximately $38,596 per year. We solicited comment to inform these burden estimates. We did not receive comments on these burden estimates and have finalized these estimates as proposed.

c. Impact of Consultations Beyond the Impact To Ordering Professionals

Although we have already discussed the time and effort to consult specified applicable AUC through a qualified CDSM here and in previous rulemaking (81 FR 80170), we believe the impact of this program is extensive as it will apply to every advanced diagnostic imaging service (for example, magnetic resonance imaging (MRI), computed tomography (CT) or positron emission tomography (PET)). Therefore, we also have described in this detailed analysis the estimated impacts of AUC consultation beyond the act of consulting specified applicable AUC which would be an upper bound.

(1) Transfers From Ordering Professionals to Qualified CDSMs and EHR Systems

The first additional impact we identified is upstream in the workflow of the AUC consultation and represents the acquisition cost, training, and maintenance of a qualified CDSM. These tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4)) of the Act or private sector mechanisms independent from certified EHR technology or established by the Secretary. Currently, none are established by the Secretary. Additionally, for the purposes of this program, as required by statute, one or more of such mechanisms is available free of charge. For this impact analysis we will illustrate three potential scenarios as low, medium, and higher burden assessments of this consultation requirement. First, we assume that some number of ordering professionals consults a qualified CDSM available free of charge. Second, we assume that some number purchase a qualified CDSM to integrate within an existing EHR system. Third, we assume that some do not currently have an EHR system and, as a result of the statutory requirement to consult with AUC, would purchase an EHR system with an integrated qualified CDSM to consult specified applicable AUC for the purposes of this program.

In the lowest estimate of burden, every AUC consultation would take place using a qualified CDSM available free of charge integrated into an EHR system and add no additional cost to the requirement in § 414.94(j) of this final rule. While we did not base this estimate on absolute behaviors by all those who have ordered advanced diagnostic imaging services, we believe it is reasonable to estimate that as many as 75 percent of an assumed annual 40,000,000 orders for advanced diagnostic imaging services could occur at no additional cost beyond the time and effort to perform the consultation. This may be an underestimate of orders that occur at no additional cost beyond time and effort because multiple free qualified CDSMs are available.

In contrast, some ordering professionals may voluntarily choose to purchase a qualified CDSM that is integrated within their EHR. To estimate how many ordering professionals may choose to purchase an integrated qualified CDSM, we consulted the 2015 National Electronic Health Records Survey [47] (NEHRS), which is conducted by the National Center for Health Statistics (NCHS) and sponsored by the Office of the National Coordinator for Health Information Technology (ONC). NEHRS is a nationally representative mixed mode survey of office-based physicians that collects information on physician and practice characteristics, including the adoption and use of EHR systems. In the United States in 2015, 86.9 percent of office-based physicians used any EHR/EMR, with significantly higher adoption by general or family practice physicians (92.7 percent, p-value <0.05), and slightly lower for medical non-primary care physicians (84.4 percent). Given that approximately 87 percent of office-based physicians have adopted EHR systems, we believe it is likely that the majority will prefer a qualified CDSM integrated with EHR. While we note that qualified CDSMs available free of charge are also integrated within one or more EHR systems, the following illustrative exercise estimates the time and effort to purchase, install, train, and maintain a qualified CDSM integrated into an EHR system. Since section 1834(q)(1)(c)(iii) requires that one or more free CDSMs be available, this is an illustrative exercise rather than an estimate of the burden of the statutory requirement.

Again, as stated above, we do not have data on the number of clinicians who order advanced diagnostic imaging services, and we have made overarching assumptions to look at particular specialty areas that in our claims analysis order these advanced diagnostic imaging services. We assumed all individual clinicians in these specialty areas could potentially be subject to these requirements. Adding the number of clinicians in each of the specialty areas results in 586,386 ordering professionals. We also did not make a distinction between individual

[47] Jamoom E, Yang N. Table of Electronic Health Record Adoption and Use among Office-based Physicians in the U.S., by State: 2015 National Electronic Health Records Survey. 2016.

professionals and groups, as further explained below.

To calculate the impact of a single purchase, we believe based on market research that ordering professionals, either in groups or individually, would spend an estimated $15,000 for a one-time purchase of an integrated qualified CDSM, including installation and training. We assume that all of these costs are based on market research and incurred over the course of 5 years. We also assume that the $15,000 purchase would be made by each ordering professional and did not take into account the potential that a group practice might incur a discounted price per user based on the number of ordering professionals in the practice. These assumptions could significantly alter the impact estimate and we sought comment on such assumptions. Given the difficult nature of deriving these illustrative estimates based on limited data, we solicited comment and information on the preference that physicians and practitioners might have for using an integrated qualified CDSM—a free CDSM or a CDSM that is not free but integrated within an existing EHR system. Also, if purchased, whether this would be purchased at the group practice level to be made available to all clinicians in the practice for the same cost that would be incurred by a single practitioner purchasing the same qualified CDSM, and whether the cost of purchasing a CDSM would be incurred in a single year or over multiple years.

For the purposes of estimating the transfer of costs from ordering professionals to qualified CDSM developers, of the estimated 579,687 practitioners that are likely subject to this program, we excluded 181,653 ordering professionals with specialties whose practitioners order on average fewer than 20 advanced diagnostic imaging services per year (physician assistant, nurse practitioner, and diagnostic radiology). The assumption is that lower volume ordering professionals would select a qualified CDSM that is free of charge. This updates the estimate to consider 398,034 ordering professionals who may purchase an integrated qualified CDSM. To this end, if we assume 346,290 (398,034 ordering professionals × 87 percent) ordering professionals already have an EHR system and 30 percent of these ordering professionals (346,290 × 30 percent, or 103,887) make this purchase for $15,000 and spend $1,000 annually to maintain their system for 5 years (initial acquisition cost in year 1 and maintenance costs in years 2–5), then the total annual cost is estimated to be $394,770,600 ((103,887 × $19,000)/5 years)).

It is also reasonable to assume that some ordering professionals may not need additional training in using a qualified CDSM because the EHR Incentive Program required CDS as a core measure. In addition, the EHR Incentive Program incentivized use of computerized provider order entry (CPOE)—an electronic submission of pharmacy, laboratory, or radiology orders. To determine readiness among Medicare practitioners for these and other measures, the 2011 Meaningful Use Census [48] (RTI International, 2012) observed that those participating in the EHR Incentive Program in 2011 on average met and exceeded the established 30 percent threshold for meaningful use of CPOE in Stage 1. Analysis of the distribution of performance on these measures shows that 86 percent of eligible participants were well over the established thresholds. It is important to note that the CPOE measure had a higher threshold in Stage 2, and 60 percent of eligible participants in 2011 attested to meaningful use are already meeting this higher threshold. This report suggests that some ordering professionals may be well prepared to adopt a qualified clinical decision support mechanism, as this experience offset may yield lower costs and burden to learn to incorporate decision support into the ordering workflow through shorter training times.

Additionally, some ordering professionals may voluntarily choose to purchase a certified EHR system to use a qualified CDSM already integrated within the EHR. The first estimate of capital costs for certified EHR system was identified in the first year of the EHR incentive program as an estimated cost of approximately $54,000 (75 FR 44518), which adjusted for inflation using the Consumer Price Index for All Urban Consumers (CPI–U) U.S. city average series for all items, not seasonally adjusted, represents $62,050.40 in 2018. If we assume that 346,290 ordering professionals subject to this program have adopted EHR, then we will also assume that 51,744 ordering professionals (398,034 ordering professionals × 13 percent) have not adopted an EHR system.

Most physicians who have not yet invested in the hardware, software, testing, and training to implement EHRs may continue to work outside the EHR for a number of reasons—lack of standards, lack of interoperability, limited physician acceptance among their peers, maintenance costs, and lack of capital. Adoption of EHR technology necessitates major changes in business processes and practices throughout a provider's office or facility. Business process reengineering on such a scale is not undertaken lightly. Therefore, while we cannot estimate the business decisions of all ordering professionals, we assume for the purposes of this analysis that as a result of this program some ordering professionals will purchase an EHR system in order to access a qualified CDSM that is integrated into that EHR system for the purposes of acquiring long-term process efficiencies in consulting specified applicable AUC.

We do not have data on the characteristics of physicians who have not purchased an EHR system. However, for the purpose of estimating the transfer of costs from ordering professionals to EHR systems, we will assume based on research from business advisors [49] that 30 percent, or 15,523 ordering professionals (51,744 ordering professionals × 30 percent) will seek to purchase an EHR system at an estimated cost of $62,050.40 for a total one-time cost of $963,208,359.20 in EHR system and integrated qualified CDSM infrastructure. As we believe not every ordering professional in this example would purchase such infrastructure immediately, for the purposes of this estimate, we annualized this cost over 5 years to $192,641,671.84/year. We recognize that qualified CDSMs may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or established by the Secretary.

We recognize that due to the limited data available to make these assumptions our estimates are likely high and we sought comment and information about these assumptions. These estimates might be viewed as an upper bound of the impact of this program beyond consultation with a free tool and note that at the time of publication there were three free tools available as indicated on the CMS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html*.

[48] Vincent, A. EHR Incentive Program: 2011 Meaningful Use Census. RTI Internatoinal. November 2012.

[49] McCormack M, ''EHR Software Buyer Report—2014'' available at *https://www.softwareadvice.com/resources/ehr-buyer-report-2014/*.

(2) Impact to Medicare Beneficiaries

Additionally, we believe that the additional 2-minute consultation will impact the Medicare beneficiary when their advanced diagnostic imaging service is ordered by the ordering professional by introducing additional time to their office visit. To estimate this annual cost, we multiplied the annual burden of 1,425,000 hours by the BLS occupation code that represents all occupations in the BLS (00–0000) as mean hourly wage plus 100 percent fringe ($47.72/hr) for a total estimate of $68,001,000 per year. Over time, there may be process efficiencies implemented in one or more practices similar to the benefits of deploying CDS [50] (Berner, 2009; Karsh, 2009) that decrease this estimate. For example, we will assume that every time an advanced diagnostic imaging service is ordered, it is the result of a visit by a Medicare beneficiary for evaluation and management. Then, let us assume that 50 percent of practices implemented an improvement process that streamlined the AUC consultation such that Medicare beneficiaries who visited those practices spent the same amount of time in the physician's office regardless of whether an advanced diagnostic imaging service was ordered. As a result of this improvement process in practice we could estimate such efficiency would offset the estimated burden by $34,000,500 annually. Although we could not at the time of the proposed rule identify a concrete solution, we sought comment on this detailed analysis to inform future rulemaking.

The following is a summary of the comments we received on the proposed estimated impact of consultations beyond ordering professionals.

Comment: Commenters responded to our solicitation for comment and information on the preference that physicians and practitioners might have for purchasing an integrated qualified CDSM. One commenter suggested that CMS did not reasonably estimate the percentage of practices that would purchase an integrated CDSM relative to using a free qualified CDSM. This commenter noted that most health systems prefer to go with a commercial product for accountability, attempted standardization, and support when a system goes down or requires updating. To this end, the commenter also asked that CMS estimate the cost of maintenance to a CDSM. In contrast, another commenter asked that CMS provide additional information in the final rule as to how it arrived at the maintenance estimate of $1,000 per year for an integrated CDSM.

Response: We appreciate these comments acknowledging the challenges with determining the percentage of practices that would purchase an integrated CDSM relative to using a free and non-integrated CDSM. While we did not receive any more precise information to change the estimated percent of practitioners that would purchase an integrated CDSM, we will continue to evaluate these estimates as information and published evidence becomes available once the AUC consultation and reporting requirements are implemented beginning January 1, 2020. To clarify our estimate of maintenance, we performed market research by gathering information from IT experts suggesting annualized costs between 5 percent and 10 percent of initial purchase cost.

Comment: A few commenters questioned the lack of ancillary costs attributed to the estimation of using a free qualified CDSM. One commenter cited the need for internet access to use the free tool. Another commenter cited AUC conferences, town hall meetings, as well as other forms of professional education to learn about CDSM consultation.

Response: We continue to believe that a free tool is a qualified CDSM available free of charge. Any ordering professional without internet access would continue to remain eligible for a significant hardship exception from performing an AUC consultation and would instead communicate to the furnishing professional their hardship. We have included updates to our estimate in this final rule to account for education and training of all ordering professionals that we estimated would be subject to this program irrespective of what qualified CDSM is used to perform the AUC consultation.

After reviewing all comments, for purposes of this RIA we are finalizing our proposed estimate representing the acquisition cost, and maintenance of a qualified CDSM. However, we note that these estimates are based on multiple assumptions, which could change the estimate in significant ways, and as such may be an overestimate of burden as a free qualified CDSM is required by law.

d. Considering the Impact of Claims-Based Reporting

In the CY 2018 PFS proposed rule (82 FR 34094), we discussed using a combination of G-codes and modifiers to report the AUC consultation information on the Medicare claim. We received numerous public comments objecting to this potential solution. In the 2018 PFS final rule, we agreed with many of the commenters that additional approaches to reporting AUC consultation information on Medicare claims should be considered, and in the opinion of some commenters, reporting unique consultation identifiers (UCIs) would be a less burdensome and preferred approach. We had the opportunity to engage some stakeholders and we understand that some commenters from the previous rule continue to be in favor of a UCI. Practically examining the workflow of an order for an advanced diagnostic imaging service before and after implementation of the Medicare AUC program, we see that in general the process remains largely unchanged. Before and after the implementation of this program, an ordering professional could employ support staff to transmit an order for an advanced diagnostic imaging service from his or her office to an imaging facility, physician office, or hospital that furnishes advanced diagnostic imaging services. After implementation of this program, the ordering professionals, furnishing professionals and facilities must adapt this existing workflow to accommodate new information not previously required on orders for advanced diagnostic imaging services.

We considered leaving the policy unchanged, and we also considered writing new regulations requiring larger modifications to the form and manner by which AUC consultation information is communicated from the ordering professional to the furnishing professional or facility. However, we believe this final rule minimizes burden and maximizes efficiency by reporting through established coding methods, to include G-codes and modifiers, to report the required AUC information on Medicare claims.

(1) Impact on Transmitting Order for Advanced Diagnostic Imaging Services

We estimate that including AUC consultation information on the order to the furnishing professional or facility is estimated as the additional 5 minutes spent by a medical secretary (BLS #43–6013) at a mean hourly rate of $17.25 plus 100 percent fringe to transmit the order for the advanced diagnostic

[50] Berner ES. Clinical decision support systems: State of the Art. AHRQ Publication No. 09–0069–EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009. Karsh B–T. Clinical practice improvement and redesign: How change in workflow can be supported by clinical decision support. AHRQ Publication No. 09–0054–EF. Rockville, Maryland: Agency for Healthcare Research and Quality. June 2009.

imaging service. Taking into account transmissions through an EHR that could occur on the order of seconds, a facsimile transmission that could occur on the order of few minutes, or a telephone call that occur on the order of several minutes, we believe the estimate of 5 minutes is an estimate that accounts for different transmittal methods, such as through an integrated EHR system, by facsimile, or via telephone call directly to the office of the furnishing professional or facility. In aggregate, if we assume that 40,000,000 advanced diagnostic imaging services are ordered annually, then the total annual burden to communicate additional information in the order is estimated as $114,540,000 ($17.25/hr × 2 × 0.083 hr × 40,000,000 orders).

(2) Impact on CDSM Developers

While we did not finalize use of a UCI to report AUC consultation information, the following section remains important to understanding the impact of standardizing the UCI should we move forward with such additional modifications in the future.

We believe that in considering a distinct UCI we also considered updating the requirements of a qualified CDSM in § 414.94(g)(1)(vi)(B). This would incur additional costs for the developers of these mechanisms to accommodate formatting changes if instructed by CMS. We continue to believe that participation by CDSM developers in this program is voluntary, that any considerations of proposed changes to this policy maximize benefits and minimize burden to ordering professionals and furnishing professionals and facilities. Internally, CMS has explored the possibility of using a UCI to determine feasibility, and provide a detailed estimate of costs to develop, test, and implement an update in the form and manner of the UCI generated by the CDSM.

To estimate the costs to develop, test, and implement this update, we will provide a relevant case study. In 1998, the Year 2000 Information and Readiness Disclosure Act (Pub. L. 105–271, enacted October 19, 1998) was passed to ensure continuity of operations in the year 2000. At the time of passage, millions of information technology computer systems, software programs, and semiconductors were not capable of recognizing certain dates after December 31, 1999, and without modification would read dates in the year 2000 and thereafter as if those dates represented the year 1900 or thereafter, or would have failed to process those dates entirely. The federal government had budgeted $8,300,000,000 to continue processing dates in 2000 and beyond (Department of Commerce, 1999). Additional estimates to repair the date in a form and manner accommodating the year 2000 varied, but one estimate [51] from analysis of the 1998–99 budget bill of the state of California estimated $241,000,000 to repair 3,000 systems, or $80,333.33 per system, which adjusted for inflation using the CPI–U, U.S. city average series for all items, not seasonally adjusted, represents $123,775.95 per system in 2018. If all 16 qualified CDSMs performed an update to the formatting of the UCI to appear on certification or documentation of every AUC consultation, then the one-time total cost incurred by all CDSM developers would be $1,980,415.20. Although this does not represent a direct transfer of costs from CDSM developers to savings and efficiencies for ordering professionals, furnishing professionals and facilities, we do believe that as a result of such a policy modification that the ordering professional could directly communicate a single AUC UCI, and furnishing professionals and facilities can report UCI in place of identifying each individual CDSM qualified for the purposes of this program.

The following is a summary of the comments we received on the proposed estimated impact of claims-based reporting.

Comment: One commenter noted that there is no standardized form and manner for submitting the AUC consultation information with the order for an advanced diagnostic imaging service. This commenter observed that each imaging facility has its own way of accepting an imaging order, therefore, the commenter stated it will be burdensome for the imaging facility to coordinate accurate information for one, let alone multiple imaging services with the many ordering clinicians from whom they receive imaging orders. The commenter also stated that facilities would need to invest considerable resources to develop an appropriate workflow to comply with this policy, such as additional staff time to translate AUC consultation information into appropriate codes and modifiers for billing.

Response: We appreciate this experience of order transmission as we included in the proposed rule burden estimates for the communication between staff of the ordering professional to those furnishing the applicable imaging service ordered in section VII.F.4.d.(1) of this RIA. We also included in section VII.F.4.e. of the proposed rule a burden estimate to account for the potential of updates to billing software to accommodate possible changes in workflow that would accommodate this policy. As we did not require in this final rule a specific form and manner standardized to transmit AUC consultation information, we did not update this area of our burden estimate in this final rule.

Comment: A few commenters expected additional time estimated for communication between ordering and furnishing professionals. For example, one commenter provided the scenario of a furnishing professional or facility receiving an order for an applicable imaging service but the order does not contain AUC consultation information. In another example, a patient obtains an advanced diagnostic imaging service as part of a clinical trial protocol that does not adhere to the AUC consulted. To this end, a few commenters requested that CMS allow the work associated with the additional consultation and communication time between the ordering and furnishing physicians and their teams be separately billable for the purposes of the AUC requirement.

Response: We disagree that additional time for communication between ordering professionals and those furnishing advanced diagnostic imaging services should be included for instances where AUC consultation information was not initially communicated. We remind the commenters that the estimated burden included communicating AUC consultation information for all advanced diagnostic imaging services. In other words, whether the information was initially communicated or whether there was an initial failure and the information was then subsequently communicated, that communication has been accounted in our 5 minute estimate per service. We did not propose to authorize a separately billable service by ordering or furnishing professionals or their teams to communicate and therefore cannot estimate the cost of billing Medicare for time to transmit AUC consultation information.

After reviewing the comments, we are finalizing the proposed estimate of impact of claims based reporting. We note that before and after the implementation of this program, an ordering professional could employ support staff to transmit an order for an advanced diagnostic imaging service

[51] LAO Analysis of the 1998–99 Budget Bill Information Technology Issues. Information Technology Issues Analysis of the 1998–99 Budget Bill. The Year 2000 (''Y2K'') Computer Problem. Published February 18, 1998. Accessed March 25, 2018 at *http://www.lao.ca.gov/analysis_1998/info_tech_anl98.html.*

from his or her office to an imaging facility, physician office, or hospital that furnishes advanced diagnostic imaging services. As a result of the flexibility afforded to the means of order communication and transmission, there are many market-based solutions available to adapt this existing workflow to accommodate new information not previously required on orders for advanced diagnostic imaging services.

e. Impact on Furnishing Professionals and Facilities

We expect that an AUC consultation must take place for every applicable imaging service furnished in an applicable setting and paid for under an applicable payment system. In the CY 2017 PFS final rule (81 FR 80170), we codified the definition of applicable setting in § 414.94(b) to include a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. In this final rule, we finalize as proposed adding IDTFs to the definition of applicable settings under this program. This was based on the following factors from 2016 CMS Statistics: (1) An IDTF is independent both of an attending or consulting physician's office and of a hospital; (2) diagnostic procedures when performed by an IDTF are paid under the PFS; (3) independent facilities have increased 5,120 percent from 4,828 in 1990 to 252,044 in 2015; (4) Of those facilities, 1,125 received total payments in excess of $100,000 in 2015; (5) there were 37,038 radiology non-institutional providers utilized by fee-for-service Medicare beneficiaries for all Part B non-institutional provider services in 2015, of which 14,341 received total payments in excess of $100,000 in 2015. Taken together, we believe this will result in a more even application of the Medicare AUC program.

To estimate this impact, we assume based on data derived from the CCW's 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during CY 2014, that approximately 40,000,000 advanced diagnostic imaging services are furnished annually, but questioned whether for the purposes of this estimate we should attribute equal weight for these services furnished by each of the following places: (1) A physician's office; (2) a hospital outpatient department; (3) an ambulatory surgical center; and (4) an IDTF. Therefore, we sought to determine the frequency of advanced diagnostic imaging services furnished by each setting.

For this estimation, we analyzed 2014 Medicare Part B claims data to weight the various applicable settings subject to this program. For this estimate, we analyzed a count of total services furnished for the following 7 Current Procedural Terminology (CPT) codes for advanced diagnostic imaging studies: 70450—computed tomography, head or brain, without contrast material; 74177—computed tomography, abdomen and pelvis, without contrast material; 70553—magnetic resonance (*e.g.,* proton) imaging, brain (including brain stem), without contrast material, followed by contrast material(s) and further sequences; 72148—magnetic resonance (*e.g.,* proton) imaging, spinal canal and contents, lumbar, without contrast material; 78452—Myocardial perfusion imaging, tomographic single-photon emission computed tomography (SPECT) including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed, multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection; 78492—myocardial imaging, positron emission tomography (PET), perfusion, multiple studies at rest and/or stress; 78803—radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s), tomographic SPECT; which represented 10,000,000 total services or approximately a 25 percent sample of the 40,000,000 total advanced diagnostic imaging services furnished under Part B in 2014.

In this sample, we found the following total services and percent of total services for each of the following settings: (1) Physician's office, 2,997,460 total services, 28.5 percent; (2) hospital outpatient department, 7,465,279 total services, 70.9 percent; (3) ambulatory surgical center, 1,062 total services, 0.01 percent; (4) IDTF, 58,900 total services, 0.6 percent. We also examined whether the total services furnished in 2015 for each setting increased more than 10 percent from 2014. We found the following total services and percent change from 2014 for each of the following settings: (1) Physician's office, 2,944,144 total services, 2 percent decrease; (2) hospital outpatient department, 7,854,997 total services, 5 percent increase; (3) ambulatory surgical center, 2,900 total services, 173 percent increase; (4) IDTF, 65,479 total services, 11 percent increase. Taken together, we believe these estimates that attribute 70 percent of all advanced diagnostic imaging services to outpatient, 28 percent to physician's office, and 1 percent each to ambulatory surgical centers and independent diagnostic testing facilities, respectively is generalizable to the total number of visits by Medicare beneficiaries to each of those applicable settings, respectively.

We do not expect that for the purposes of this program furnishing professionals and facilities will need to create new billing practices; however, we assume that the majority of furnishing professionals and facilities will work to alter billing practices through automation processes that accommodate AUC consultation information when furnishing advanced diagnostic imaging services to Medicare beneficiaries. Therefore, we believe a transfer of costs and benefits will be made from furnishing professionals and facilities to medical billing companies to create, test, and implement changes in billing practice for all affected furnishing professionals and facilities.

As mentioned earlier, the 2016 CMS Statistics identified 37,038 radiology non-institutional providers (Table II.8), and 5,470 ambulatory surgical centers (Table II.5) as of December 31, 2015. Because the classification of independent facilities includes both diagnostic radiology and diagnostic laboratory tests, we will assume that 50 percent of the 252,044 facilities existing in 2015 according to 2016 CMS Statistics (126,022 facilities) furnish advanced diagnostic imaging services. The American Hospital Association (AHA) Hospital Statistics published in 2018 by Health Forum, an affiliate of the AHA, identifies the total number of all U.S. registered hospitals to be 5,534. Taken together, we have identified an estimated 174,064 furnishing professionals (37,038 radiologists + 5,470 ASCs + 126,022 independent diagnostic testing facilities + 5,534 hospitals). We will assume for the purposes of this calculation that every identified furnishing professional and facility will choose to update their processes for the purposes of this program in the same way by purchasing an automated solution to reporting AUC consultation information.

The effective date of January 1, 2020 provides some but not extensive time to prepare to update billing processes to accept and report AUC consultation information. Requirements at § 414.94(k) include the following additional information that must be reported: (1) The qualified CDSM consulted by the ordering professional; (2) information indicating whether the service ordered would or would not

adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; (3) the NPI of the ordering professional who consulted specified applicable AUC as required in paragraph (j) of this section, if different from the furnishing professional. Although we are not familiar with any automated billing solution currently available that accommodates this new information, we based our estimate on medical billing and coding for experienced professionals (*http://www.mb-guide.org/*), which provides estimates ranging from $1,000 to $50,000 for medical billing software. For example,[52] the basic Medisoft software program costs around $1300 while a premium can cost $11,900 for an unlimited amount of users. In another example,[7] a simple claims processing interface through McKesson's Relay Health Clearinghouse costs $200 for preliminary set up, and added monthly service fees that were not described explicitly. Therefore, for the purposes of this calculation such a solution will be estimated to cost each furnishing professional or facility an estimated $10,000. This estimate is based on the assumption that the number of available furnishing professionals and facilities does not equal the number of professionals and facilities furnishing advanced diagnostic imaging services in the Medicare program and although we recognize that more than one furnishing professional or facility may use the same billing service, the combined effectiveness for an automated solution may decrease overall cost. Although we note that this estimate is based on certain assumptions, we estimate that the one-time update will cost $1,740,640,000 (174,064 × $10,000).

The Congressional Budget Office estimates that section 218 of the PAMA would save approximately $200,000,000 in benefit dollars over 10 years from FY 2014 through 2024, which could be the result of identification of outlier ordering professionals and also includes section 218(a) of the PAMA—a payment deduction for computed tomography equipment that is not up to a current technology standard. Because we have not yet proposed a mechanism or calculation for outlier ordering professional identification and prior authorization, we are unable to quantify the impact of prior authorization at this time.

The following is a summary of the comments we received on the proposed estimated impact on furnishing professionals and facilities.

Comment: A few commenters noted that the Medicare claim form would change as a result of the Medicare AUC program. These commenters observed that the electronic claim standard for the institutional provider (837i) does not capture or have a placeholder for reporting the ordering physician's NPI. These commenters stated that hospitals and health systems would need to make sweeping and costly system changes to interface with a modified 837i as a result.

Response: We appreciate the opportunity to clarify our sentence and recognize the overlap between reporting AUC consultation information and standardized communications on Medicare claims forms. The X12N insurance subcommittee develops and maintains standards for healthcare administrative transactions on professional (837p), institutional (837i), and dental (837d) transactions when submitting healthcare claims for a service or encounter. The current mandated version of 837 transactions is 5010™. While we have not finalized a process for implementing the reporting requirements at § 414.94(k), we clarify that implementation of changes to the claim form transactions would not take place outside of the existing process we described.

After reviewing all comments, we are finalizing our proposed estimate without modification. However, we note that these estimates are based on multiple assumptions and as such may be an overestimate of burden.

f. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We believe that the first 5 years of this program will be dedicated to implementation activities, from installation of the technology to training to operational and behavioral changes. Information on the benefits of adopting qualified CDSMs or automating billing practices specifically meeting the requirements in this final rule does not yet exist—and information on benefits overall is limited. Nonetheless, we believe there are benefits that can be obtained by ordering professionals, furnishing professionals and facilities, beneficiaries and technology infrastructure developers including qualified CDSM developers, EHR systems developers, and medical billing practices. We describe these estimated benefits in more detail in the following sections.

(1) Estimates of Savings

It has been suggested that one-third of imaging procedures are inappropriate, costing the United States between $3 billion and $10 billion annually [53] (Stein, 2003). Data derived from the CCW 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during CY 2014, identified approximately $3,300,000,000 in total payments for advanced diagnostic imaging services. For illustrative purposes, if implementation of this program were to lead to a 30 percent decrease in total payments, then we could potentially expect $990,000,000 in fewer payments annually. To address this suggestion, the insertion of a pause in the ordering workflow to introduce AUC is a potentially beneficial and cost-effective solution. Some believe that savings could be achieved through the reduction of inappropriate orders, and expenses associated with radiology benefit managers.[54] Indeed, the Institute for Clinical Systems Improvement in Bloomington, Minnesota, performed a clinical decision support pilot project [55] to (1) improve the utility of diagnostic radiology tests ordered, (2) reduce radiation exposure, (3) increase efficiency, (4) aid in shared decision making, and (5) save Minnesota $84,000,000 in 3 years. While not directly tested in Miliard et al., we believe this estimate may be generalizable on a national level and applicable to the Medicare AUC program, as both activities seek to achieve improvements in quality and decrease costs. Therefore, if savings estimated in Minnesota were a general representation of the nation, and on average a single state achieved 50-percent of that representative savings, annualized over 3 years this estimate could be extrapolated to account for $700,000,000 savings per year (($84,000,000/3 years) × 50-percent × 50 states). It is hypothesized [56] that these benefits are the result of educating ordering professionals on the appropriate test for a set of clinical symptoms, rather than just adding time and electronic obstacles between

[52] *http://www.mb-guide.org/medical-billing-software-prices.html.*

[53] Stein C. Code red: partners program aims to rein in skyrocketing costs of diagnostic imaging. Boston Globe, 2003.

[54] Hardy, K. Decision Support for Rad Reports. Radiology Today. Vol. 11, No. 1, p. 16., 2010.

[55] Miliard, M. Nuance, ICSI aim to prevent unnecessary imaging tests. Healthcare IT News. November 10, 2010.

[56] Sistrom CL, Dang PA, Weilburg JB, et al., Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis. Radiology. 251(1), 2009.

ordering physicians and advanced diagnostic imaging services as such transfer of knowledge can alter clinical practice. The Center for Health Care Solutions at Virginia Mason Medical Center in Seattle, Washington examined approaches to control imaging utilization, including external authorization methods and clinical decision support systems. A retrospective cohort study [57] was performed by Blackmore and colleagues in 2011 of the staged implementation of evidence-based clinical decision support for the following advanced diagnostic imaging services: Lumbar MRI; brain MRI; and sinus CT. Brain CT was included as a control. The number of patients imaged as a proportion of patients with selected clinical conditions before and after the decision support interventions were determined from billing data from a regional health plan and from institutional radiology information systems. The imaging utilization rates after the implementation of clinical decision support resulted in decreases for lumbar MRI (p-value = 0.001), head MRI (p-value = 0.05), and sinus CT (p-value = 0.003), while a decrease in control service head CT was not statistically significant (p-value = 0.88). Although there are limitations to this retrospective claims data analysis, the authors concluded that clinical decision support is associated with large decreases in the inappropriate utilization of advanced diagnostic imaging services.

It seems reasonable from this and other studies [58] of local implementation of clinical decision support to assume that there may be some savings when regulations become effective January 1, 2020; however, there are also a few hesitations to extrapolating these and other findings broadly to the Medicare population. First, ordering professionals in this program are aware that CMS will pay for advanced diagnostic imaging services that do not adhere to the specified applicable AUC consulted. This awareness may impact the level of interest or extent of behavior modification from exposing ordering professionals to a qualified CDSM. Second, the statute distinguishes between the ordering professional, furnishing professional and facility, recognizing that the professional who orders an applicable imaging service is usually not the same professional or facility reporting to Medicare for that service when furnished. As a result, some ordering professionals may believe that since they are not required to submit AUC consultation information directly to CMS, there are no direct consequences of adhering to specified applicable AUC. Third, many advanced diagnostic imaging services may not have relevant or applicable AUC. Indeed a recent study [59] implementing CDS was only able to prospectively generate a score for 26 percent and 30 percent of requests for advanced diagnostic imaging services before and after implementation of decision support, respectively. Without AUC available, there can be no decision support intervention into the workflow of the ordering professional. Fourth, even when an ordering professional identifies an advanced diagnostic imaging service recognized as adhering to specified applicable AUC from one qualified PLE, discordance between AUC from different specialty societies has been reported,[60] suggesting that full benefits and savings cannot be realized without standard levels of appropriateness. Taken together, these concerns will form the basis for our continued examination of the impact of this and future rulemaking to maximize the benefits of this program.

(2) Benefits to Medicare Beneficiaries

Although qualified CDSMs are not required to demonstrate that their tools provide measurable benefits, we believe that as a result of installation and use, some ordering professionals may find benefits to the patients they serve. For example, if a qualified CDSM creates a flag or alert to obsolete tests, then the patient will benefit from avoiding unnecessary testing. The same outcome would be likely if a qualified CDSM implemented algorithms that recognize advanced diagnostic imaging services that may produce inaccurate results because of medications being taken by the patient. In addition, if the CDSM provides standardized processes for advanced diagnostic imaging orders or clarification for confusing test names, then the patient benefits from a potential decrease in medical errors and less exposure. Finally, we believe it is reasonable to assume that some improvements in shared decision making could result from use of a qualified CDSM, because some CDSMs could provide cost information associated with advanced diagnostic imaging services and/or identify situations of repeated testing.

The following is a summary of the comments we received on the proposed estimated benefits that can be obtained by ordering professionals, furnishing professionals and facilities, beneficiaries and technology infrastructure developers including qualified CDSM developers, EHR systems developers, and medical billing practices.

Comment: A few commenters disagreed that there are any benefits to the Medicare AUC program. As an example, one commenter submitted their experience with a CDSM and found that a change in utilization was not significant. Additionally, a few commenters indicated that every dollar spent on this program is a dollar that cannot be used elsewhere, more specifically, for patient care. One commenter disagreed with these comments, citing a published study [61] that exposing ordering professionals to evidence based medicine improves quality and reduces inappropriate utilization. Another commenter cited several evidence-based studies [15 62 63] that demonstrate the improvement in the quality of clinical outcomes and reduction of cost resulting from engagement using AUC.

Response: We thank the commenters for sharing their experience, and experiences cited in peer-reviewed published literature. This RIA is presented in conjunction with statutory AUC program requirements. We provide these estimates in addition to policies that are consistent with statute and finalized in this rule. However, we note that these estimates are based on multiple assumptions and as such may be an overestimate of burden as a free qualified CDSM is available and required by law.

[57] Blackmore, CC; Mecklenburg, RS; Kaplan GS. Effectiveness of Clinical Decision Support in Controlling Inappropriate Imaging. Journal of the American College of Radiology. 8(1) 2011.

[58] Curry, L. and Reed, M.H. Electronic decision support for diagnostic imaging in a primary care setting. J Am Med Inform Assoc. 2011; 18: 267–270; Ip, I.K., Schneider, L.I., Hanson, R. et al. Adoption and meaningful use of computerized physician order entry with an integrated clinical decision support system for radiology: ten-year analysis in an urban teaching hospital. J Am Coll Radiol. 2012; 9: 129–136.

[59] Moriarity, AK, Klochko C, O'Brien M, Halabi S. The Effect of Clinical Decision Support for Advanced Inpatient Imaging. Journal of American College of Radiology. 12(4) 2015.

[60] Winchester DE et al., Discordance Between Appropriate Use Criteria for Nuclear Myocardial Perfusion Imaging from Different Specialty Societies: a potential concern for health policy. JAMA Cardiol. 1(2) 2016:207–210.

[61] Huber TC, Krishmaraj A, Patrie J, et al. Impact of a commercially available clinical decision support program on provider ordering habits. J Am Coll Radiol. 2018:15:951–7.

[62] Bunt CW, Burke HB, Towbin AJ, et al. Point-of-care estimated radiation exposure and imaging guidelines can reduce pediatric radiation burden. J Am Board Fam Med. 2015:28:343–50.

[63] Tajmir S, Raja AS, Ip IK, et al. Impact of clinical decision support on radiography for acute ankle injuries: a randomized trial. West J Emerg Med. 2017:18(3):487–95.

5. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2019 with those available for MIPS eligible clinicians for the CY 2019 performance period. We explained that we anticipated that this proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS and therefore should be prepared to report on those eCQMs for 2019. We explained that we expected that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2019 to maintain current eCQM lists and specifications. State expenditures to make any systems changes required as a result of this proposal would be eligible for ninety percent enhanced Federal financial participation. After careful consideration of the comments received on this proposal, we are finalizing it without change. See discussion of comments in section III.E. of this final rule.

For 2019, we proposed that Medicaid EPs would report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). After careful consideration of the comments received on this proposal, we are finalizing it without change, and also explain that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she may report on any six eCQMs that are relevant. We also proposed that the eCQM reporting period for EPs in the Medicaid Promoting Interoperability Program would be a full CY in 2019 for EPs who have demonstrated meaningful use in a prior year, in order to align with the corresponding performance period for the quality performance category in MIPS. This proposal is also finalized without change, after careful consideration of comments received. (See discussion of comments in section III.E. of this final rule.) We continue to align Medicaid Promoting Interoperability Program requirements with requirements for other CMS quality programs, such as MIPS, to the extent practicable, to reduce the burden of reporting different data for separate programs.

In order to help states to make incentive payments to Medicaid EPs by December 31, 2021, consistent with section 1903(t)(4)(A)(iii) of the Act, we proposed to amend § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program would be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. Similarly, we proposed to change the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program to a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that the state can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021.

We proposed to allow states the flexibility to set alternative, earlier final deadlines for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from CMS, through their State Medicaid HIT Plans (SMHP). Providing states with the flexibility to set an alternative, earlier last possible date for the EHR or eCQM reporting period for Medicaid EPs in 2021 would make it easier for states to ensure that all payments are made by the December 31, 2021 deadline, especially for states whose prepayment process may take longer than the 61 days provided for by an October 31, 2021 deadline. We explained that we expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems to meet specifications for the proposed reporting periods, especially because we are also proposed to permit states to set a different end date for all EHR and eCQM reporting periods for Medicaid EPs in 2021. As previously noted, state expenditures for any systems changes required as a result of this proposal would be eligible for 90 percent enhanced Federal financial participation. After careful consideration of the comments received on this proposal, as discussed above in section III.E. of this final rule, we are finalizing it without change. However, in light of comments received from EPs, we are also considering whether to propose in future rulemaking that no state may set a reporting period deadline for CY 2021 that is earlier than June 30, 2021, or an attestation deadline for CY 2021 that is earlier than July 1, 2021.

Finally, we proposed changes to the EP Meaningful Use Objective 6, (Coordination of care through patient engagement) Measure 1 (View, Download, or Transmit) and Measure 2 (Secure Electronic Messaging), and to EP Meaningful Use Objective 8, Measure 2 (Syndromic surveillance reporting). We proposed to amend these measures in response to feedback about the burdens they create for EPs seeking to demonstrate meaningful use, and about how they may not be fully aligned with how states and public health agencies collect syndromic surveillance data. These proposed amendments were expected to reduce EP burden. Again, we expected that any changes these proposals might require to state systems would be minimal and that state expenditures to make any such changes would also be eligible for 90 percent enhanced federal financial participation. After careful consideration of the comments received on these proposals, as discussed in section III.E. of this final rule, we are finalizing them without change.

6. Medicare Shared Savings Program

In section III.F.1.b. of this final rule, we summarize the proposed certain modifications to the quality measure set used to assess the quality of performance of ACOs participating in the Shared Savings Program. Specifically we proposed: (1) The addition of two Patient Experience of Care Survey measures, and (2) the removal of four claims-based outcome measures. After consideration of the comments received, we are finalizing these proposed modifications to the quality measure set for the Shared Savings Program in sections III.F. of this final rule.

The modifications to the Shared Savings Program quality measure set reduce the number of measures in the Shared Savings Program quality measure set from 31 to 23 measures, making the quality measure set more outcome oriented. This reduction in the number of measure is expected to reduce ACO reporting burden and

improve quality outcomes for beneficiaries.

7. Physician Self-Referral Law

The physician self-referral law provisions are discussed in section III.G. of this final rule. We are finalizing regulatory updates to implement the provisions of section 50404 of the Bipartisan Budget Act of 2018 pertaining to the writing and signature requirements in certain compensation arrangement exceptions to the statute's referral and billing prohibitions. The regulatory language for the writing requirement reflects current policy, so we do not anticipate that it will have an impact. We expect that the update regarding temporary non-compliance with signature arrangements will reduce burden by giving parties additional time to obtain all required signatures.

8. Changes Due to Updates to the Quality Payment Program

In section III.I. of this final rule, we included our finalized policies for the Quality Payment Program. In this section of the final rule, we present the overall and incremental impacts to the number of expected QPs and associated APM incentive payments. In MIPS, we analyze the total impact and incremental impact of statutory changes to eligibility from the Bipartisan Budget Act of 2018, as well as final policies to expand MIPS eligibility by expanding the MIPS eligible clinician definition and adding a third criterion for the low-volume threshold and an opt-in policy option for any clinician that exceeds at least one, but not all, of the low-volume threshold criteria. Finally, we estimate the payment impacts by practice size based on various final policies to modify the MIPS final score, such as the new Promoting Interoperability performance category policies, for the performance threshold and additional performance threshold, and as required by the Bipartisan Budget Act of 2018, the impact of applying the MIPS payment adjustments to covered professional services (services for which payment is made under, or is based on, the PFS and that are furnished by an eligible clinician) rather than items and services covered under Part B.

The submission period for the first MIPS performance period ended in early 2018; however, the final data sets were not available in time to incorporate into the CY 2019 PFS proposed rule analysis (83 FR 36057). We stated in the proposed rule that if technically feasible, we intended to use data from the CY 2017 MIPS performance period for the final rule. In this analysis, we have updated our analyses from the proposed rule to consider data submitted for the 2017 MIPS performance period (which we refer to in this section as Quality Payment Program Year 1 data). In section VII.F.8.b. of this final rule, we summarize the high level findings of updating our model with Quality Payment Program Year 1 data.

a. Estimated Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services in the preceding year. In addition, beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option will allow eligible clinicians to become QPs by meeting the QP thresholds through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payment for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year would not need to report to MIPS and would not receive a MIPS payment adjustment to their Part B PFS payments. Eligible clinicians who do not become QPs, but meet a slightly lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment, but will not receive the APM Incentive Payment. For the 2019 Medicare QP Performance Period, we define Partial QPs to be eligible clinicians in Advanced APMs who collectively have at least 40 percent, but less than 50 percent, of their payments for Part B covered professional services through an APM Entity, or collectively furnish Part B covered professional services to at least 20 percent, but less than 35 percent, of their Medicare beneficiaries through an APM Entity. If the Partial QP elects to be scored under MIPS, they would be subject to all MIPS requirements and would receive a MIPS payment adjustment. This adjustment may be positive, negative or neutral. If an eligible clinician does not meet either the QP or Partial QP standards, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although MACRA amendments established overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the third payment year (2021 MIPS payment year) of the Quality Payment Program in detail.

In section III.I.4.g.(4)(b) of this final rule, we summarized our finalized policy to add a third alternative to allow requests for QP determinations at the TIN level in instances where all clinicians who have reassigned billing rights under the TIN participate in a single APM Entity. This option will therefore be available to all TINs participating in Full TIN APMs, such as the Medicare Shared Savings Program. It will also be available to any other TIN for whom all clinicians who have reassigned billing rights to the TIN are participating in a single APM Entity. We also finalized that this third alternative will only be available to eligible clinicians who meet the Medicare threshold at the APM Entity level; it will not be available for eligible clinicians who meet the Medicare threshold individually.

In section III.I.4.g.(4)(c)(ii) of this final rule, we also discussed our finalized policy to extend the same weighting methodology to TIN level Medicare Threshold Scores in situations where a TIN is assessed under the Medicare Option as part of an APM Entity group, and receives a Medicare Threshold Score at the APM Entity group level. In this scenario, we believe that the Medicare portion of the TIN's All-Payer Combination Option Threshold Score should not be lower than the Medicare Threshold Score that they received by

participating in an APM Entity group (82 FR 53881 through 53882). We note this extension of the weighting methodology will only apply to a TIN when that TIN represents a subset of the eligible clinicians in the APM Entity, because when the TIN and the APM Entity are the same there is no need for this weighted methodology. We finalized our proposal to calculate the TIN's QP Threshold Scores both on its own and with this weighted methodology, and then use the most advantageous score when making a QP determination. We believe that, as it does for QP determinations made at the APM Entity level, this approach promotes consistency between the Medicare Option and the All-Payer Combination Option to the extent possible. Additionally, the application of this weighting approach in the case of a TIN level QP determination is consistent with our established policy.

These finalized policies affect the estimated number of QPs for the 2021 payment year. We estimate that approximately 8,100 eligible clinicians in 8 APM Entities representing approximately 225 TINs will become QPs due to these finalized policies representing TIN level QP determinations under the All-Payer Combination Option. Therefore, they will be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services, which are estimated to be approximately $545 million in the 2019 performance year. We also estimated the corresponding increase of the APM incentive payment of 5 percent of Part B allowed charges for these QPs will be approximately $27 million for the 2021 payment year. However, we note that the majority, if not all, of the 8,100 eligible clinicians that would become QPs if these policies are finalized, had already attained QP status in the 2018 QP performance period. Therefore, the associated APM incentive payments for these 8,100 would not be additional impacts in comparison to previous performance years, only additional impacts in the absence of finalizing these proposed policies.

Overall, we estimated that between 165,000 and 220,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum incentive payment based on 5 percent of their Part B allowable charges for covered professional services in the preceding year, which are estimated to be between approximately $12,000 million and $16,000 million in total for the 2019 performance year. We estimated that the aggregate total of the APM incentive payment of 5 percent of Part B allowed charges for QPs will be between approximately $600 and $800 million for the 2021 payment year. The estimated number of QPs in this final rule is slightly higher than the estimates of 160,000 and 215,000 clinicians included in the proposed rule due to more updated information being available for the final rule. The proposed rule used the APM Participation Lists on the most recent MDM provider extract for the Predictive QP determination file for 2018, whereas this final rule uses the APM Participation Lists on the most recent MDM provider extract for the Second QP determination file for the 2018 performance period. This more updated information did not significantly change the estimated amount of total Part B allowed charges and the amount of total APM incentive payments.

We projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2019 QP performance period, as well as Advanced APMs anticipated to be operational during the 2019 QP performance period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. The following APMs are expected to be Advanced APMs in performance year 2019: Next Generation ACO Model, Comprehensive Primary Care Plus (CPC+) Model, Comprehensive ESRD Care (CEC) Model (Two-Sided Risk Arrangement), Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative),[64] Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), Oncology Care Model (Two-Sided Risk Arrangements), Medicare ACO Track 1+ Model, Bundled Payments for Care Improvement Advanced, Maryland Total Cost of Care Model (Maryland Care Redesign Program; Maryland Primary Care Program), and the Shared Savings Program Tracks 2 and 3. We used the APM Participant Lists (see 81 FR 77444 through 77445 for information on the APM participant lists and QP determination) on the most recent MDM provider extract for the Second QP determination file for 2018 QP performance period to estimate QPs, total Part B allowed charges for covered professional services, and the aggregate total of APM incentive payments for the 2019 QP performance period. We examine the extent to which Advanced APM participants would meet the QP thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

[64] Vermont ACOs are participating in an Advanced APM during 2018 through a version of the Next Generation ACO Model. The Vermont Medicare ACO Initiative is expected to be an Advanced APM beginning in CY 2019.

b. Updates to MIPS Estimates Using Quality Payment Program Year 1 Data

In the CY 2019 PFS proposed rule (83 FR 36058 through 36068), the RIA modeled MIPS eligibility and performance using data from the Physician Quality Reporting System (PQRS), the Value Modifier, and the Medicare/Medicaid EHR Incentive programs to account for the absence of MIPS performance data. We indicated, that if feasible, we would integrate performance data from the CY 2017 MIPS performance period (which we refer to in this section of the final rule as Quality Payment Program Year 1 data). The model in the 2019 PFS proposed rule had several assumptions to proxy MIPS performance and we noted the limitations of the model (83 FR 36067).

In this final rule, we integrated Quality Payment Program Year 1 data into our model estimates and we chose to summarize in this section important differences or findings that are needed for context when interpreting the RIA in this final rule. It should be noted that although we are using Quality Payment Program Year 1 data, the estimates described in this RIA reflect the impact of the finalized policies in this final rule and do not reflect actual CY 2017 MIPS performance period/2019 MIPS payment year results.

First, the Quality Payment Program Year 1 data had more complete group and individual participation and performance data. In the CY 2019 PFS proposed rule (83 FR 36053 through 36061), we estimated group reporting solely based on the submission of quality data as a group to 2016 PQRS. For this final rule, we were able to identify group reporting through submissions to quality, improvement activities or Promoting Interoperability performance categories. As a result, we observed higher group reporting than was previously estimated using PQRS performance data. This finding led to a 42 percent increase (from approximately 390,000 in the CY 2019 PFS proposed

rule to 553,000 in this final rule) in group reporters who otherwise would not have been MIPS eligible clinicians. (See section VII.F.8.c. for more details on eligibility.) The second benefit of group and individual level data through the Quality Payment Program Year 1 data led to our improved ability to better estimate group and individual scores and to appropriately apply scoring policies at the group and individual level. (See section VII.F.8.d.(2) for more details on methodologies for estimating the performance category scores.)

Second, we observed an increase in participation among small practices than previously estimated in the CY 2019 PFS proposed rule. The number of clinicians in small practices (who we believe are estimated to be in MIPS year 3) estimated to submit data increased from 79.7 percent to 89.9 percent. We believe this is related to our policies for the 2017 MIPS performance period which was designed to encourage participation, engage clinicians and help them transition smoothly into MIPS. (See section VII.F.8.d.(3) for more details.)

Third, the Quality Payment Program Year 1 data allowed for the direct observation of performance for the MIPS performance categories. With the availability of actual advancing care information and improvement activities performance category data from the Quality Payment Program Year 1, we improved our estimates for the Promoting Interoperability and improvement activities performance category scores at the individual and group level for the 2019 MIPS performance period/2021 MIPS payment year. This led to more variation in performance at the individual and group level for these performance categories compared to the model in the 2019 PFS proposed rule and to the ability to accurately assess which clinicians are measured on Promoting Interoperability or are reweighted (see section III.I.3.h.(5) of this final rule for more details).

Finally, the Quality Payment Program Year 1 data improved our ability to estimate who is excluded from MIPS, such as newly enrolled clinicians. We found that the previous proxy for the CY 2019 PFS proposed rule overestimated the number of newly enrolled clinicians than the observed with the Quality Payment Program Year 1 data. As a result, fewer clinicians were excluded from MIPS compared to the CY 2019 PFS proposed rule. (See section VII.F.8.c.(2) of this final rule for more details.)

In summary, the estimates presented in the RIA of this final rule differ from the CY 2019 PFS proposed rule due to our ability to improve our estimates of eligibility and performance in MIPS. As a result of data source and methodology changes for the final policies of this final rule, we observe a slight decrease in final scores. For example, the mean and median final scores in the CY 2019 PFS proposed rule analysis were 73.41 and 82.41 respectively,[65] and the mean and median in this final rule are 69.53 and 78.72, respectively. As a result, a higher percentage of clinicians submitting data have scores below the final performance threshold of 30 points for this final rule (8.8 percent) compared to the CY 2019 PFS proposed rule (3.9 percent). Given the increase in participation, we are not surprised by these changes. However, it should be noted we are still using historic data to predict future performance. Therefore, behaviors due to policies in MIPS Year 1 may not reflect behaviors in Year 3. For example, MIPS eligible clinicians had to earn 3 out of 100 points to receive at least a neutral payment adjustment in CY 2017 MIPS performance period/CY 2021 MIPS payment year and therefore may have only submitted a limited amount of information. As the performance threshold increases in Year 3, we anticipate clinicians will continue to participate and will likely increase their performance to meet the higher performance threshold. Therefore, the results presented in this final rule may not accurately reflect performance for CY 2019 performance period/CY 2021 payment year, which is an important limitation of our findings. See section VII.F.8.f. for more limitations of this rule.

c. Estimated Number of Clinicians Eligible for MIPS Eligibility

(1) Summary of Final Policies Related to MIPS Eligibility and Application of MIPS Payment Adjustments

In section III.I.3 of this final rule, we finalized three sets of policy changes that would impact the number of MIPS eligible clinicians starting with CY 2019 MIPS performance period and the associated CY 2021 MIPS payment year. Two of the changes were finalized as proposed and affect the low-volume threshold. The third policy affects the definition of a MIPS eligible clinician and was finalized with modifications.

In section III.I.3.c.(2) of this final rule, we finalized as proposed changes to our policy to comply with the Bipartisan Budget Act of 2018. Specifically, we updated the low-volume threshold starting with the 2020 MIPS payment year to be based on covered professional services (services for which payment is made under, or is based on the PFS and that are furnished by an eligible clinician) rather than items and services covered under Part B, as provided in section 1848(q)(1)(B) as amended by section 51003(a)(1)(A)(i) of the Bipartisan Budget Act of 2018. This finalized policy may affect the previously finalized calculation for the low-volume threshold for certain clinicians because payment for items, such as Part B drugs, which were previously considered in the low-volume determination, are now excluded. In addition, section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 revised section 1848(q)(6)(E) to apply the MIPS payment adjustments to covered professional services rather than to items and services covered under Part B. This change is effective with the 2019 MIPS payment year. Its effect on the amount of payment adjustments under MIPS is included in this analysis.

Second, in section III.I.3.a. of this final rule, beginning with the 2021 MIPS payment year, we finalized with modification the expansion of the definition of MIPS eligible clinicians to include physical therapists, occupational therapists, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals. This finalized list differs from the proposed list of physical therapists, occupational therapists, clinical social workers, and clinical psychologists (83 FR 36058). Specifically, we finalized the definition of MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, as any of the following: A physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional; and a group that includes such clinicians.

Third, as discussed in sections III.I.3.c.(4) and III.I.3.c.(5) of this final rule, in addition to the amendments to comply with Bipartisan Budget Act of 2018, we finalized as proposed our definition of the low-volume threshold by adding a third criterion (for ''covered

[65] The mean and median was not published in the CY 2019 PFS proposed rule RIA, but the methodology is summarized in the CY 2019 PFS proposed rule (83 FR 36058 through 36066).

professional services''). The low-volume threshold now includes a third criterion: Set at 200 covered professional services to Part B-enrolled individuals. Taken together, the low-volume threshold is as follows: (1) Those with $90,000 or less in allowed charges for covered professional services; or (2) 200 or fewer Part B-enrolled individuals who are furnished Medicare PFS services; or (3) 200 or fewer covered professional services. The low volume threshold assessment is applied at the TIN/NPI level for individual reporting, the TIN level for group reporting, or the APM Entity Level for reporting under the APM scoring standard. We also finalized as proposed for any clinician who exceeds the low-volume threshold on at least one, but not all three, low-volume threshold criteria may elect to opt-in to MIPS to be measured on performance, thereby qualifying to receive a positive, neutral, or negative MIPS payment adjustment based on performance. The absence of the opt-in election within this cohort means they are not MIPS eligible clinicians. If a MIPS eligible clinician does not meet at least one of these low-volume criteria, they are excluded from MIPS. For purposes of this impact analysis we refer to these revisions to the low-volume threshold and its application collectively as the ''opt-in policy''.

We discuss how the three finalized policy changes impact MIPS eligibility and payments, later in this section.

(2) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior to Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the CY 2019 performance period in this final rule, our scoring model used the first determination period from CY 2020 MIPS payment year eligibility file as described in the CY 2018 Quality Payment Program Final Rule (82 FR 53587 through 53592). The first determination period from the CY 2020 MIPS payment year eligibility file was selected to maximize the overlap with the performance period data used in the model. In addition, the low-volume threshold for with the 2020 MIPS payment year was originally finalized in the CY 2018 Quality Payment Program final rule (82 FR 53587 through 53592) as using Part B items and services, but was later finalized in section III.I.3.c of this final rule to be based on covered professional services (services for which payment is made under, or is based on the PFS and that are furnished by an eligible clinician). Therefore, this data file provided the information to calculate a baseline as well as understand the incremental impact of basing the low-volume threshold on covered professional services rather than all items and services under Part B. We included 1.5 million clinicians (see Table 97) who had PFS claims from September 1, 2016 to August 31, 2017 and included a 30-day claim run-out.We excluded individual clinicians who were affected by the automatic extreme and uncontrollable policy finalized for the 2017 MIPS performance period/2019 MIPS payment year in section III.I.3.i.(2)(b)(ii)(B) of this final rule as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold. Therefore, we excluded these clinicians when calculating those clinicians eligible for MIPS.

For our baseline population, we restricted to clinicians who are a physician (as defined in section 1861(r) of the Act); a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act). For the estimated MIPS eligible population for the CY 2021 MIPS payment year, we added in clinicians who are physical therapists, occupational therapists, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional.

As noted previously, we excluded QPs from our scoring model, since these clinicians are not eligible for MIPS. To determine which QPs should be excluded, we used the QP List for the first snapshot date of the 2018 QP performance period because these data were available by TIN and NPI and could be merged into our model. This data also included participants in APMs, such as the Medicare ACO Track 1+ Model, which were not available models in the 2017 QP performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2019 QP performance period. We assumed that all partial QPs would participate in MIPS and included them in our scoring model and eligibility counts. The estimated number of QPs excluded from our model is lower than the projected number of QPs (165,000 to 220,000) for the 2019 QP performance period due to the expected growth in APM participation. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2019 Medicare QP Performance Period; hence, our model may overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the indicator that was used for the 2017 MIPS performance period/2019 MIPS payment year. The number of newly enrolled clinicians identified using this approach and data source was approximately one third the estimated number of newly enrolled clinicians estimated in the proposed rule which indicates we overestimated the number of newly enrolled clinicians in the CY 2019 PFS proposed rule impact analysis and that more clinicians are eligible for MIPS.

In section III.I.3.j.(4)(c) of this final rule, we finalized that beginning with the 2019 MIPS payment year the MIPS payment adjustment factors would not apply to certain model-specific payments for the duration of a section 1115A model's testing. Due to the aggregated data in our analysis, we were not able to incorporate this policy into our estimate.

In section III.I.3.j.(4)(d) of the final rule, we finalized the proposal to waive the payment consequences (positive, negative or neutral adjustments) of MIPS and to waive the associated MIPS reporting requirements adopted to implement the payment consequences for certain participating clinicians in the MAQI Demonstration subject to conditions outlined in the Demonstration, starting with the 2020 MIPS payment period. Removing eligible clinicians from MIPS may affect the payment adjustments for other MIPS eligible clinicians in each year the waiver is offered. At this time we are unable to identify specific clinicians that would be affected by this proposal (that is, removed from the MIPS payment adjustments), but estimate the first year number of clinicians to be less than 0.1 percent of all MIPS eligible clinicians. We plan to monitor the impact of the MAQI Demonstration on payments received by MIPS eligible

clinicians to whom the waivers do not apply; however, we note that it may be challenging to draw significant conclusions from such monitoring as there are many variables that may impact and influence a clinician's final MIPS adjustment. Due to the lack of information currently available we are unable to account for this proposal in the eligibility or payment adjustment tables.

(b) Assumptions Related to Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN or APM entity) levels based on how data are submitted. If no data are submitted, then the low-volume threshold is applied at the TIN/NPI level. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

Table 97 compares the MIPS eligibility status and the associated PFS allowed charges from the CY 2019 PFS proposed rule (83 FR 36060) with the estimates of MIPS eligibility and the associated PFS allowed charges after using Quality Payment Program Year 1 data and applying the finalized policies for the CY 2019 MIPS performance period.

For the purposes of modeling, we made assumptions on group reporting to apply the low-volume threshold. One extreme and unlikely assumption is that no practices elect group reporting and the low-volume threshold would always be applied at the individual level. Although we believe a scenario in which only these clinicians would participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For final rule model, we estimate there are approximately 217,000 clinicians [66] who would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 97,[67] we identify clinicians under this assumption as having ''required eligibility.'' Using this assumption, the number of clinicians with required eligibility in this final rule and their associated PFS allowed charges are very similar to the estimate in the CY 2019 PFS proposed rule (approximately 218,000 clinicians).

Based on CY 2017 Quality Payment Program Year 1 data, we anticipate that group and APM Entities that submitted to MIPS as a group and APM Entity will continue to do so for the CY 2019 MIPS performance period. Therefore, if we revise our model's group reporting assumption such that all clinicians that were participating in ACOs in 2017 (including ACOs participating under the Shared Savings Program or Next Generation ACO Model) or who reported to the Quality Payment Program Year 1 as a group would continue to do so in MIPS, then the MIPS eligible clinician population would be approximately 770,000 clinicians if we only include the 218,000 required clinicians and the 553,000 clinicians who are only eligible because of group reporting. In Table 97, we identify these clinicians who do not meet the low-volume threshold individually but are anticipated to submit to MIPS as a group based on Quality Payment Program Year 1 data as having ''group eligibility.'' Updating the data source for identifying group reporting led to a 42 percent increase (from approximately 390,000 in the proposed rule to 553,000 in this final rule) in clinicians in the ''group eligibility'' category. We also observed a 33 percent increase in the PFS allowed charges in MIPS from $10,262 million in the proposed rule to $13,662 million in this final rule for the clinicians in the ''group eligibility'' category. The previous estimate presented in the proposed rule likely underestimated the number of clinicians using group reporting since previously group reporting could only be identified through the submission of quality data to PQRS. With the availability of CY 2017 Quality Payment Program Year 1 data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data.To model the proposed opt-in policy, we assumed that 33 percent of the clinicians who exceed at least one low-volume threshold and submitted data to CY 2017 MIPS performance period would elect to opt-in to MIPS. We selected a random sample of 33 percent of clinicians without accounting for performance. We believe this assumption of 33 percent is reasonable because some clinicians may choose not to submit data due to performance, practice size, or resources or alternatively, some may submit data, but elect to be a voluntary reporter and not be subject to a MIPS payment adjustment based on their performance. Similar to the proposed rule (83 FR 36060), we applied a 33 percent opt-in assumption to estimate opt-in eligibility in this final rule. We sought comment on these assumptions in the proposed rule, including whether modeling eligibility only among clinicians or groups who submitted at least 6 quality measures to PQRS would be more appropriate. As we describe in more detail below, we also explored an alternate opt-in assumption where only high-performers would opt-in to MIPS. In the alternate model, we saw a difference in the maximum payment adjustment of approximately one-tenth of a percent. Given the minimal differences between the two alternatives, we elected to continue the assumption from the CY 2019 PFS proposed rule and present results with the 33 percent random opt-in for this impact analysis. This 33 percent participation assumption is identified in Table 97 as ''Opt-In eligibility''. In the final rule analysis, we estimate an additional 28,000 clinicians would be eligible through this policy for a total MIPS eligible population of approximately 798,000. The leads to an associated $66.6 billion allowed PFS charges estimated to be included in the 2019 MIPS performance period.

We observed a decrease of approximately 14,000 clinicians compared to the proposed rule in the ''opt-in eligibility'' category after updating the data source and applying the finalized policies. This observed decrease in the number of clinicians that would elect to opt-in to MIPS is because there were fewer clinicians from which to randomly select for opt-in eligibility due to the increase in group reporting.

[66] The count of 216,612 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (196,236 MIPS eligible clinicians) as well as those who did not participate (17,376 MIPS eligible clinicians).

[67] Estimates for the proposed rule available at 83 FR 36060.

TABLE 97—DESCRIPTION OF MIPS ELIGIBILITY STATUS FOR CY 2021 MIPS PAYMENT YEAR USING THE PROPOSED AND FINALIZED ASSUMPTIONS ***

Eligibility status	Predicted participation status in MIPS among clinicians *	Proposed rule estimates		Final Rule estimates †	
		Legacy data *		QPP Year 1 data	
		Number of clinicians	PFS allowed charges ($ in mil) ****	Number of clinicians	PFS allowed charges ($ in mil) ****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria).	Participate in MIPS	186,549	43,546	199,236	47,653
	Do not participate in MIPS.	31,921	7,605	17,376	3,916
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group).	Submit data as a group	389,670	10,262	553,475	13,662
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data).	Elect to opt-in and submit data.	42,025	2,099	27,903	1,380
Total Number of MIPS Eligible Clinicians	.....	650,165	63,512	** 797,990	66,611
Not MIPS eligible:					
Potentially MIPS eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: 1) meet group eligibility or 2) opt-in eligibility criteria).	Do not opt-in; or ..... Do not submit as a group.	482,574	11,695	390,244	9,290
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria).	Not applicable	88,070	690	77,617	404
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP).	Not applicable	302,172	13,688	209,403	9,735
Total Number of Clinicians Not MIPS Eligible.	.....	872,816	26,073	677,264	19,429
Total Number of Clinicians (MIPS and Not MIPS Eligible).	.....	1,522,981	89,585	1,475,254	86,040

* Participation in MIPS defined as previously submitting quality or EHR data for PQRS. Group reporting based on 2016 PQRS group reporting.
** Updated Estimated MIPS Eligible Population.
*** Facility-based eligible clinicians are not modeled separately in this table and are captured in the individual eligible category. This table does not consider the impact of the MAQI Demonstration waiver. This table also does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 22,000 clinicians and $3.7 billion in PFS allowed charges).
† These estimates reflect the finalized policies, which differ from the proposed rule (that is, change in MIPS eligible clinician types and those identified as QPs).
**** Allowed charges estimated using 2016 and 2017 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

There are approximately 390,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate. We describe this group as ''Potentially MIPS eligible.'' This is the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate that the MIPS eligible clinician population could be as high as 1.2 million clinicians. We observed a decrease of approximately 92,000 clinicians compared to the model in the proposed rule after updating the data source and applying the finalized policies. This observed decrease is due to the increase in group reporting.

Finally, there are some clinicians who would not be MIPS eligible either because they are below the low-volume threshold on all three criteria (approximately 78,000) or because they are excluded for other reasons (approximately 209,000). We observed a decrease of approximately 93,000 clinicians after updating the data source and applying the finalized policies. This observed decrease is due to much lower estimated number of newly enrolled clinicians but slightly higher number of QPs in the 2017 Quality Payment Program Year 1 data.

Since eligibility among some clinicians is contingent on submission to MIPS as a group or election to opt-in, we will not know the exact number of MIPS eligible clinicians until the submission period for the CY 2019 MIPS performance period is closed. For this impact analysis, we are using the estimated population of 797,990 MIPS eligible clinicians described above.

We received the following comments on our methodology:

Comment: One commenter requested CMS explain how the number of clinicians affected by the proposed MIPS opt-in policy for the 2021

payment year was estimated. The commenter supported the proposed MIPS opt-in policy starting in 2019 but would like to know how CMS estimated the number of clinicians that would be impacted by the policy.

Response: For the proposed rule, to estimate the number of clinicians that may elect to opt-in to MIPS, we randomly selected 33 percent of clinicians that met at least one but not all the low-volume criteria and submitted data to 2016 PQRS. This led to an estimated 42,025 number of clinicians that will opt-in to MIPS.

For this final rule, we randomly selected 33 percent of clinicians that met at least one but not all the low-volume criteria and submitted to CY 2017 MIPS performance period. This led to an estimated 27,903 number of clinicians that will opt-in to MIPS. We also estimated the impact if we had assumed only those who expect to perform well would elect to opt-in. In the alternate model assumption where only high performers would opt-in to MIPS, we assumed 100 percent of clinicians with final scores above the additional performance threshold would opt-in and 50 percent of clinicians above the performance threshold but below the additional performance threshold would opt-in. We observed a decrease in the budget neutral pool from $310 million to $296 comparing the model with the 33 percent random opt-in to the model where only high-performers opt-in. We observed a minimal impact to the maximum payment adjustment compared to the model with 33 percent random opt-in (4.7 percent versus 4.6 percent). We refer readers to section III.I.3.c.(5) of this final rule for additional results on that analysis. Because we did not see much difference in results, we present the model with the 33 percent random opt-in this impact analysis.

Comment: One commenter recommended CMS present specialty-specific data for exemption criteria. Specifically, the commenter recommended CMS present specialty specific information on the number of clinicians exempt from MIPS because they are newly enrolled in Medicare and/or Qualified Participants (QPs) or Partial QPs in Advanced APMs, and the number of clinicians assigned to certain special categories (for example, non-patient facing, hospital-based, facility-based, and ASC-based for the purposes of the ACI exemption). The commenter noted the provision of this information will allow for the assessment of how many clinicians are exempt by specialty and for member education activities.

Response: We appreciate that some stakeholders would like specialty specific information; however, given the numerous assumptions for group reporting and opt-in participation, we believe presenting the overall number of MIPS eligible clinicians is the most transparent way to present the information.

After consideration of the public comments, we have updated our methodology to estimate the number of MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year to account for the Quality Payment Program Year 1 data and the policies finalized in this final rule.

(3) Impact of MIPS Eligibility Finalized Policies

We illustrate in Table 98[68] how each finalized policy for the CY 2021 payment year affects the estimated number of MIPS eligible clinicians. The baseline is the number of individuals that would have been MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year if this regulation did not exist. In the CY 2019 PFS proposed rule (83 FR 36060), we estimated the baseline was 591,010. After updating the model to reflect the updated data sources, the new baseline population is 751,498. All incremental impact estimates are relative to this baseline.

TABLE 98—INCREMENTAL CHANGE TABLE FOR FINALIZED POLICIES FOR 2021 MIPS PAYMENT YEAR

Policy changes *	Estimated number of MIPS eligible clinicians impacted by policy change	Estimated effect of policy changes on number of MIPS eligible clinicians	Estimated % change from baseline	Estimated Part B allowed charges (mil) ***	Estimated PFS allowed charges (mil) ***	Estimated % change in PFS from baseline
Baseline: Applying previously finalized policy for the 2021 payment year if this regulation did not exist	N/A	751,498	N/A	79,375	64,382	N/A
Policy Change 1: Low-volume threshold (LVT) determination based on covered professional services (as required by Bipartisan Budget Act of 2018)	−1,651	749,847	−0.2	79,160	64,266	−0.2%
Policy Change 2: Expansion of eligible clinician types to include physical therapists, occupational therapists, qualified speech-language pathologist, or qualified audiologist, clinical psychologist, and registered dietician or nutrition professional based with policy change 1	20,240	770,087	2.5	N/A	65,231	1.3%
Policy Change 3: Cumulative change of Opt-in Policy with policy changes 1 and 2 **	27,903	797,990	6.2	N/A	66,611	3.5%

* This table does not consider the impact of the MAQI Demonstration waiver and does not include clinicians impacted by the extreme and uncontrollable policy.

** Model assumption is 33 percent clinicians who are eligible will elect to opt-in.

*** Allowed charges estimated using 2016 and 2017 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

[68] Estimates for the proposed rule available at 83 FR 36061.

First, as shown in Table 98, the first row shows the effect of changing the application of the MIPS payment adjustments, as required by section 51003(a)(1)(E) of the Bipartisan Budget Act of 2018 to apply them to covered professional services (services for which payment is made under, or is based on, the Medicare PFS and are furnished by an eligible clinician) rather than to items and services covered under Part B. As shown, the baseline allowed charges for Part B is $79.4 billion, compared with $64.4 billion in covered professional services, which is a difference of almost $15 billion. Beginning in the 2019 MIPS payment year, payment adjustments will only be applied to the total paid amount for covered professional services.

In Table 98, under the first policy change, basing the low-volume threshold on covered professional services (services provided under the PFS rather than items and services covered under Part B) has minimal impact in terms of clinicians (less than half of one percent decrease).

When the second policy change, to expand the definition of MIPS eligible clinician types, was added to the first policy change, the total effect is small. The change in the potential MIPS eligible clinician population increased by less than 3 percent and the allowed charges in the PFS increased by 1.3 percent.

When the third policy change, which implements the opt-in policy, is added to the other two policies, the estimated number of MIPS eligible clinicians increases by 6.2 percent. The estimated increase in the allowed charges in the PFS is 3.5 percent.

d. Estimated Impacts on Payments to MIPS Eligible Clinicians

(1) Summary of Approach

In sections III.I.3.h., III.I.3.i. and III.I.3.j. of this final rule, we finalized several proposals which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.F.8.d.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2021 MIPS payment year. We note that many of the MIPS policies from the CY 2018 Quality Payment Program final rule were only defined for the 2018 MIPS performance period and 2020 MIPS payment year (including the performance threshold, the additional performance threshold, the policy for redistributing the weights of the performance categories, and many scoring policies for the quality performance category) which precludes us from developing a baseline for the 2019 MIPS performance period and 2021 MIPS payment year if there was no new regulatory action. Therefore, our impact analysis looks at the total effect of the finalized MIPS policy changes on the MIPS final score and payment adjustment for CY 2019 MIPS performance period/CY 2021 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As described in the CY 2019 PFS proposed rule (83 FR 36061), the performance and participation data submitted for the 2017 MIPS performance period were not available to estimate the final score and the projected payment adjustments for MIPS eligible clinicians. This analysis has been updated with the Quality Payment Program Year 1 data and those results are presented in this final rule. We refer readers to CY 2019 PFS proposed rule (83 FR 36061 through 36066) for additional details on how we estimated the final scores and payment adjustments in the proposed rule.

The estimated payment impacts presented in this final rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System or Medicare Advantage that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2019 Quality Payment Program for this final rule, we used CY 2017 Quality Payment Program Year 1 performance period data. Our scoring model includes the 797,990 estimated number of MIPS eligible clinicians as described in section VII.F.8.c of this RIA.

To estimate the impact of MIPS on eligible clinicians, we used the Quality Payment Program Year 1 submission data, including data submitted for the quality, improvement activities, and advancing care information performance categories, CAHPS for MIPS and CAHPS for ACOs, the total per capita cost measure, Medicare Spending Per Beneficiary (MSPB) measures and other data sets.[69] We calculated a hypothetical final score for the 2019 MIPS performance period/2021 MIPS payment year for each MIPS eligible clinician based on quality, cost, Promoting Interoperability, and improvement activities performance categories.

Starting in CY 2018 MIPS performance period, solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group (82 FR 53604). We had two virtual groups register for the 2018 performance period, of which one had all its participants participating in a MIPS APM for the 2018 performance period. While we anticipate an increase in the number of virtual groups for the 2019 MIPS performance period, we did not attempt to model virtual groups in this model as the participants in one virtual group who are in a MIPS APM would receive the MIPS APM score which left just one virtual group to measure.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using measures submitted to MIPS for the 2017 performance period. For the quality measures, we started with the assigned measure achievement points assigned for the 2017 MIPS performance period. As finalized as proposed in III.I.3.i.(1)(b)(iii)(A) of this final rule, we applied a 3-point floor for measures that cannot be reliably scored against a baseline benchmark in the 2019 MIPS performance period. As described in section III.I.3.h.(2)(b)(iii) of this final rule, we finalized the proposal to remove many measures that were previously able to be reported in PQRS and in previous MIPS performance periods. For our estimates, we assumed that clinicians who reported Medicare Part B claims, eCQM, MIPS CQM and QCDR measures that are removed would find alternate measures; therefore, we assigned points to these measures and included them in our scoring model. For CY 2019, we maintained the policies for

[69] 2016 PQRS and Value Modifier data was used for the improvement score for the quality performance category.

scoring measures that do not meet the quality category requirements (case minimum, benchmark, and data completeness) as described in the CY 2018 Quality Payment Program final rule (82 FR 53727 through 53730). As finalized in the CY 2018 Quality Payment Program final rule, we also applied a 7-point cap for measures that are topped out for two or more years (82 FR 53721 through 53727).

As stated in section III.I.3.h.(2)(a)(iii)(A)(bb) of this final rule, we finalized the proposal to remove several Web Interface measures. For that collection type, which has a standard set of measures, we estimated performance on the measures that we propose to continue.

As finalized in sections III.I.3.i.(1)(b)(ix) and (x) of this final rule, we maintained the cap on bonus points for high-priority measures and end-to-end electronic bonus points at 10 percent of the denominator and, beginning with the 2019 MIPS performance period, discontinue high priority bonus points for CMS Web Interface Reporters. Because we are able to use MIPS performance data in our models, we assigned 1 point for each measure that was submitted with end-to-end electronic reporting with a cap of 10 percent of the total possible measure achievement points. To be consistent with our small practice bonus finalized policy in section III.I.3.i.(1)(b)(viii) of this final rule, we added 6 measure achievement points to the quality performance category score for small practices that had a quality performance category score greater than 0 points.

As finalized in the CY 2018 Quality Payment Program final rule (82 FR 53625 through 52626) and further discussed in III.I.3.h.(2)(a)(iii) of this final rule, we are allowing MIPS eligible clinicians and groups to submit data collected via multiple collection types within a performance category beginning with the 2019 performance period. The requirements for the performance categories remain the same regardless of the number of collection types used. We do not apply the validation process that is discussed in section III.I.3.i.(1)(b)(vii) of this final rule.

To estimate the impact of improvement for the quality performance category, we estimated a quality performance category percent score using 2019 MIPS data, 2015 and 2018 CAHPS for ACOs and MIPS data, and 2016 PQRS VM data. For MIPS eligible clinicians with an estimated quality performance category score less than or equal to a 30 percent score in the previous year, we compared 2019 performance to an assumed 2018 quality score of 30 percent for their improvement score as described in III.I.3.i.(1)(b)(xiii) of this final rule.

Due to data limitations, we are unable to model all the finalized policies in this rule. We are not able to incorporate the policy to reduce the denominator for the quality performance category score by 10 points for groups that registered for CAHPS for MIPS but were unable to report due to insufficient sample size as discussed in section III.I.3.i.(1)(b)(iii)(B) of this final rule. We also did not apply the finalized scoring policy for measures that are significantly impacted by clinical guideline or other changes discussed in section III.I.3.i.(1)(b)(vi) of this final rule.

Our model applied the MIPS APM scoring standards finalized in section III.I.3.h.(6) of this final rule to quality data from MIPS eligible clinicians that participated in the Shared Savings Program, and the Next Generation ACO Model in 2017.

(b) Methodology To Estimate the Cost Performance Category Score

In section III.I.3.h.(3)(b)(ii) of this final rule, we finalized the proposal to add 8 episode-based measures to the cost performance category beginning with the 2019 performance period. For the episode-based measures, we used the episode specifications proposed in the CY 2019 PFS proposed rule (83 FR 35902 through 35903) and claims data from June 2016 through May 2017. As discussed in section III.I.3.h.(3)(b)(ii) of this final rule, we made updates to the specifications for three episode measures. Due to timing constraints we were not able to incorporate the updated specifications into this impact analysis; however, we anticipate that the updates will only have a marginal effect on the cost measure scores.

We estimated the cost performance category score using the total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) measures from the CY 2017 Quality Payment Period Year 1 data that was presented in the MIPS feedback reports. Cost measure scores were used only when the associated case size met or exceeded the previously finalized or newly finalized case minimum: 20 for the total per capita cost measure, 35 for MSPB, 10 for procedural episodes, and 20 for acute medical inpatient medical condition episodes. The cost measures are computed for both the TIN/NPI and the TIN. For clinicians participating as individuals, the TIN/NPI level score was used if available and if the minimum case size was met. For clinicians participating as groups, the TIN level score was used, if available, and if the minimum case size was met. For clinicians with no measures meeting the minimum case requirement, we did not estimate a score for the cost performance category, and the weight for the cost performance category was reassigned to the quality performance category. The raw cost measure scores were mapped to scores on the scale of 1–10, using benchmarks based on all measures that met the case minimum during the relevant performance period. For the episode-based cost measures, separate benchmarks were developed for TIN/NPI level scores and TIN level scores. For each clinician, a cost performance category score was computed as the average of the measure scores available for the clinician.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As discussed in section III.I.3.i.(1)(d) of this final rule, we are implementing facility-based measurement for the 2019 MIPS performance period. In facility-based measurement, we determine the eligible clinician's MIPS score based on Hospital VBP Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. Given that we are not requiring eligible clinicians to opt-in to facility-based measurement, it is possible that a MIPS eligible clinician or a group is automatically eligible for facility-based measurement but they participate in MIPS as an individual or a group. In these cases, we use the higher combined quality and cost performance category score from facility-based scoring compared to the combined quality and cost performance category score from MIPS submission based scoring.

Data was not available to attribute specific Hospital VBP Total Performance Score to MIPS eligible clinicians, hence we made the following assumptions. For MIPS eligible clinicians and groups who are eligible for facility-based measurement and who submitted quality data to the Quality Payment Program for the 2017 MIPS performance period, we did not estimate a facility-based score. We instead calculated a MIPS quality and cost score based on the available quality measures and cost data. Some clinicians who submitted Quality Payment Program quality data may receive a higher combined quality and cost score through facility-based measurement, but we are unable to identify those clinicians due to data limitations and therefore believe the score based on

their submitted data is more likely to reflect their performance.

For MIPS eligible clinicians that did not submit data to the Quality Payment Program for the 2017 MIPS performance period and were eligible for facility-based measurement, we estimated a facility-based score by taking the median MIPS quality and cost performance score. We believe it is important to develop an estimate for this cohort because we would have otherwise assigned this group a quality performance category percent score of zero percent which we believe would underestimate their MIPS final score. Given the data limitations in assigning a specific hospital score to a clinician, we selected the median MIPS quality and cost performance scores as that represents the quality and cost performance category scores that a clinician working in a hospital with median performance would receive.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

As discussed in section III.I.3.h.(5)(d)(ii) of this final rule, we finalized the proposal to modify the measures and scoring for the Promoting Interoperability performance category score. We simplified scoring by eliminating the concept of base and performance scores and focusing on a smaller set of measures which are scored on performance. We estimated Promoting Interoperability performance category scores using the advancing care information performance category data from the CY 2017 Quality Payment Period Year 1 data. The Promoting Interoperability performance category scores were based on the individual level for individual submissions and on the group level for clinicians that were part of a group submission or part of an APM entity.

For the e-Prescribing objective, we only estimated the e-Prescribing measure and did not assume any bonus points for the Query of Prescription Drug Monitoring Program (PDMP) or the Verify Opioid Treatment Agreement measures. To estimate the e-Prescribing measure, we used the reported numerator and denominator values for the e-Prescribing measure for the advancing care information performance category, unless a measure exclusion applied.

For the Health Information Exchange objective, we used the required measures in the Health Information Exchange objective from the advancing care information performance category to proxy performance for the two finalized measures in the Promoting Interoperability objective. We used the Send Summary of Care measure and the Health Information Exchange transition measure for the Support Electronic Referral Loops by Sending Health Information measure. For MIPS eligible clinicians that reported data using 2015 CEHRT, we used the Request/Accept Summary of Care measure for the Support Electronic Referral Loops by Receiving and Incorporating Health Information. If this information was not available, then we used just the Send Summary of Care measure. If there was an exclusion for the Send Summary of Care measure or the Health Information Exchange transition measure, then for purpose of this model, we reweighted the measure to the Patient Electronic Access objective.

For the Provider to Patient Exchange objective, we used the Provide Patient Access measure to estimate performance for the finalized Provide Patients Electronic Access to Their Health Information measure.

For the Public Health and Clinical Data Exchange objective, we estimated the score by using the reported responses for the following advancing care information measures: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting and Specialized Registry Reporting.

To calculate the Promoting Interoperability performance category, we summed the performance category measure scores and divided the total sum by the total number of possible points (100), as described in section III.I.3.i.(1)(d) of this final rule. As discussed in section III.I.3.i.(1)(d) of this final rule, a TIN/NPI must report on all required measures in the Promoting Interoperability performance category and complete all actions included in the Security Risk Analysis measure during the year to receive a non-zero performance category score. For APM Entities, we aggregated the scores of the participants consistent with the requirements for the 2017 MIPS performance period.

For eligible clinicians who did not submit a required Promoting Interoperability measure and did not complete all actions included in the Security Risk Analysis measure, we evaluated whether the MIPS eligible clinician could have their Promoting Interoperability performance category reweighted and applied the reweighting policies described in section III.I.3.h.(5)(d) of this final rule. For the Registry Reporting measures, which did not have an exclusion defined for the 2017 MIPS performance period, we assumed that failure to submit data or submissions with all ''No'' answers implied a request for exclusion. A group was only reweighted for the Promoting Interoperability performance category if all the TIN/NPIs were eligible for reweighting, thereby reweighting only applying to 24 percent of MIPS eligible clinicians as opposed to 62 percent of MIPS eligible clinicians scores in the CY 2019 PFS proposed rule (83 FR 36063) in which Promoting Interoperability was always assessed at the individual level.

As finalized in the CY 2017 (81 FR 77069 through 77070) and CY 2018 (82 FR 53625 through 52626) Quality Payment Program final rules, the Promoting Interoperability performance category weight is set equal to 0 percent, and the weight is redistributed to the quality or improvement activities performance category for non-patient facing MIPS eligible clinicians, hospital-based MIPS eligible clinicians, ASC-based MIPS eligible clinicians, or those who request and are approved for a significant hardship or other type of exception, including a significant hardship exception for small practices, or clinicians who are granted an exception based on decertified EHR technology (82 FR 53780 through 53786). We also finalized in section III.I.3.h.(5)(h) of this final rule to continue automatic reweighting for NPs, PAs, CNSs and CRNAs and to add an automatic reweighting policy for physical therapists, occupational therapist, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals, which we have incorporated into our model. We used the non-patient facing and hospital-based indicators and specialty and small practice indicators as calculated in the initial MIPS eligibility run for the 2017 MIPS performance period (81 FR 77069 through 77070). For significant hardship exceptions, we used the approved significant hardship file for the 2017 MIPS performance period.

If a TIN/NPI did not report on all required measures and did not qualify for reweighting for a required measure, then their Promoting Interoperability performance category score was set to zero percent.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2017 Quality Payment Period Year 1 data and APMs participation in the 2017 MIPS performance period. We did not make

any policy changes that impact scoring for the improvement activities performance category. Our model identified participants in APMs during the 2017 performance period, including but not limited to those in the Shared Savings Program, Next Generation ACO Model, and assigned them an improvement activity score of 100 percent, consistent with our policy to assign an improvement activities score of 100 percent to ACO participants who were not excluded due to being QPs.

Clinicians and groups not participating in a MIPS APM were assigned their CY 2017 Quality Payment Period Year 1 improvement activities performance category score.

(f) Methodology To Estimate the Complex Patient Bonus

In sections III.I.3.i.(2)(a)(ii) of this final rule, we finalized the proposed policy to continue the complex patient bonus. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model calculated the bonus by using the average Hierarchical Condition Category (HCC) risk score, as well as the MIPS eligible clinician's patients dual eligible proportion calculated for each NPI in the 2016 Physician and Other Supplier Public Use File. The dual eligible proportion for each MIPS eligible clinician was multiplied by 5. We also generated a group average HCC risk score by weighing the scores for individual clinicians in each group by the number of beneficiaries they have seen. We generated group dual eligible proportions using the weighted average dual eligible patient ratio for all MIPS eligible clinicians in the groups, which was then multiplied by 5. The complex patient bonus was calculated by adding together the average HCC risk score and the percent of dual eligible patients multiplied by 5, with a 5-point cap.

(g) Methodology To Estimate the Final Score

As finalized in sections III.I.3.h.(2)(a)(ii), III.I.3.h.(3)(a), III.I.3.h.(4)(a), III.I.3.h.(5)(d)(i) and summarized in section III.I.3.i.(2)(b) of this final rule, our model assigns a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for the Promoting Interoperability due to a significant hardship or other type of exception, the weight for the Promoting Interoperability performance category was redistributed to the quality performance category. For MIPS eligible clinicians who did not have a cost performance category score, the weight for the cost performance category was redistributed to the quality performance category. In our scoring model, we did not address scenarios where a zero percent weight would be assigned to the quality performance category or the improvement activities performance category.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we applied a hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available (for example if a clinician qualifies for a score for an APM entity and a group score, we select the APM entity score).

We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using a performance threshold of 30 points and the additional performance threshold of 75 points (as finalized in sections III.I.3.j.(2) and III.I.3.j.(3) of this final rule). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the PFS paid amount. We considered other performance thresholds which are discussed in section VII.G. of this RIA.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $310 million would be redistributed through budget neutrality and that the maximum positive payment adjustments are 4.7 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. The observed decrease in the funds available for redistribution and the maximum positive payment adjustment from the proposed rule to the final rule is due to the change in the data sources used to estimate final scores for MIPS eligible clinicians and the decrease in the additional performance threshold.

The use of 2017 Quality Payment Program Year 1 data to estimate the impact of the 2019 Quality Payment Program Year 3 finalized policies led to lower average final scores compared to the proposed rule. The main contributors to the lower estimated final scores were the changes in the estimated quality and Promoting Interoperability performance categories scores. The average quality scores were lower because some of the group reporters did not have quality data. As described in section VII.F.8.c.(2) of this final rule, we previously identified group reporters based on the submission of quality data submitted to PQRS; therefore, all group reporters submitted quality data and had a quality score. As a result of the 2017 Quality Payment Program Year 1 data, we can identify group reporters through submissions for the improvement activities or the Promoting Interoperability performance category who may not have submitted quality data. Therefore, these new groups in the estimated MIPS population received a zero (or close to zero) quality performance category score for not submitting quality data.

Table 99 shows the impact of the payments by practice size and whether clinicians are expected to submit data to MIPS.[70] We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger size practices. Overall, clinicians in small practices participating in MIPS would receive a 1.2 percent increase in their paid amount, which is similar to the payment amount received by MIPS eligible clinicians in practices with 16 to 24 and 25 to 99 clinicians. After considering the positive adjustments and subtracting the negative adjustments, eligible clinicians in small practices would have an increase in funds which is consistent with all MIPS eligible clinicians. Table 99 also shows that 91.2 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. The combined impact of negative and positive adjustments and exceptional performance payment as percent of paid

[70] The proposed rule estimated MIPS participation and performance using historical PQRS and EHR data because MIPS CY 2017 performance period data were not available in time for analysis in the proposed rule (83 36058 through 36066). This final rule presents the results from analysis of MIPS CY 2019 performance period data. Previous estimates are available in the proposed (83 FR 36066).

amount among those that do not submit data to MIPS was not the maximum negative payment adjustment possible because not all MIPS eligible clinicians that do not submit to MIPS receive a final score of zero. Indeed, some MIPS eligible clinicians that do not submit data to MIPS may receive final scores above zero through the cost performance category, which does not require submission to MIPS. Among those who we estimate would not submit data to MIPS, 90 percent are in small practices (15,680 out of 17,376 clinicians). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs.

TABLE 99—MIPS ESTIMATED PAYMENT YEAR 2021 IMPACT ON TOTAL ESTIMATED PAID AMOUNT BY PARTICIPATION STATUS AND PRACTICE SIZE * [a]

Practice size *	Number of MIPS eligible clinicians	Percent MIPS eligible clinicians with positive or neutral payment adjustment (percent)	Percent MIPS eligible clinicians with a positive adjustment with exceptional payment adjustment (percent)	Percent MIPS eligible clinicians with negative payment adjustment (percent)	Combined Impact of negative and positive adjustments and exceptional performance payment as percent of paid amount ** (percent)
Among those submitting data * **					
(1) 1–15	140,251	80.1	47.2	19.9	1.2
(2) 16–24	41,226	86.1	41.4	13.9	1.1
(3) 25–99	185,140	89.8	48.6	10.2	1.3
(4) 100+	413,997	96.1	69.0	3.9	2.0
Overall	780,614	91.2	58.8	8.8	1.5
Among those not submitting data					
(1) 1–15	15,680	0.0	0.0	100.0	−6.3
(2) 16–24	629	0.0	0.0	100.0	−6.6
(3) 25–99	860	0.0	0.0	100.0	−6.6
(4) 100+	207	0.0	0.0	100.0	−6.9
Overall	17,376	0.0	0.0	100.0	−6.4

* Practice size is the total number of TIN/NPIs in a TIN.
** 2016 and 2017 data used to estimate 2019 performance period payment adjustments. Payments estimated using 2016 and 2017 dollars.
*** Includes facility-based clinicians whose quality data is submitted through hospital programs.
[a] This table does not account for clinicians that are in the MAQI Demonstration waiver.

The following is a summary of the public comments received regarding the estimated impact on payments for MIPS eligible clinicians:

Comment: A few commenters encouraged CMS to use Year 1 MIPS participation data to inform changes to the program, citing that actual QPP data is needed for assessing the best ways to improve the program and how these changes will impact clinicians financially.

Response: We thank the commenter for this suggestion. As described in this RIA for this final rule, the 2017 Quality Payment Program Year 1 data were available in time to assess impact of the finalize policies and are now presented in this final rule.

Comment: A few commenters recommended CMS present specialty specific tables. Specifically, they requested the estimated payment impact table by specialty as presented in previous years and additional performance data by specialty on each performance category (Data on reporting and performance rates for quality measures (similar to what was released via the PQRS Experience Reports); Statistics on clinical improvement activities reported; Statistics on clinician attribution to cost measures and performance on cost measures.). This would allow for better understanding of MIPS for their stakeholders.

Response: We chose to only present the payment impact by practice size in this final rule; however, we may provide additional analyses via the Quality Payment Program website or other forums.

After consideration of public comments, we have updated our analyses to incorporate the Quality Payment Program Year 1 data and the final policies.

e. Potential Costs of Compliance With the Promoting Interoperability and Improvement Activities Performance Categories for Eligible Clinicians

(1) Potential Costs of Compliance With Promoting Interoperability Performance Category

In section III.I.3.h.(5)(c) of this final rule, we discussed the requirement to use EHR technology certified to the 2015 Edition beginning with the 2019 MIPS performance period for the Promoting Interoperability performance category. As discussed in section V.B.3 of this final rule, we assumed a slight decrease in overall information collection burden costs for the Promoting Interoperability performance category related to having fewer measures to submit.

With respect to any costs unrelated to data submission, although this final rule would require some investment in systems updates, our policy prior to this regulation as reflected in § 414.1305, is that 2015 Edition CEHRT will be required beginning with the 2019 MIPS

performance period/2021 MIPS payment year (82 FR 53671). Therefore, we do not anticipate any additional costs due to this regulation.

The following is a summary of the public comments received regarding these assumptions:

Comment: A few commenters stated that complying with Promoting Interoperability performance category is a financial burden for many clinicians due to their practice size and their administrative capability, and the costs required by the EMR and EHR vendors. One commenter suggested that state and federal legislation ought to take these challenges into account, while another commenter suggested CMS work with stakeholders to establish mechanisms for providers to be compensated for creating interoperable data.

Response: We reiterate that this policy was finalized in the CY 2018 Quality Payment Program final rule (82 FR 53671) and thus this is not a new obligation for this final rule. We do have policies that recognize challenges, such as significant hardship exceptions for small practices.

After consideration of public comments, we are not making any modifications on our potential cost for compliance with Promoting Interoperability performance category.

(2) Potential Costs of Compliance With Improvement Activities Performance Category

Under the policies established in the CY 2017 Quality Payment Program final rule, the costs for complying with the improvement activities performance category requirements could have potentially led to higher expenses for MIPS eligible clinicians. Costs per full-time equivalent primary care clinician for improvement activities will vary across practices, including for some activities or certified patient-centered medical home practices, in incremental costs per encounter, and in estimated costs per (patient) member per month.

Costs for compliance with previously finalized policies may vary based on panel size (number of patients assigned to each care team) and location of practice among other variables. For example, Magill (2015) conducted a study of certified patient-centered medical home practices in two states.[71] That study found that costs associated with a full-time equivalent primary care clinician, who was associated with certified patient-centered medical home practices, varied across practices. Specifically, the study found an average cost of $7,691 per month in Utah practices, and an average of $9,658 in Colorado practices. Consequently, incremental costs per encounter were $32.71 for certified patient-centered medical home practices in Utah and $36.68 in Colorado (Magill, 2015). The study also found that the average estimated cost per patient member, per month, for an assumed panel of 2,000 patients was $3.85 in Utah and $4.83 in Colorado. However, given the lack of comprehensive historical data for improvement activities, we are unable to quantify those costs in detail at this time. The findings presented in these papers have not changed. We have improvement activities information from the 2017 performance period, but additional analysis would be required before using that data to report the costs and benefits of implementing the improvement activities; and we are not able to do this in time for publication of this final rule. We have considered factors that also contribute to the difficulty of identifying compliance costs for the improvement activities performance category in the CY 2018 Quality Payment Program final rule (82 FR 53845).

We believe that because we finalized an opt-in policy (as described in section II.C.2.c of this final rule), we would add approximately 28,000 additional clinicians to the MIPS eligible clinicians. In section V.B.4 of this final rule, we assumed that those who have elected to opt-in have already been voluntary reporters in MIPS and would not have additional compliance costs as a result of this regulation. Thus, we believe the overall potential cost of compliance would not increase because of this final rule.

Further, we anticipate that the vast majority of clinicians submitting improvement activities data to comply with existing MIPS policies could continue to submit the same activities under the policies established in this final rule. Previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rule-making (82 FR 54175). We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199) and Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) for our previously finalized 112 improvement activities established in the Improvement Activities Inventory. In section III.I.3.h.(4)(d)(ii) of this final rule, we finalized 6 new improvement activities, 5 modifications, and 1 removal of an existing activity.

Similarly, we believe that third parties who submit data on behalf of clinicians who prepared to submit data in the transition year will not incur additional costs as a result of this final rule. We requested comments that provide additional information that would enable us to quantify the costs, costs savings, and benefits associated with implementation of improvement activities in the inventory, but did not receive comments with information that would enable us to quantify the costs, costs savings, and benefits associated with the implementation and compliance with the requirements of the improvement activities performance category: In section III.I.3.h.(4)(e) of this final rule, we discuss how eligible clinicians can participate in the CMS study on burdens associated with reporting quality measures for each MIPS performance period. Eligible clinicians who are interested in participating can sign up and an adequate sample size is then selected by CMS from these potential participants. In the CY 2018 Quality Payment Program final rule, the sample size for the CY 2018 performance period was set at a minimum of 102 MIPS eligible clinicians (81 FR 77196). Each study participant is required to complete a survey prior to submitting MIPS data and another survey after submitting MIPS data. In section III.I.3.h.(4)(e) of this final rule, for the CY 2019 performance period, we finalized the increase to the sample size to a minimum of 200 MIPS eligible clinicians.

However, we made the focus group a requirement only for a selected subset of the study participants, using purposive sampling and random sampling methods, beginning with the CY 2019 performance period and future years. Completing each survey is estimated to require approximately 15 minutes; therefore, the annual hourly burden per participant is approximately 30 minutes. The annual hourly burden associated with the increase in sample size by 98 clinicians (from 102 clinicians to 200) is estimated to be 49 hours (98 clinicians $\times$ 0.5 hours). Using the hourly rate for physicians in section V.A of this final rule, the total estimated annual cost burden is estimated to be $10,116 ($206.44/hour $\times$ 49 hours). While the sample size of the study is increasing, we did not make a change to the sample size of MIPS eligible clinicians participating in the focus group, so no burden is estimated for participating in that activity. We did

[71] Magill et al. ''The Cost of Sustaining a Patient-Centered Medical Home: Experience from 2 States.'' Annals of Family Medicine, 2015; 13:429–435.

receive a comment on the burden associated with the study.

f. Assumptions & Limitations

We note several limitations to our estimates of MIPS eligible clinicians' eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2021 MIPS payment year. We based our analyses on the data prepared to support the 2018 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*),[72] participant lists using the APM Participation List for the first snapshot date of the 2018 QP performance period, CY 2017 Quality Payment Program Year 1 data and CAHPS for ACOs. The scoring model results presented in this final rule assume that CY 2017 Quality Payment Program Year 1 data submissions and performance are representative of CY 2017 Quality Payment Program Year 3 data submissions and performance. The scoring model does not reflect the growth in Advanced APM participation between 2018 and 2019 (Quality Payment Program Years 2 and 3) because that data is not available at the detailed level needed for our scoring analysis. The estimated performance for CY 2019 MIPS performance period using Quality Payment Program Year 1 data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2017 MIPS performance period/2019 MIPS payment year was significantly lower (3 out of 100 points) than the performance threshold for the 2019 MIPS performance period/2021 MIPS payment year (30 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that 33 percent of the opt-in eligible clinicians that participated in the CY 2017 Quality Payment Program Year 1 would elect to opt-in to the MIPS program. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policy.

There are additional limitations to our estimates: (1) We only estimated the potential impact of facility-based scoring for MIPS eligible clinicians that are eligible for facility-based measurement and would have a quality performance category score of zero from failure to submit quality data; (2) because we used historic data, we assumed participation in the three performance categories in MIPS Year 1 would be similar to MIPS Year 3 performance; and (3) to the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 99. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify in detail.

9. Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success

This final rule includes certain provisions originally proposed for the Medicare Shared Savings Program (Shared Savings Program) in a proposed rule titled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' (hereinafter referred to as the ''August 2018 proposed rule'') that appeared in the **Federal Register** on August 17, 2018 (83 FR 41786). As described in section V. of this final rule, certain provisions of the August 2018 proposed rule are being finalized in this final rule in order to ensure that certain payment and policy changes for the Medicare Shared Savings Program are in place prior to the start of performance years under the program that begin on January 1, 2019. In a forthcoming final rule, we anticipate summarizing and responding to public comments on the remaining proposals in the August 2018 proposed rule that are not addressed in this final rule.

The most consequential of the changes to the Medicare Shared Savings Program being finalized in this final rule is the option for existing ACOs whose agreement periods expire on December 31, 2018, to elect an extension to their current agreement period for a fourth performance year, defined as the period from January 1, 2019, through June 30, 2019. Absent the voluntary 6-month extension as finalized in this rule, approximately 203 ACOs would be required to leave the program at least temporarily until the availability of an opportunity to enter a new agreement period for program participation. We estimate that up to 200 ACOs would elect the extension for the first 6 months of 2019, and therefore, would continue to improve care coordination and efficiency, and have the opportunity to receive shared savings for such period estimated to total approximately $170 million. As noted in the August 2018 proposed rule (83 FR 41922), we assumed that ACOs dropping out of the program may continue to produce residual savings in certain years following their exit from the program because of efficient practices put in place that may continue even after participation in the program ends. Therefore, while we estimate that ACOs electing the extension would produce additional savings on claims exceeding the cost of the anticipated $170 million in shared savings payments for the extension period, we note that lesser residual claims savings would also be expected for the baseline where such ACOs are not allowed to extend their participation in the program in the first 6 months of 2019 and therefore would not earn shared savings payments for that period. However, when considering the residual difference in savings on claims attributable to the 6-month extension period over the 12 months following the end of the extension we estimate that the $170 million in shared savings payments for the extension period would be fully offset by the effect of the extension on preserving a higher savings trajectory than the up to 200 ACOs that are expected to elect the extension would have exhibited absent the extension.

Lastly, we note that the modifications to the Shared Savings Program finalized in this rule that rely on the authority of section 1899(i)(3) of the Act, including most notably the methodology for determining the financial performance for the 6-month performance year from January 1, 2019, through June 30, 2019, for ACOs that voluntarily elect the extension, based on the entire 12-month CY 2019 and pro-rating the amount of any shared savings or shared losses to reflect the ACO's participation during a 6-month period, comply with requirements of section 1899(i)(3)(B). The considerations we described in the August 2018 proposed rule (83 FR 41851) (as well as those considerations discussed in section V.B.1. of this final rule) were relevant in making this determination. Specifically, we do not believe that the methodology for determining the financial performance of ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology prescribed in section 1899(d) of the Act.

Finalizing the voluntary 6-month extension for ACOs whose agreement periods expire on December 31, 2018, supports continued participation by these ACOs, and therefore also allows

[72] The time period for this eligibility file (September 1, 2016 to August 31, 2017) maximizes the overlap with the performance data in our model.

for lower growth in Medicare FFS expenditures based on projected participation trends. The extension is estimated to produce net savings over the baseline non-extension scenario when considering the residual benefit to savings on claims for Parts A and B services over a period of one or more years after the end of the 6-month extension period. Further, we believe the approach we are finalizing for determining the performance of ACOs for the 6-month performance year from January 1, 2019, through June 30, 2019, would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries. As described in section V.B.1.c.4. of this final rule, the approach to measuring ACO quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019, based on quality data reported for CY 2019, would maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would have an incentive to perform well on the quality measures in order to maximize any shared savings they may receive and minimize any shared losses they must pay in tracks where the loss sharing rate is determined based on the ACO's quality performance.

The anticipated forthcoming final rule will provide a detailed estimate of the impact of all other changes that may be finalized from the August 2018 proposed rule.

G. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our proposed policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty. The alternatives we considered, as discussed in the preceding preamble sections, would result in different payment rates, and therefore, result in different estimates than those shown in Table 94 (CY 2019 PFS Estimated Impact on Total Allowed Charges by Specialty).

1. E/M Coding and Payment Alternatives Considered

For the CY 2019 PFS proposed rule, we considered a number of other options for simplifying coding and payment for E/M services to align with the proposed reduction in documentation requirements and better account for the resources associated with inherent complexity, visit complexity, and visits furnished on the same day as a 0-day global procedure. For example, as we noted in the proposed rule, we considered establishing single payment rates for new and established patients for combined E/M visit levels 2 through 4, as opposed to combined E/M visit levels 2 through 5, as we proposed. We considered the potential impacts of making this change in isolation.

TABLE 100—UNADJUSTED ESTIMATED SPECIALTY IMPACTS OF SINGLE PFS RATE FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4

[As displayed in the CY 2019 PFS proposed rule]

Specialty	Allowed charges (millions)	Impact (percent)
Podiatry	$2,022	10
Dermatology	3,525	6
Hand Surgery	202	5
Oral/Maxillofacial Surgery	57	4
Otolaryngology	1,220	4
Cardiology	6,723	−3
Hematology/Oncology	1,813	−3
Neurology	1,565	−3
Rheumatology	559	−6
Endocrinology	482	−8

Note: All other specialty level impacts were within +/−3%.

Table 100 shows the specialties that would experience the greatest increase or decrease by establishing single payment rates for E/M visit levels 2 through 4, while maintaining the value of the level 1 and the level 5 E/M visits. We note that this alternative is similar to the policy we are finalizing for CY 2021. However, we are also finalizing the inherent visit complexity add-on codes that will likely result in mitigating some of the more significant estimated specialty-level impacts of establishing a single rate for the level 2–4 visits.

While considering whether to finalize a single payment rate for new and established office/outpatient E/M visit levels 2–5, we explored a number of alternative scenarios based on commenters' varied responses to aspects of our proposal. For example, we considered the potential impacts on finalizing all elements of the proposal except for the MPPR and the single PE/hr value across the office/outpatient E/M code set.

TABLE 101—SPECIALTY LEVEL IMPACTS OF FINALIZING AS PROPOSED WITH THE EXCEPTION OF THE MPPR AND PE/hr ADJUSTMENTS

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	1	1	0	2
Anesthesiology	1,981	0	0	0	−1
Audiologist	68	0	1	0	1
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	0	−1	0	−1
Chiropractor	754	0	0	0	−1
Clinical Psychologist	776	0	2	0	1
Clinical Social Worker	728	−1	2	0	2
Colon And Rectal Surgery	166	0	1	0	2
Critical Care	342	−1	−1	0	−2
Dermatology	3,486	3	4	0	7
Diagnostic Testing Facility	733	0	−4	0	−5
Emergency Medicine	3,121	−1	0	0	−1
Endocrinology	482	0	−1	0	−1
Family Practice	6,208	0	0	0	0
Gastroenterology	1,757	−1	0	0	−1
General Practice	429	0	0	0	0
General Surgery	2,093	0	0	0	1
Geriatrics	197	−2	−1	0	−4
Hand Surgery	214	3	2	0	5
Hematology/Oncology	1,741	−1	−1	0	−2
Independent Laboratory	646	0	4	0	3
Infectious Disease	649	−1	−1	0	−2
Internal Medicine	10,767	−1	0	0	−1
Interventional Pain Mgmt	868	2	3	0	5
Interventional Radiology	386	0	−1	0	−1
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−2	−1	0	−3
Neurology	1,529	−1	−1	0	−2
Neurosurgery	804	0	0	0	0
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	−1	0	0	−1
Nurse Practitioner	4,065	1	1	0	1
Obstetrics/Gynecology	638	3	3	0	6
Ophthalmology	5,448	0	−1	0	−1
Optometry	1,309	1	0	0	1
Oral/Maxillofacial Surgery	68	1	1	0	2
Orthopedic Surgery	3,743	1	2	0	3
Other	31	−1	3	0	3
Otolarngology	1,210	4	4	0	8
Pathology	1,165	0	−1	0	−1
Pediatrics	61	−1	0	0	−1
Physical Medicine	1,107	−1	0	0	−1
Physical/Occupational Therapy	3,950	0	−2	0	−2
Physician Assistant	2,457	1	2	0	3
Plastic Surgery	377	1	1	0	3
Podiatry	1,974	0	−3	0	−4
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,715	−2	−2	0	−4
Radiation Oncology And Radiation Therapy Centers	1,766	−1	−1	0	−2
Radiology	4,911	0	−1	0	−1
Rheumatology	541	0	0	0	0
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	3	3	0	6
Vascular Surgery	1,148	0	−2	0	−1
Total	92,771	0	0	0	0

We also explored an alternative of finalizing all elements of the proposal except for separate coding for podiatric E/M visits and the application of a single PE/hr across the office/outpatient E/M codes.

TABLE 102—SPECIALTY LEVEL IMPACTS OF FINALIZING AS PROPOSED WITH THE EXCEPTION OF THE SEPARATE PODIATRIC G CODES AND PE/hr ADJUSTMENTS

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	1	1	0	2
Anesthesiology	1,981	0	0	0	0
Audiologist	68	0	2	0	1
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	0	−1	0	−1
Chiropractor	754	0	1	0	0
Clinical Psychologist	776	0	2	0	1
Clinical Social Worker	728	0	2	0	2
Colon And Rectal Surgery	166	0	0	0	0
Critical Care	342	−1	−1	0	−2
Dermatology	3,486	1	1	0	2
Diagnostic Testing Facility	733	0	−4	0	−4
Emergency Medicine	3,121	0	0	0	−1
Endocrinology	482	0	−1	0	−1
Family Practice	6,208	0	0	0	0
Gastroenterology	1,757	−1	0	0	−1
General Practice	429	0	0	0	0
General Surgery	2,093	0	0	0	0
Geriatrics	197	−2	−1	0	−3
Hand Surgery	214	1	1	0	2
Hematology/Oncology	1,741	−1	−1	0	−2
Independent Laboratory	646	0	4	0	4
Infectious Disease	649	−1	−1	0	−2
Internal Medicine	10,767	−1	0	0	−1
Interventional Pain Mgmt	868	2	2	0	4
Interventional Radiology	386	1	−1	0	0
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	−1	0	−2
Neurology	1,529	−1	−1	0	−2
Neurosurgery	804	0	0	0	0
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	0	0	0	0
Nurse Practitioner	4,065	0	1	0	1
Obstetrics/Gynecology	638	3	2	0	5
Ophthalmology	5,448	0	−1	0	−1
Optometry	1,309	1	0	0	1
Oral/Maxillofacial Surgery	68	1	1	0	2
Orthopedic Surgery	3,743	1	1	0	1
Other	31	−1	4	0	3
Otolarngology	1,210	2	2	0	4
Pathology	1,165	0	−1	0	−1
Pediatrics	61	−1	0	0	−1
Physical Medicine	1,107	−1	0	0	−1
Physical/Occupational Therapy	3,950	0	−1	0	−1
Physician Assistant	2,457	0	1	0	1
Plastic Surgery	377	1	1	0	2
Podiatry	1,974	5	5	0	10
Portable X-Ray Supplier	99	0	0	0	1
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,715	−2	−1	0	−4
Radiation Oncology And Radiation Therapy Centers	1,766	0	0	0	−1
Radiology	4,911	0	−1	0	0
Rheumatology	541	−1	−1	0	−2
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	5
Vascular Surgery	1,148	0	−1	0	−1
Total	92,771	0	0	0	0

We considered alternatives that included finalizing all elements of the proposal, except for the PE/hr change and separate coding for podiatric E/M visits and establishing a single payment rate for office/outpatient new and established E/M visit levels 2 through 4, rather than a single payment rate for office/outpatient E/M levels 2 through 5 as proposed. Table 103 illustrates the specialty level impacts of this alternative.

TABLE 103—SPECIALTY LEVEL IMPACT OF FINALIZING SINGLE PFS RATES FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4 AND OTHER PROPOSED ELEMENTS WITH THE EXCEPTION OF PE/hr ADJUSTMENT AND THE G-CODES FOR PODIATRIC VISITS

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	1	1	0	1
Anesthesiology	1,981	−1	0	0	−1
Audiologist	68	−1	1	0	1
Cardiac Surgery	294	−1	−1	0	−1
Cardiology	6,618	0	−1	0	−1
Chiropractor	754	−1	0	0	−1
Clinical Psychologist	776	−1	1	0	1
Clinical Social Worker	728	−1	2	0	1
Colon And Rectal Surgery	166	−1	0	0	−1
Critical Care	342	−1	−1	0	−2
Dermatology	3,486	0	0	0	0
Diagnostic Testing Facility	733	0	−4	0	−4
Emergency Medicine	3,121	−1	0	0	−1
Endocrinology	482	0	−1	0	−1
Family Practice	6,208	1	1	0	2
Gastroenterology	1,757	−1	0	0	−2
General Practice	429	−1	0	0	−1
General Surgery	2,093	0	0	0	0
Geriatrics	197	0	0	0	−1
Hand Surgery	214	0	0	0	0
Hematology/Oncology	1,741	1	0	0	1
Independent Laboratory	646	0	4	0	4
Infectious Disease	649	−1	−1	0	−2
Internal Medicine	10,767	0	0	0	1
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−1	0	−1
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−2	−1	0	−2
Neurology	1,529	0	0	0	0
Neurosurgery	804	−1	0	0	−1
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	−1	0	0	−1
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	4
Ophthalmology	5,448	−1	−1	0	−2
Optometry	1,309	0	−1	0	0
Oral/Maxillofacial Surgery	68	0	1	0	1
Orthopedic Surgery	3,743	0	0	0	0
Other	31	−1	4	0	3
Otolarngology	1,210	1	1	0	2
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−1	0	−2
Physician Assistant	2,457	1	1	0	2
Plastic Surgery	377	0	0	0	1
Podiatry	1,974	3	4	0	8
Portable X-Ray Supplier	99	0	1	0	1
Psychiatry	1,187	0	1	0	1
Pulmonary Disease	1,715	−2	−1	0	−3
Radiation Oncology And Radiation Therapy Centers	1,766	0	0	0	−1
Radiology	4,911	0	−1	0	−1
Rheumatology	541	−1	−1	0	−2
Thoracic Surgery	358	−1	0	0	−1
Urology	1,738	1	2	0	4
Vascular Surgery	1,148	0	−1	0	−1
Total	92,771	0	0	0	0

In this scenario, specialties that furnish a large volume of standalone office/outpatient E/M visits in conjunction with minor procedures see decreases in overall impacts, while specialties who tend to only bill E/M office/outpatient visits see minor increases and in many instances, the application of the MPPR adjustment is

not enough to overcome the negative impacts of the single payment rate on specialties that bill a higher volume of level 4 visits relative to their overall allowed services.

We also modeled the specialty level impacts associated with finalizing all elements of the proposal with the exception of the PE/hr adjustment and the MPPR, but establishing a single payment rate for office/outpatient new and established E/M visit levels 2–4, rather than a single payment rate for office/outpatient E/M levels 2–5 as proposed. Table 104 illustrates the specialty level impacts for this alternative.

TABLE 104—SPECIALTY LEVEL IMPACT OF FINALIZING SINGLE PFS RATES FOR OFFICE/OUTPATIENT E/M LEVELS 2 THROUGH 4 AND OTHER ELEMENTS AS PROPOSED

Specialty	Allowed charges (mil)	Impact of work RVU changes (%)	Impact of PE RVU changes (%)	Impact of MP RVU changes (%)	Combined impact (%)
(A)	(B)	(C)	(D)	(E)	(F)
Allergy/Immunology	$239	0	0	0	1
Anesthesiology	1,981	−1	0	0	−2
Audiologist	68	−1	1	0	0
Cardiac Surgery	294	−1	−1	0	−2
Cardiology	6,618	−1	−1	0	−2
Chiropractor	754	−1	−1	0	−2
Clinical Psychologist	776	−1	1	0	0
Clinical Social Worker	728	−1	2	0	1
Colon And Rectal Surgery	166	0	1	0	1
Critical Care	342	−2	−1	0	−3
Dermatology	3,486	2	3	0	5
Diagnostic Testing Facility	733	0	−5	0	−5
Emergency Medicine	3,121	−1	0	0	−2
Endocrinology	482	−1	−1	0	−1
Family Practice	6,208	1	1	0	3
Gastroenterology	1,757	−2	0	0	−2
General Practice	429	2	1	0	4
General Surgery	2,093	0	0	0	0
Geriatrics	197	−1	0	0	−1
Hand Surgery	214	1	2	0	3
Hematology/Oncology	1,741	0	0	0	0
Independent Laboratory	646	−1	3	0	3
Infectious Disease	649	−1	0	0	−1
Internal Medicine	10,767	0	0	0	0
Interventional Pain Mgmt	868	1	2	0	3
Interventional Radiology	386	0	−1	0	−1
Multispecialty Clinic/Other Phys	149	−1	−1	0	−2
Nephrology	2,190	−1	0	0	−1
Neurology	1,529	0	0	0	−1
Neurosurgery	804	−1	0	0	−1
Nuclear Medicine	50	−1	−1	0	−2
Nurse Anes/Anes Asst	1,242	−1	0	0	−2
Nurse Practitioner	4,065	2	1	0	3
Obstetrics/Gynecology	638	2	2	0	5
Ophthalmology	5,448	−1	−1	0	−2
Optometry	1,309	0	−1	0	−1
Oral/Maxillofacial Surgery	68	1	1	0	1
Orthopedic Surgery	3,743	0	1	0	1
Other	31	−1	3	0	2
Otolarngology	1,210	3	3	0	6
Pathology	1,165	−1	−1	0	−2
Pediatrics	61	1	0	0	1
Physical Medicine	1,107	−1	0	0	−2
Physical/Occupational Therapy	3,950	−1	−2	0	−3
Physician Assistant	2,457	2	2	0	4
Plastic Surgery	377	0	1	0	1
Podiatry	1,974	−1	−4	0	−5
Portable X-Ray Supplier	99	0	0	0	0
Psychiatry	1,187	3	2	0	5
Pulmonary Disease	1,715	−1	−1	0	−1
Radiation Oncology And Radiation Therapy Centers	1,766	0	−1	0	−1
Radiology	4,911	−1	−1	0	−2
Rheumatology	541	0	0	0	0
Thoracic Surgery	358	−1	−1	0	−2
Urology	1,738	2	3	0	5
Vascular Surgery	1,148	0	−2	0	−2
Total	92,771	0	0	0	0

2. E/M Documentation Alternatives Considered

We considered several alternatives to our final policies on documentation of E/M office/outpatient visits. Under all of these alternatives, we would finalize the documentation proposals that are not associated with coding and payment changes (the documentation proposals for home visits and avoiding redundant data recording that we are finalizing for January 1, 2019 as proposed).

Regarding the rest of the documentation policies, one alternative we considered was to maintain all five current E/M office/outpatient visit levels and eliminate additional documentation requirements. Under this option, there would be no minimum documentation standard because payment rates for multiple code levels would not be combined, but we could still have allowed choice in documentation methodology (current framework, MDM or time). Overall payments would likely change due to increased ability to use different key components to reach different code levels relative to the status quo. There would be no new add-on codes for primary care, other non-procedural specialty care or prolonged services, since the current code set would continue to differentiate levels of complexity. We estimate that this alternative would have reduced the documentation burden for office/outpatient visits by approximately 5 percent or 0.32 minutes per impacted visit. However, this alternative could result in significant and unpredictable redistributive effects as there would be a financial incentive to code to the highest possible visit level. Given that possibility, we chose not to finalize this alternative.

Another alternative was our proposed policies, which in the proposed rule we estimated would have reduced administrative burden by approximately 1.6 minutes per impacted visit. A large part of this time savings was attributed to the associated application of the minimum level 2 visit documentation standard to most visits (levels 2 through 5). We did not finalize this proposal because we were persuaded by public comments (detailed elsewhere in this final rule), indicating that Medicare should continue to recognize distinctions in visit complexity among the current level 2 through 5 visits.

3. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services Alternatives Considered

We considered not finalizing our proposal in the CY 2019 PFS proposed rule to recognize a discrete set of services that are defined by and inherently involve the use of communication technology. If we had not finalized making separate coding and payment for HCPCS codes G2010 ((Remote evaluation of recorded video and/or images submitted by an established patient (*e.g.,* store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment) and G2012 ((Brief communication technology-based service, *e.g.* virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion) for CY 2019, we estimate that there would have been a 0.2 percent increase to the CF, based on our estimate that usage of these services will result in fewer than 1 million visits in the first year but will eventually result in more than 19 million visits per year, ultimately increasing payments under the PFS by about 0.2 percent.

4. Alternatives Considered for the AUC Program

For the purposes of estimating potential alternatives to the proposals in the CY 2019 PFS proposed rule for the AUC program, we considered the alternative scenarios below.

a. Consultation With More Than One Qualified CDSM

We considered an alternative scenario that would result in ordering professionals or auxiliary staff consulting more than one qualified CDSM prior to ordering advanced diagnostic imaging. In this scenario, we assumed a goal of decreasing the frequency that a ''not applicable'' consultation result would be reported on Medicare claims. One outcome of reducing ''not applicable'' responses is the potential to improve the quality and quantity of claims-based data available for calculating outlier ordering professionals. In future rulemaking the agency will establish the methodology to identifying outlier ordering professionals. Reducing ''not applicable'' responses will increase responses for adherence or non-adherence thereby increasing the total number of responses that can be used to calculate outlier ordering professionals. Additionally, according to the Medicare Imaging Demonstration Evaluation Report,[1] clinicians were conceptually interested in learning about how to improve ordering patterns. Ordering professionals receiving ''not applicable'' responses for some of their orders may not be able to achieve desired learning directly through the CDSM and may have to seek information elsewhere. Therefore reducing the number of ''not applicable'' responses may allow ordering professionals to achieve more of their learning within the CDSM.

In this assumption, the ordering professional or auxiliary personnel would consult their primary, qualified CDSM to find that such AUC were not available. For example, a consultation using CDSM 1 for a patient with unspecified abdominal pain results in no specified applicable AUC being available, and therefore, provides a ''not applicable'' result. In this clinical scenario, we know that specified applicable AUC are available (*https://acsearch.acr.org/docs/69467/Narrative/*) in qualified CDSM 2 and that CDSM 2 is available free of charge. Second, we assumed that additional requirements to reduce ''not applicable'' consultation outcomes, through tighter stipulations on AUC consultation, would change behavior in that a second consultation would occur (qualified CDSM 2). For example, we know that all CDSMs are required, consistent with § 414.94(g)(1)(iii) of our regulations to make available, at a minimum, specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas. Therefore, there may be clinical scenarios (for example, unspecified abdominal pain) outside of priority clinical areas that are not addressed within all qualified CDSMs. However, tighter requirements on AUC consultation—to consult a second CDSM when a ''not applicable'' response is the result of the first consultation in specific clinical scenarios—would reduce ''not applicable'' reporting on Medicare claims and would motivate ordering professionals to access a secondary CDSM that is qualified and available free of charge. CMS did not propose to require any ordering professional to

perform any additional AUC consultation if the initial consultation yields a result of ''not applicable.'' Rather, the ordering professional would have completely satisfied their AUC consultation requirement under § 414.94(j) with the first AUC consultation, regardless of the determination of the qualified CDSM.

Based on these assumptions, we identified examples of the advanced diagnostic imaging services that are outside the priority clinical areas yet have AUC available for a specific clinical scenario in a qualified, free CDSM. We focused our analysis on abdominal pain (any locations and flank pain). In addition, we identified the top five advanced diagnostic imaging services from data derived from the CCW's 2014 Part B non-institutional claim line file, which includes services covered by the Part B benefit that were furnished during calendar year 2014. These data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/data.html*.

We estimated the burden of consulting a second, free CDSM to reduce the frequency of ''not applicable'' responses, which we did not propose. We did this by calculating the number of advanced diagnostic imaging services for unspecified abdominal pain based on 2014 claims data (Computed tomography of abdomen & pelvis with contrast—CPT 74177—299,644 services; Computed tomography of abdomen & pelvis with and without contrast—CPT 74176—233,088 services; Computed tomography of abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions—CPT 74178—36,992 services; Diagnostic nuclear medicine procedures on the gastrointestinal system with pharmacologic intervention—CPT 78227—20,997 services; Diagnostic nuclear medicine procedures on the gastrointestinal system—CPT 78226–10,713 services). According to the Medicare Imaging Demonstration Evaluation Report,[1] clinicians were conceptually interested in learning about how to improve ordering patterns, and in the context of clinical practice, most clinician focus group participants noted that they expected that a clinical decision support tool would provide more detailed feedback that would help clinicians reduce the number of inappropriately rated orders. Unfortunately, data compiled [73] as of 2002 suggested that appropriateness criteria could not be applied to 41-percent of MRI imaging requests. These gaps in appropriateness criteria often prompt local providers to augment the criteria produced by professional societies with their own decisions on appropriateness. One study [74] has shown that clinicians use appropriateness criteria far less often than other resources, such as specialist consults and UpToDate (Wolters Kluwer Health), to guide the management of their patients. In order to meet the expressed needs of ordering professionals, and direct ordering behaviors towards qualified CDSMs with specific applicable AUC, we considered pursuing tighter requirements in the context of the following impact estimate.

If we assume that 50 percent of these 601,434 total services required a second consultation because the specified applicable AUC were available in CDSM 1 then this estimate would be the time and effort for a 2-minute repeat consultation with another qualified CDSM available free of charge for 300,717 services annually (601,434 services × 50 percent). If 90 percent of those consultations (300,717 services × 90 percent × 0.033 hr/service) for 8,931.285 total hours were performed by a medical assistant (occupation code 31–9092) at a rate of $32.30/hour for a total of $288,480.50 and 10 percent of consultations (300,717 services × 10 percent × 0.033 hr/service) for 992.376 total hours were performed by the ordering professional at a rate of $200.54/hour for a total of $199,011.08 then annually the burden estimate would be 9,923.661 total hours (8,931.285 hours + 992.376 hours) and $487,491.58 ($288,480.50 + $199,011.08) to perform the second consultations. This analysis was limited to abdominal pain because that is one example of a clinical scenario that falls outside of the priority clinical areas. In the proposed rule we did not propose tighter requirements on the frequency to which ordering professionals or applicable staff would be required to consult at this time this was due to the agency's efforts to minimize burden whereas a second consultation would result in added time and cost to the ordering professional.

b. Significant Hardship Application Process

To illustrate the consideration that a self-attestation of a significant hardship exception is a less burdensome approach, we compared this to the alternative consideration of requiring a significant hardship exception application process to review and approve applicants in near real-time. We recognize that there are some benefits to a significant hardship exception application that could not be directly quantified. For instance, some ordering professionals may gain confidence knowing that they have documentation confirming that a significant hardship exception application was submitted and/or received by CMS. Those same ordering professionals and others may appreciate a process that includes receipt of a determination from CMS as to the acceptance of their application for significant hardship exception. Finally some furnishing professionals and facilities that provide advanced diagnostic imaging services as a result of orders placed by ordering professionals could have reassurance knowing that such ordering professionals have a significant hardship exception granted by CMS and confirmed for 1 year.

As a basis for comparison of the significant hardship exception application to self-attestation, we estimate that such an application would be similar to the existing application (CMS–10621, OCN 0938–1314) to request a reweighting to zero for the advancing care information performance category (renamed the promoting interoperability performance category) due to significant hardship. This is a short online form that requires identifying which type of hardship applies, and a description of how the circumstances impair the ability to submit advancing care information data, as well as some proof of circumstances. The estimate for the $44.59 mean hourly wage and 100-percent fringe benefits of a computer system analyst (BLS #15–1121) to submit this application is 0.5 hours. Given that we would expect 6,699 AUC hardship applications per year, the annual total burden hours are estimated to be 3349.50 hours (6,699 respondents × 0.5 burden hours per respondent). The estimated total annual burden is $298,708.41 (3349.50 hours × $89.18 per hour). Based in part on the cost and burden estimates, we did not propose the use of a significant hardship exception application.

[73] Levy, G et al. 2006. Nonradiologist utilization of American College of Radiology appropriateness criteria in apreauthorization center for MRI requests: Applicability and effects. AJR Am J Roentgenol, 187(4), 855–858. doi: 10.2214/AJR.05.1055.

[74] Bautista, AB et al. 2009. Do clinicians use the American College of Radiology appropriateness criteria in the management of their patients? AJR Am J Roentgenol, 192(6), 1581–1585. doi: 10.2214/AJR.08.1622.

5. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold and the additional performance threshold, as the critical factors affecting the distribution of payment adjustments. We ran two separate models with performance thresholds of 25 and 35 respectively (as an alternative to the finalized performance threshold of 30) to estimate the impact of a moderate and aggressive increase in the performance threshold. A lower performance threshold would be a more gradual transition and could potentially allow more clinicians to meet or exceed the performance threshold. The lower performance threshold would lower the amount of budget neutral dollars to redistribute and increase the number of clinicians with a positive payment adjustment but the scaling factor would be lower. In contrast, a more aggressive increase would likely lead to higher positive payment adjustments for clinicians that exceed the performance threshold because the budget neutral pool would be redistributed among fewer clinicians. We ran each of these models using the finalized additional performance threshold of 75. In the model with a performance threshold of 25, we estimate that $271 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 4.5 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 7.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with a performance threshold of 35, we estimate that $349 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 4.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 10.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. We finalized a performance threshold of 30 because we believe increasing the performance threshold to 30 points was not unreasonable or too steep, but rather a moderate step that encourages clinicians to gain experience with all MIPS performance categories. We refer readers to section III.I.3.j.(2) of this final rule for additional rationale on the selection of performance threshold.

To evaluate the impact of modifying the additional performance threshold, we ran two models with additional performance thresholds of 70 and 80 as an alternative to the finalized 75 points. We ran each of these models using a performance threshold of 30. The benefit of the model with the additional performance threshold of 70 would maintain the additional performance threshold that was in years 2 and 3. In the model with the additional performance threshold of 70, we estimate that $310 million would be redistributed through budget neutrality, and there would be a maximum payment adjustment of 3.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 8.8 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. In the model with an additional performance threshold of 80, for which the benefit was to assess the impact of the proposed additional performance threshold in the 2019 PFS proposed rule, we estimate that $310 million would be redistributed through budget neutrality, and that there would be a maximum payment adjustment of 6.1 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance among those that submit data. Also, that 8.8 percent of MIPS eligible clinicians will receive a negative payment adjustment. We finalized the additional performance threshold at 75 points, which is halfway between our proposal of 80 and the CY 2018 MIPS performance period additional performance threshold at 70 because we believe raising the additional performance threshold, but for less than the original amount proposed, would incentivize continued improved performance while accounting for policy changes in the third year of the program. We refer readers to section III.I.3.j.(3) of this final rule for additional rationale on the selection of additional performance threshold.

To examine the impact of changes to the low-volume threshold on the number of MIPS eligible clinicians, we ran estimates for three different low-volume threshold criteria. As we discuss in section III.I.3.c of this final rule, we analyzed the impact of alternate low-volume thresholds because the low-volume threshold can affect the number of MIPS eligible clinicians and some public commenters were concerned about the associated impacts of the exclusions on the MIPS payment adjustments. When we set the third low volume threshold at 100 as an alternative to 200 covered professional services, we estimate that 32,828 clinicians would elect to opt-in for a total population of 802,915. When we apply the opt-in policy without adding the third finalized low-volume criterion at 200 covered professional services, we estimate that 12,242 clinicians would elect to opt-in for a total population of 782,329. When we lower the low-volume threshold criteria to $30,000 or fewer allowed charges for covered professional services; 100 or fewer Part B-enrolled individuals; and 100 or fewer furnished covered professional services to Medicare Part B-enrolled beneficiaries, we estimate a total of 871,238 MIPS eligible clinicians. To assess the impact of the number of MIPS eligible clinicians on payment adjustments, we ran a model with the lowest low-volume threshold and, therefore, highest number of MIPS eligible clinicians (871,238). We estimate that $440 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 5.0 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 9.7 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data. These alternative low-volume thresholds were not selected because we did not observe a meaningful difference on the maximum payment adjustment from the finalized low-volume threshold in this final rule. As we stated in section III.I.3.c.(4) of this final rule, we will continue to strike a balance between ensuring sufficient participation in MIPS while also addressing the needs of small practices that may find it difficult to meet the program requirements. We refer readers to section III.I.3.c.(4) of this final rule for additional rationale on the selection of the low-volume threshold.

H. Impact on Beneficiaries

There are a number of changes in this final rule that will have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, will have a positive impact and improve the quality and value of care provided to Medicare providers and beneficiaries.

I. Burden Reduction Estimates

1. Evaluation and Management Documentation

All health care practitioners, as part of their routine record keeping activities, create and maintain documentation in the patient medical record for clinical and payment purposes. It is standard industry practice that when healthcare practitioners bill insurers, payers and health plans, such as Medicare, state plans under Title XIX, and commercial or other third party payers, for office and outpatient E/M services, that health care practitioners report the services using the common coding framework and definitions developed and maintained by the AMA CPT Editorial Panel. The 1995/1997 E/M services documentation guidelines provide guidance to medical practitioners regarding medical record documentation of E/M services based on the AMA CPT coding framework and definitions. In response to comments received from RFIs released to the public under our Patients Over Paperwork Initiative, we proposed to address medical documentation by simplifying the payment framework for E/M services and allowing greater flexibility on the components practitioners could choose to document when billing Medicare for E/M visits.

We estimate that the E/M visit documentation changes finalized in section II.I. of this final rule may significantly reduce the amount of time practitioners spend documenting office/outpatient E/M visits. Although little research is available on exactly how much time physicians and non-physician practitioners (NPPs) spend specifically documenting E/M visits, according to one recent estimate, primary care physicians spend on average, 84 minutes or 1.4 hours per day (24 percent of the time that they spend working within an EHR) documenting progress notes.[75] Another study found that primary care physicians spend an average of 2.1 hours per day writing progress notes (both in-clinic and remote access).[76] Assuming an average of 20 patient visits per day, one E/M visit per patient, and using the higher figure of 2.1 hours per day spent documenting these visits, in our proposed rule we estimated that documentation of an average outpatient/office E/M visit takes 6.3 minutes.[77]

We stated our belief that our proposals to reduce redundancy in visit documentation, to allow auxiliary staff and the beneficiary to enter certain information in the medical record that would be verified but not required to be re-documented by the billing practitioner, to allow the choice of visit level and documentation based on MDM or time as alternatives to the current framework, and to require only minimum documentation (the amount required for a level 2 visit) for all visits except level 1 visits may reduce the documentation time by one quarter of the current time for the average office/outpatient visit. Under this assumption, we estimated these proposals would save clinicians approximately 1.6 minutes of time per office/outpatient E/M visit billed to Medicare. For a full-time practitioner whose panel of patients is 40 percent Medicare (60 percent other payers), this would translate to approximately 51 hours saved per year.[78]

We noted that stakeholders had emphasized to us in public comments that whatever reductions may be made to the E/M documentation guidelines for purposes of Medicare payment, physicians and non-physician practitioners will still need to document substantial information in their progress notes for clinical, legal, operational, quality reporting and other purposes, as well as potentially for other payers. Furthermore, we recognized that there may be a ramp-up period for physicians and non-physician practitioners to implement the proposed documentation changes in their clinical workflow and EHR such that the effects of mitigating documentation burden may not be immediately realized. Accordingly, we believed the total amount of time practitioners spend on E/M visit documentation may remain high, despite the time savings that we estimated in our proposed rule could result from our E/M documentation proposals. These and all other improvements to payment accuracy that we proposed for CY 2019 were described in greater detail in section II.I. of the proposed rule. We welcomed public comments on our assumptions for the estimated reduction in documentation burden related to our E/M visit proposals.

Comment: We received many public comments on our assumptions regarding the potential burden reduction associated with our E/M proposals. The commenters stated that CMS overestimated how much the proposals would reduce burden, and noted they would reduce burden less than CMS estimated or, according to some commenters, might increase burden overall. Some commenters stated that the time and labor saved on documentation would be time currently spent after hours and on weekends, so it would not translate into additional ''work time'' or availability to see more patients. They stated that documentation time, in general, would remain high, due to the need to continue documenting for clinical, legal and many other purposes such as risk adjustment, quality reporting and other payers. Many of the commenters stated concerns that other payers including Medicaid and secondary payers might not adopt the same policies as Medicare, and that incongruities in documentation rules between payers would necessitate extra effort by practices to assess the best or required documentation method, among so many choices, for different patients. They noted that which payer(s) a given patient has is not always known at the outset of the visit.

Many commenters stated there would be significant burden and cost to update EHRs and educate and train coders, staff and auditors. Also, they noted that without appropriate medical documentation for each visit, the proposals might result in insufficient documentation by one member of the care team that another member might have to make up for, and that fractured care from incomplete or insufficient documentation might inadvertently create additional burdens, as well as impact quality of care. While many commenters supported allowing a choice in documentation methodology (current framework, medical decision-making, or time), other commenters noted such a policy would increase burden due to increased variation in how visits would be documented, and the need to restructure EHR templates to accommodate different options and decide which method was best for a given patient or practice. Most of the commenters noted our proposals regarding billing eligibility and supporting documentation for the proposed add-on codes for primary care, other specialty care, prolonged services, and documenting using time were unclear and might create new burdens that would equal or exceed the current

[75] Arndt BG, Beasley JW, Watkinson MD, et al. Tethered to the EHR: Primary care physician workload assessment using EHR event log data and time-motion observations. Ann Fam Med. 2017;15:427–33.

[76] Tai-Seale M, Olson CW, Li J, et al. Electronic health record logs indicate that physicians split time evenly between seeing patients and desktop medicine. Health Aff (Milwood). 2017;36:655–62.

[77] 20 patient visits per day based on the average number reported in the Physicians Foundation 2016 Survey of America's Physicians, available online at *https://physiciansfoundation.org/wp-content/uploads/2018/01/Biennial_Physician_Survey_2016.pdf.*

[78] Forty percent of 20 total patients per day = 8 Medicare vists per day. (8 visits per day)*(1.6 minutes per visit)*(240 days per year) = 51.2 hours.

burden. Some commenters stated that our proposals layered on complexity that would counteract the goal of reducing administrative burden, and that the negative impacts of the payment proposals would outweigh positive impacts of documentation changes.

Other commenters were concerned about impacts on MA plan payments, plan quality, and provider access. Some commenters were concerned that paying for visits based on a single rate would not allow an understanding of the complexity of care being delivered and might lead to abuse. Another commenter noted that the proposed add-on codes to account for care complexity would increase complexity and result in a need for perpetual fixes from unanticipated consequences. Similar to other commenters, this commenter was concerned that a single payment rate would redistribute payments without reducing the burden associated with determining the right codes, because the coding structure would remain the same. The commenter also expressed concern that practitioners would be less willing to see complex patients, and that the proposal would incentivize gaming by certain specialties to make up for lost revenue. The commenter's preferred approach was to simplify the current guidelines and rather than implement a single payment rate, CMS should wait for the AMA/CPT's E/M workgroup results. Finally, the commenter recommended that if CMS finalized as proposed, CMS should phase implementation and create a monitoring process.

Response: We understand that practitioners would continue to need to document substantial information in the medical record for clinical, legal and many other purposes such as risk adjustment, quality reporting, productivity measures and potentially other payers. In making our proposal, we did not aim to eliminate the need to document any history, exam, and/or MDM, but rather, we ocused on eliminating unnecessary, and outdated requirements that are associated with payment for visit ''levels.'' This would allow the practitioner to document what is clinically relevant and needed to support the service within whatever framework they chose to apply—along with medical necessity—rather than outdated aspects of the current guidelines. We understand that other payers might not adopt the same approach, at least not in the short term. The AMA/CPT has stated an intention to revise the E/M code set by 2020 or 2021, which would help to establish uniformity among payers. However, we agree with the commenters that it would be critical to allow time for education, changing workflows and billing systems. We understand that particularly in the initial year(s) of any changes, there would be a cost to these activities for practitioners and providers, including a cost to update EHRs. We are reducing our estimate of burden reduction to account for these issues.

We note that we believe that time physicians spend fulfilling current documentation requirements on evenings and weekends are burdensome, and that even if that additional time would not necessarily be spent seeing additional patients, that time is a quantifiable resource cost to physicians and other practitioners.

After considering the comments, we adjusted our proposed burden reduction estimate, including our estimates on the documentation of an average outpatient/office E/M. We are still assuming an average of 20 patient visits per day, one E/M visit per patient, but instead are using the more conservative figure of 1.4 hours per day spent documenting E/M visits that we identified in our review of available research. As a result, we estimate that documentation of an average outpatient/office E/M visit takes 4.2 minutes versus our initial estimate of 6.3 minutes. The final rule estimated time savings is monetized into practitioner wages and summarized as follows.

TABLE 105—ESTIMATED BURDEN REDUCTION FOR E/M DOCUMENTATION FINAL POLICIES

[Practitioner wages]

	2019	2020	2021	2022	2023 and annually thereafter
Grand Total	$84,059,794.68	$84,059,794.68	$298,522,913.92	$405,754,473.54	$512,986,033.15

We calculated the time savings associated with documentation changes annually, and converted this time to practitioner wages using 2016 hourly wage data from the Bureau of Labor Statistics (BLS) [79] multiplied by two to adjust for overhead and benefits. We adjusted for the estimated proportion of impacted visits furnished by NPPs earning lower wages than physicians, which we acknowledge is unclear due to the ability to report services as ''incident to'' a physician when they are furnished directly by an NPP. We approximated the portion attributable to NPP wages using the number of visits directly reported by NPPs (reported with a specialty of NP, PA, CNS or CNM).

The estimated savings for 2019 and 2020 are for the initial changes to documentation in these years (those not impacted by coding and payment changes, including provisions to no longer require documentation of the medical necessity of a home visit in lieu of an office visit and to expand current policy reducing the need to re-document prior data in the medical record). These savings would impact levels 2 through 5 visits, and are estimated to save 0.11 minutes [80] per impacted visit, which translates into approximately $84 million in wages across all impacted visits.

Additional savings are estimated annually starting in 2021 for the finalized payment and coding-related changes. These savings would impact levels 3 and 4 visits, and are estimated to save 0.63 minutes [81] per impacted visit, which translates into approximately $513 million annually in wages across all impacted visits. We assume half of these estimated savings in year 1 (2021), 75 percent in year 2 (2022) and 100 percent each subsequent year (2023 and each year thereafter) to account for information provided in the public comments that there is

[79] *https://www.bls.gov/oes/2016/may/oes_nat.htm.*

[80] 2.5% of the 4.2 minutes we estimate that it currently takes to document an office/outpatient E/M visit.

[81] We reduced the final rule time savings estimate of 25% (1.1 minutes) to 15 percent (0.63 minutes). We reduced it by 10 percentage points to account for the burden of documenting level 5 visits, as well as the level 2–4 combined visit. This is to account for the uncertainty of the future code structure/definitions, as well as public comments that introducing variation in documentation choices and methods and providing for a bare bones minimum standard could increase burden).

potentially off-setting burden associated with the continued need to document for MA and potentially other payers, quality reporting, and clinical, legal and other purposes, as well as ramp-up costs to update EHRs and conduct training and education. The estimate assumes very minimal burden associated with use and documentation of the add-on codes for primary care and other specialty care, as well as the extended visit add-on code and otherwise documenting using time, as we are clarifying these policies and establishing minimal documentation rules discussed in section II.I. of this final rule. We intend to allow flexibility in how office/outpatient visits are documented and to allow a choice in using the current framework, medical decision-making or time, though we will take into consideration any changes in the code set that may impact these options in future years.

2. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services

As noted in section II.D. of this final rule, for CY 2019, we aimed to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology. Accordingly, we made several proposals for modernizing Medicare physician payment for communication technology-based services.

The use of communication technology-based services will provide new options for physicians to treat patients. These services could help to avoid unnecessary office visits, could consist of services that are already occurring but are not being separately paid, or could constitute new services. Medicare would pay $14 per visit in the first year for these communication technology-based services, compared with $92 per visit for the corresponding established patient visits.

Practitioners have a choice of when to use the communication technology-based services. Because of the low payment rate relative to that for an office visit, we are assuming that usage of these services will be relatively low. In addition, we expect that the number of new or newly billable visits and subsequent treatments will outweigh the number of times that communication technology-based services will be used instead of more costly services. As a result, we expect that the financial impact of paying for the communication technology-based services will be an increase in Medicare costs. We estimate that usage of these services will result in fewer than 1 million visits in the first year but will eventually result in more than 19 million visits per year, ultimately increasing payments under the PFS by about 0.2 percent. In order to maintain budget neutrality in setting proposed rates for CY 2019, we assumed the number of services that would result in a 0.2 percent reduction in the CF.

As with all estimates, and particularly those for new separately billable services, this outcome is highly uncertain. Because recognition of communication technology-based services is a new area for healthcare coverage, the available information on which to base estimates is limited and is usually not directly applicable, particularly to a new Medicare payment. The cost and utilization estimates are based on Medicare claims data together with a study published in *Health Affairs,*[82] which examined the cost and utilization of telehealth in the private sector. While this study was the most applicable for an estimate, we note that the results from this program may be different because Medicare experience may differ from private sector behavior and because the study was limited to acute respiratory infection visits. We also note that the study cites the use of direct-to-consumer telehealth companies, many of which provide access to care 24 hours per day, 7 days per week, 365 days per year, whereas the services described by HCPCS codes G2010 and G2012 are limited to only established patients.

We proposed to make separate payment for these services when furnished by RHCs and FQHCs. A potential estimate of utilization and overall cost of these services by RHCs and FQHCs could be derived by comparing their use of chronic care management and other care management services to the same services furnished by practitioners paid under the PFS, since these care management services are also separately billable and do not take place in-person. Based on this comparison, and without considering potential variables and issues specific to these services, the impact the finalized policy would be less than $1 million in additional Medicare spending in the first year and could eventually result in up to $20 million in spending per year in future years. These estimates are uncertain and could change after further consideration of the potential variables and issues specific to these services.

3. Outpatient Therapy Services

As noted in section II.M. of this final rule, we are finalizing our proposal to end functional reporting for outpatient therapy services as part of our burden reduction efforts in response to the RFI on CMS Flexibilities and Efficiencies that was issued in the CY 2018 PFS proposed rule (82 FR 34172 through 34173). Under our functional reporting system therapy practitioners and providers are required to report, whenever functional reporting is required, non-payable HCPCS G-codes and modifiers—typically in pairs—to convey information about the beneficiary's functional limitation category and functional status throughout the PT, OT, or SLP episode of care. In addition, each time functional reporting is required on the claim, the therapy provider must also document the functional reporting G-codes and their modifiers in the medical record. In this final rule, we are finalizing our proposal to eliminate this requirement that therapy practitioners and providers report HCPCS G-codes and modifiers or document in the medical record to convey functional reporting status for PT, OT or SLP episode of care.

To quantify the amount of burden reduction, we estimated the total amount of time that therapy practitioners spend doing functional reporting. To do this, we first looked at our data for CY 2017 for professional claims by the type of plan of care reported primarily by therapists in private practice (TPPs), including physical therapists, occupational therapists, and speech-language pathologists. We found that the overall utilization of the 42 functional reporting HCPCS G-codes totaled 15,456,421 single units, or 7,728,211 pairs.

We then considered the time, on average, it might take to report on the claim and document in the medical record each pair of HCPCS G-codes. We noted this includes the time it takes to make the initial determination of the HCPCS G-code functional limitation category, as well as the time needed to make each initial and/or subsequent assignments for the applicable severity modifiers in order to define the patient's functional status. We then made the assumption that it would take between 1 minute and 1.5 minutes, on average, to report the HCPCS G-code and modifier pair each time functional reporting is required. Using the total utilization of G-code pairs and the range of 1 minute to 1.5 minutes, we

[82] Ashwood, J.S. (2017 March) Direct-To-Consumer Telehealth May Increase Access To Care But Does Not Decrease Spending. *Health Affairs.*

calculated that TPPs would have saved between 128,804 and 193,206 hours (or 7,728,211 to 11,592,317 minutes) collectively in CY 2017 if the functional reporting requirements had not been in place. We continue to believe this is a reasonable projection for the potential savings to TPPs, physicians and certain nonphysician practitioners in future years with the finalization of our proposal to end functional reporting effective January 1, 2019.

Because therapy services are also furnished by providers of outpatient therapy services such as hospitals, SNFs and rehabilitation agencies that submit institutional claims, typically representing a greater amount of expenditures than practitioners submitting professional claims, we calculated additional savings for these providers using the same time assumptions of 1 to 1.5 minutes to report the HCPCS G-code and modifier pair each time functional reporting is required. Our 2017 data showed a total utilization of the functional reporting HCPCS G-codes is 29,053,921 single units, or 14,526,961 pairs, indicating that therapy providers would collectively save between 242,116 to 363,174 hours (or 14,526,961 to 21,790,442 minutes) for CY 2017 if the functional reporting requirements had not been effective during that year.

As discussed in section II.M. of this final rule, we received many comments on our burden reduction proposal to eliminate our functional reporting requirements, and nearly all comments were supportive. We believe it is reasonable to estimate that in CY 2019 TPPs and other practitioners submitting professional claims and therapists working for providers submitting institutional claims will collectively save, at a minimum, the same number of collective hours we calculated they would save for CY 2017, as specified previously in this RIA, with dates of service on and after January 1, 2019.

4. Physician Supervision of Diagnostic Imaging Procedures

We believe that the changes to the physician supervision requirements for RAs furnishing diagnostic imaging procedures as described in section II.F. of this final rule will significantly reduce burden for physicians. While approximately 215,000 diagnostic imaging services per year are currently performed that require personal supervision, we are not able to determine the number of these services that are performed by an RA due to limitations in the claims data. As a result, we are not able to quantify the amount of time potentially saved by physicians and practitioners under the policy we are finalizing to require direct supervision of diagnostic imaging procedures done by RAs in cases where personal supervision would ordinarily be required. That said, stakeholders representing the practitioner community have indicated that changing the required supervision level for RAs will result in a redistribution of workload from radiologists to RAs, potentially resulting in improved practice efficiency and patient satisfaction. Stakeholders have stated that practitioners that utilize RAs have experienced improvements in practice efficiency, as use of RAs allows radiologists more time for professional services such as interpretation of images, and these practitioners cite greater flexibility that results in reduced wait times. Furthermore, stakeholders contend that the Medicare supervision requirements currently create disincentives to use RAs, as practitioners cannot make full use of them for Medicare patients, and the change to the supervision requirement would allow RAs to be more fully utilized. For these reasons, we believe the change in supervision requirements we are finalizing for RAs will contribute to burden reduction for physicians and practitioners providing diagnostic imaging procedures for Medicare beneficiaries.

5. Beneficiary Liability

Many proposed policy changes could result in a change in beneficiary liability as it relates to coinsurance (which is 20 percent of the fee schedule amount, if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in our public use file Impact on Payment for Selected Procedures available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/,* the CY 2018 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $109.80, which means that in CY 2018, a beneficiary would be responsible for 20 percent of this amount, or $21.96. Based on this final rule, using the CY 2019 CF, the CY 2019 national payment amount in the nonfacility setting for CPT code 99203, as shown in the Impact on Payment for Selected Procedures public use file, is $109.92, which means that, in CY 2019, the final beneficiary coinsurance for this service would be $21.98.

J. Impact on Beneficiaries in the Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new proposed measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment.[83] Further, the proposed policy changes in the Promoting Interoperability performance category shifts the focus to the interoperable, seamless exchange of electronic information. With the requirement that program participants use 2015 Edition CEHRT, the interoperable exchange of patient health information should be easier because the certification criteria are designed to facilitate information exchange. In combination with the newly proposed Promoting Interoperability measure to receive and incorporate health information, beneficiaries should begin to experience improved care coordination and care transitions because clinicians have improved access to the beneficiaries' health information across the spectrum of care.

Impact on Other Health Care Programs and Providers

We estimate that CY 2019 Quality Payment Program will not have a significant economic effect on eligible clinicians and groups and believe that MIPS policies, along with increasing participation in APMs over time may succeed in improving quality and reducing costs. This may in turn result in beneficial effects on both patients and some clinicians, and we intend to continue focusing on clinician-driven, patient-centered care.

[83] Institute of Medicine. 2013. Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington, DC: The National Academies Press. *https://doi.org/10.17226/18359.*

K. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $859.04 (8.0 hours × $107.38). Therefore, we estimated that the total cost of reviewing this regulation is $5,105,275 ($859.04 × 5,943 reviewers).

L. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 106 and 107 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2018 to CY 2019 based on the FY 2019 President's Budget baseline.

TABLE 106—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2019 Annualized Monetized Transfers	Estimated increase in expenditures of $0.3 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 107—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2019 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.1 billion.
From Whom to Whom?	Beneficiaries to Federal Government.

M. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 is revised to read as follows:

Authority: 42 U.S.C. 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)) and 42 U.S.C. 263a.

■ 2. Section 405.2401 is amended in paragraph (b) by—

■ a. Revising the introductory text of the definition of ''Federally qualified health center''; and

■ b. Revising the definition of ''Secretary''.

The revisions read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

* * * * *

Secretary means the Secretary of Health and Human Services or his or her delegate.

* * * * *

■ 3. Section 405.2462 is amended by revising paragraph (g) introductory text to read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(g) To receive payment, the RHC or FQHC must do all of the following:

* * * * *

■ 4. Section 405.2464 is amended by—

■ a. Revising paragraphs (a)(1), (b) heading, (b)(1), (c), and (d); and

■ b. Adding a new paragraph (e)

The revisions and additions read as follows:

§ 405.2464 Payment rate.

(a) * * *

(1) Except as specified in paragraphs (d) and (e) of this section, an RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

* * * * *

(b) *Payment rate for FQHCs that are authorized to bill under the prospective payment system.* (1) Except as specified in paragraphs (d) and (e) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

* * * * *

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished on or after January 1, 2018, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services.

(d) *Payment for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* Grandfathered tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

(e) *Payment for communication technology-based and remote evaluation services.* For communication technology-based and remote evaluation services furnished on or after January 1, 2019, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 5. The authority citation for part 410 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 6. Section 410.32 is amended by adding paragraph (b)(4) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(4) *Supervision requirement for RRA or RPA.* Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

* * * * *

§ 410.59 [Amended]

■ 7. Section 410.59 is amended by removing paragraph (a)(4).

§ 410.60 [Amended]

■ 8. Section 410.60 is amended by removing paragraph (a)(4).

■ 9. Section 410.61 is amended by revising paragraph (c) to read as follows:

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

* * * * *

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

* * * * *

§ 410.62 [Amended]

■ 10. Section 410.62 is amended by removing paragraph (a)(4).

■ 11. Section 410.78 is amended by—

■ a. Adding paragraphs (b)(3)(ix), (x), (xi), and (xii);

■ b. Revising paragraph (b)(4) introductory text, and

■ c. Adding paragraph (b)(4)(iv).

The additions and revision read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(3) * * *

(ix) A renal dialysis facility (only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act);

(x) The home of an individual (only for purposes of the home dialysis ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act).

(xi) A mobile stroke unit (only for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke provided in accordance with section 1834(m)(6) of the Act).

(xii) The home of an individual (only for purposes of treatment of a substance use disorder or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a substance use disorder diagnosis.

(4) Except as provided in paragraph (b)(4)(iv) of this section, originating sites must be:

* * * * *

(iv) The geographic requirements specified in paragraph (b)(4) of this section do not apply to the following telehealth services:

(A) Home dialysis monthly ESRD-related clinical assessment services furnished on or after January 1, 2019, at an originating site described in paragraphs (b)(3)(vi), (ix) or (x) of this section, in accordance with section 1881(b)(3)(B) of the Act; and

(B) Services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

(C) Services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis, for purposes of treatment of a substance use disorder or a co-occurring mental health disorder.

* * * * *

§ 410.105 [Amended]

■ 12. Section 410.105 is amended—

■ a. In paragraph (c)(1)(ii) by removing the phrase ''that are consistent with the patient function reporting on the claims for services''; and

■ b. By removing paragraph (d).

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 13. The authority citation for part 411 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 14. Section 411.353 is amended by—
■ a. Revising paragraph (g)(1); and
■ b. Removing and reserving paragraph (g)(2).

The revision reads as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) * * *

(1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception.

(2) [Reserved]

■ 15. Section 411.354 is amended by adding paragraph (e) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(e) *Special rule on compensation arrangements*—(1) *Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 16. The authority citation for part 414 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 17. Section 414.65 is amended by—
■ a. Revising paragraph (a) introductory text;
■ b. Removing paragraph (a)(1);
■ c. Redesignating paragraphs (a)(2) and (3), as paragraphs (a)(1) and (2), respectively; and
■ d. Adding paragraph (b)(3).

The revision and addition reads as follows:

§ 414.65 Payment for telehealth services.

(a) *Professional service.* The Medicare payment amount for telehealth services described under § 410.78 of this chapter is equal to the current fee schedule amount applicable for the service of the physician or practitioner, subject to paragraphs (a)(1) and (2) of this section, but must be made in accordance with the following limitations:

* * * * *

(b) * * *

(3) No originating site facility fee payment is made to an originating site described in § 410.78(b)(3)(x), (xi), or (xii); or to an originating site for services furnished under the exception at § 410.78(b)(4)(iv)(A) or (B) of this chapter.

* * * * *

■ 18. Section 414.94 is amended—
■ a. In paragraph (b), by revising the definition of ''Applicable setting''; and
■ b. By revising paragraphs (i)(3), (j), and (k) introductory text.

The revisions read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

* * * * *

(b) * * *

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, an independent diagnostic testing facility, and any other provider-led outpatient setting determined appropriate by the Secretary.

* * * * *

(i) * * *

(3) Significant hardships for ordering professionals who experience any of the following:

(i) Insufficient internet access.

(ii) EHR or CDSM vendor issues.

(iii) Extreme and uncontrollable circumstances.

(j) *Consulting.* (1) Except as specified in paragraphs (i) and (j)(2) of this section, ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system, and ordered on or after January 1, 2020.

(2) Ordering professionals may delegate the consultation with specified applicable AUC required under paragraph (j)(1) of this section to clinical staff acting under the direction of the ordering professional.

(k) *Reporting.* The following information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting, paid for under an applicable payment system defined in paragraph (b) of this section, and ordered on or after January 1, 2020:

* * * * *

■ 19. Section 414.502 is amended in the definition of ''Applicable laboratory'' by adding paragraph (2)(i), adding and reserving paragraph (2)(ii), and revising paragraph (3) introductory text to read as follows:

§ 414.502 Definitions.

* * * * *

Applicable laboratory * * *

(2) * * *

(i) For hospital outreach laboratories—bills Medicare Part B on the CMS 1450 under bill type 14x;

(ii) [Reserved]

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

* * * * *

■ 20. Section 414.610 is amended—
■ a. In paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date ''December 31, 2017'' and adding in its place the date ''December 31, 2022''; and
■ b. By revising paragraph (c)(8).

The revision reads as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(8) *Transport of an individual with end-stage renal disease for renal dialysis services.* For ambulance services furnished during the period October 1, 2013 through September 30, 2018, consisting of non-emergency basic life support (BLS) services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B) of the Act) furnished other than on an emergency basis by a provider of services or a renal dialysis facility, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 10 percent. For such services furnished on or after October 1, 2018, the fee schedule amount otherwise applicable (both base rate and mileage) is reduced by 23 percent.

* * * * *

§ 414.904 [Amended]

■ 21. Section 414.904 is amended in paragraph (e)(4) by removing the phrase

''acquisition cost or the applicable Medicare Part B drug payment'' and adding in its place the phrase ''acquisition cost or the Medicare Part B drug payment''.

■ 22. Section 414.1305 is amended by—

■ a. Revising the definition of ''Ambulatory Surgical Center (ASC)-based MIPS eligible clinician'';

■ b. Adding in alphabetical order definitions for ''Collection type'' and ''Health IT vendor'';

■ c. Revising the definitions of ''High priority measure'', ''Hospital-based MIPS eligible clinician'', and ''Low-volume threshold'';

■ d. Adding in alphabetical order a definition for ''MIPS determination period'';

■ e. Revising the definitions of ''MIPS eligible clinician'', ''Non-patient facing MIPS eligible clinician'', ''Qualified Clinical Data Registry (QCDR)'', ''Qualifying APM Participant (QP)'', and ''Small practice''; and

■ f. Adding in alphabetical order a definition for ''Submission type'', ''Submitter type'', and ''Third party intermediary''.

The revisions and additions read as follows:

§ 414.1305 Definitions.

* * * * *

Ambulatory Surgical Center (ASC)-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an ambulatory surgical center setting based on claims for the MIPS determination period.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs), QCDR measures, Medicare Part B claims measures, CMS Web Interface measures, the CAHPS for MIPS survey, and administrative claims measures.

* * * * *

Health IT vendor means an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's CEHRT).

* * * * *

High priority measure means:

(1) For the 2019 and 2020 MIPS payment years, an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, or care coordination quality measure.

(2) Beginning with the 2021 MIPS payment year, an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

Hospital-based MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the Place of Service (POS) codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus-outpatient hospital, or emergency room setting based on claims for a period prior to the performance period as specified by CMS; and

(2) Beginning with the 2021 MIPS payment year, a MIPS eligible clinician who furnishes 75 percent or more of his or her covered professional services in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims for the MIPS determination period.

* * * * *

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) Beginning with the 2021 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

* * * * *

MIPS determination period means:

(1) Beginning with the 2021 MIPS payment year, a 24-month assessment period consisting of:

(i) An initial 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out; and

(ii) A second 12-month segment beginning on October 1 of the calendar year preceding the applicable performance period and ending on September 30 of the calendar year in which the applicable performance period occurs.

(2) Subject to § 414.1310(b)(1)(iii), an individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold

or as having special status during the first segment of the MIPS determination period will be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician, group, or APM Entity group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of such segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under § 414.1310(b)):

(1) For the 2019 and 2020 MIPS payment years:

(i) A physician (as defined in section 1861(r) of the Act);

(ii) A physician assistant, a nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act);

(iii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); and

(iv) A group that includes such clinicians.

(2) For the 2021 MIPS payment year and future years:

(i) A clinician described in paragraph (1) of this definition;

(ii) A physical therapist or occupational therapist;

(iii) A qualified speech-language pathologist;

(iv) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act);

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act);

(vi) A registered dietician or nutrition professional; and

(vii) A group that includes such clinicians.

* * * * *

Non-patient facing MIPS eligible clinician means:

(1) For the 2019 and 2020 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the non-patient facing determination period described in paragraph (4) of this definition, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(2) Beginning with the 2021 MIPS payment year, an individual MIPS eligible clinician who bills 100 or fewer patient facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act), as described in paragraph (3) of this definition, during the MIPS determination period, and a group or virtual group provided that more than 75 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable, meet the definition of a non-patient facing individual MIPS eligible clinician.

(3) For purposes of this definition, a patient-facing encounter is an instance in which the individual MIPS eligible clinician or group bills for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.

(4) For the 2019 and 2020 MIPS payment year, the non-patient facing determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible MIPS clinician, group, or virtual group that is identified as non-patient facing during the initial 12-month segment will continue to be considered non-patient facing for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the non-patient facing determination period includes a 60-day claims run out. For the 2020 MIPS payment year and future years, each segment of the non-patient facing determination period includes a 30-day claims run out.

* * * * *

Qualified clinical data registry (QCDR) means:

(1) For the 2019, 2020 and 2021 MIPS payment year, a CMS-approved entity that has self-nominated and successfully completed a qualification process to determine whether the entity may collect medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

(2) Beginning with the 2022 MIPS payment year, an entity that demonstrates clinical expertise in medicine and quality measurement development experience and collects medical or clinical data on behalf of a MIPS eligible clinician for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients.

* * * * *

Qualifying APM participant (QP) means an eligible clinician determined by CMS to have met or exceeded the relevant QP payment amount or QP patient count threshold under § 414.1430(a)(1), (a)(3), (b)(1), or (b)(3) for a year based on participation in an APM Entity that is also participating in an Advanced APM.

* * * * *

Small practice means:

(1) For the 2019 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians.

(2) For the 2020 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during a 12-month assessment period that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding the performance period and includes a 30-day claims run out.

(3) Beginning with the 2021 MIPS payment year, a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

* * * * *

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface.

Submitter type means the MIPS eligible clinician, group, virtual group, or third party intermediary acting on behalf of a MIPS eligible clinician, group, or virtual group, as applicable, that submits data on measures and activities under MIPS.

Third party intermediary means an entity that has been approved under § 414.1400 to submit data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the quality, improvement activities, and promoting interoperability performance categories.

* * * * *

■ 23. Section 414.1310 is amended by revising paragraphs (a), (b)(1)(ii), (iii), (d), (e)(1) and (2) to read as follows:

§ 414.1310 Applicability.

(a) *Program implementation.* Except as specified in paragraph (b) of this section, MIPS applies to payments for

covered professional services furnished by MIPS eligible clinicians on or after January 1, 2019.

(b) * * *

(1) * * *

(ii) Is a Partial Qualifying APM Participant and does not elect to participate in MIPS as a MIPS eligible clinician; or

(iii) Does not exceed the low-volume threshold. Beginning with the 2021 MIPS payment year, if an individual eligible clinician, group, or APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician, group, or APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year.

* * * * *

(d) *Clarification.* In no case will a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) apply to payments for items and services furnished during a year by a eligible clinician, including an eligible clinician described in paragraph (b) or (c) of this section, who is not a MIPS eligible clinician, including an eligible clinician who voluntarily reports on applicable measures and activities under MIPS.

(e) * * *

(1) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the group's combined performance assessment.

(2) For individual MIPS eligible clinicians to participate in MIPS as a group, all of the following requirements must be met:

(i) Groups must meet the definition of a group at all times during the applicable performance period.

(ii) Individual eligible clinicians that elect to participate in MIPS as a group must aggregate their performance data across the group's TIN.

(iii) Individual eligible clinicians that elect to participate in MIPS as a group will have their performance assessed at the group level across all four MIPS performance categories.

(iv) Groups must adhere to an election process established by CMS, as applicable.

* * * * *

■ 24. Section 414.1315 is revised to read as follows:

§ 414.1315 Virtual groups.

(a) *Eligibility.* (1) For a MIPS payment year, a solo practitioner or a group of 10 or fewer eligible clinicians may elect to participate in MIPS as a virtual group with at least one other such solo practitioner or group. The election must be made prior to the start of the applicable performance period and cannot be changed during the performance period. A solo practitioner or group may elect to be in no more than one virtual group for a performance period, and, in the case of a group, the election applies to all MIPS eligible clinicians in the group.

(2) Except as provided under § 414.1370(f)(2), each MIPS eligible clinician in the virtual group receives a MIPS payment adjustment factor and, if applicable, an additional MIPS payment adjustment factor based on the virtual group's combined performance assessment.

(b) *Election deadline.* The election deadline is December 31 of the calendar year preceding the applicable performance period.

(c) *Election process.* For the 2020 MIPS payment year and future years, the virtual group election process is as follows:

(1) *Stage 1: Virtual group eligibility determination.* (i) For the 2020 MIPS payment year, the virtual group eligibility determination period is an assessment period of up to 5 months beginning on July 1 and ending as late as November 30 of the calendar year preceding the applicable performance period, and that includes a 30-day claims run out.

(ii) Beginning with the 2021 MIPS payment year, the virtual group eligibility determination period is the first segment of the MIPS determination period.

(2) *Stage 2: Virtual group formation.* (i) Solo practitioners and groups that elect to participate in MIPS as a virtual group must establish a formal written agreement that satisfies paragraph (c)(3) of this section prior to the election.

(ii) A designated virtual group representative must submit an election, on behalf of the solo practitioners and groups that compose a virtual group, to participate in MIPS as a virtual group for a performance period in a form and manner specified by CMS by the election deadline specified in paragraph (b) of this section. The virtual group election must include each TIN and NPI associated with the virtual group and contact information for the virtual group representative.

(iii) After an election is made, the virtual group representative must contact their designated CMS contact to update any election information that changed during a performance period at least one time prior to the start of data submission.

(3) *Virtual group agreement.* The virtual group arrangement must be set forth in a formal written agreement among the parties, consisting of each solo practitioner and group that composes a virtual group. The agreement must comply with the following requirements:

(i) Identifies each party by name, TIN, and each NPI under the TIN, and includes as parties only the solo practitioners and groups that compose the virtual group.

(ii) Is for a term of at least one performance period.

(iii) Requires each party to notify each NPI under the party's TIN regarding their participation in the MIPS as a virtual group.

(iv) Sets forth each NPI's rights and obligations in, and representation by, the virtual group, including, but not limited to, the reporting requirements and how participation in the MIPS as a virtual group affects the NPI's ability to participate in the MIPS outside of the virtual group.

(v) Describes how the opportunity to receive payment adjustments will encourage each member of the virtual group (and each NPI under each TIN in the virtual group) to adhere to quality assurance and improvement.

(vi) Requires each party to update its Medicare enrollment information, including the addition or removal of NPIs billing under its TIN, on a timely basis in accordance with Medicare program requirements and to notify the other parties of any such changes within 30 days of the change.

(vii) Requires completion of a close-out process upon termination or expiration of the agreement that requires each party to furnish all data necessary for the parties to aggregate their data across the virtual group's TINs.

(viii) Expressly requires each party to participate in the MIPS as a virtual group and comply with the requirements of the MIPS and all other applicable laws (including, but not limited to, Federal criminal law, the Federal False Claims Act, the Federal

anti-kickback statute, the Federal civil monetary penalties law, the Federal physician self-referral law, and the Health Insurance Portability and Accountability Act of 1996).

(ix) Is executed on behalf of each party by an individual who is authorized to bind the party.

(d) *Virtual group reporting requirements.* For solo practitioners and groups of 10 or fewer eligible clinicians to participate in MIPS as a virtual group, all of the following requirements must be met:

(1) Virtual groups must meet the definition of a virtual group at all times during the applicable performance period.

(2) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group must aggregate their performance data across the virtual group's TINs.

(3) Solo practitioners and groups of 10 or fewer eligible clinicians that elect to participate in MIPS as a virtual group will have their performance assessed at the virtual group level across all four MIPS performance categories.

(4) Virtual groups must adhere to the election process described in paragraph (c) of this section.

■ 25. Section 414.1320 is amended by revising paragraphs (b)(2) and (c)(2) and adding paragraphs (d) and (e) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(b) * * *

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2018, up to and including the full CY 2018 (January 1, 2018 through December 31, 2018).

(c) * * *

(2) Promoting Interoperability and improvement activities performance categories is a minimum of a continuous 90-day period within CY 2019, up to and including the full CY 2019 (January 1, 2019 through December 31, 2019).

(d) Beginning with the 2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(e) For purposes of the 2022 MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 26. Section 414.1325 is revised to read as follows:

§ 414.1325 Data submission requirements.

(a) *Applicable performance categories.* (1) Except as provided in paragraph (a)(2) of this section or under § 414.1370, as applicable, individual MIPS eligible clinicians and groups must submit data on measures and activities for the quality, improvement activities, and Promoting Interoperability performance categories in accordance with this section. Except for the Medicare Part B claims submission type, the data may also be submitted on behalf of the individual MIPS eligible clinician or group by a third party intermediary described at § 414.1400.

(2) There are no data submission requirements for:

(i) The cost performance category or administrative claims-based quality measures. Performance in the cost performance category and on such measures is calculated by CMS using administrative claims data, which includes claims submitted with dates of service during the applicable performance period that are processed no later than 60 days following the close of the applicable performance period.

(ii) The quality and cost performance categories, as applicable, for MIPS eligible clinicians and groups that are scored under the facility-based measurement scoring methodology described in § 414.1380(e).

(b) *Data submission types for individual MIPS eligible clinicians.* An individual MIPS eligible clinician may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, and Medicare Part B claims (beginning with the 2021 MIPS payment year for small practices only) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(c) *Data submission types for groups.* Groups may submit their MIPS data using:

(1) For the quality performance category, the direct, login and upload, Medicare Part B claims (beginning with the 2021 MIPS payment year, for small practices only), and CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

(2) For the improvement activities or Promoting Interoperability performance categories, the direct, login and upload, or login and attest submission types.

(d) *Use of multiple data submission types.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians, groups, and virtual groups may submit their MIPS data using multiple data submission types for any performance category described in paragraph (a)(1) of this section, as applicable; provided, however, that the MIPS eligible clinician, group, or virtual group uses the same identifier for all performance categories and all data submissions.

(e) *Data submission deadlines.* The data submission deadlines are as follows:

(1) For the direct, login and upload, login and attest, and CMS Web Interface submission types, March 31 following the close of the applicable performance period or a later date as specified by CMS.

(2) For the Medicare Part B claims submission type, data must be submitted on claims with dates of service during the applicable performance period that must be processed no later than 60 days following the close of the applicable performance period.

■ 27. Section 414.1330 is revised to read as follows:

§ 414.1330 Quality performance category.

(a) For a MIPS payment year, CMS uses the following quality measures, as applicable, to assess performance in the quality performance category:

(1) Measures included in the MIPS final list of quality measures established by CMS through rulemaking;

(2) QCDR measures approved by CMS under § 414.1400;

(3) Facility-based measures described in § 414.1380; and

(4) MIPS APM measures described in § 414.1370.

(b) Unless a different scoring weight is assigned by CMS, performance in the quality performance category comprises:

(1) 60 percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 50 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 45 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

■ 28. Section 414.1335 is amended by revising paragraphs (a)(1) through (3) to read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(1) *For Medicare Part B claims measures, MIPS CQMs, eCQMs, or QCDR measures.* (i) Except as provided in paragraph (a)(1)(ii) of this section, submit data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(ii) MIPS eligible clinicians and groups that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician or group, report on each measure that is applicable.

(2) *For CMS Web Interface measures.* (i) Report on all measures included in the CMS Web Interface. The group is required to report on at least one measure for which there is Medicare patient data.

(ii) [Reserved]

(3) *For the CAHPS for MIPS survey.* (i) For the 12-month performance period, a group that wishes to voluntarily elect to participate in the CAHPS for MIPS survey must use a survey vendor that is approved by CMS for the applicable performance period to transmit survey measures data to CMS.

(ii) [Reserved]

* * * * *

■ 29. Section 414.1340 is amended by revising paragraphs (a) introductory text, (b) introductory text, and (c) to read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs must submit data on:

* * * * *

(b) MIPS eligible clinicians and groups submitting quality measure data on Medicare Part B claims measures must submit data on:

* * * * *

(c) Groups submitting quality measures data on CMS Web Interface measures or the CAHPS for MIPS survey must submit data on the sample of the Medicare Part B patients CMS provides, as applicable.

(1) *For CMS Web Interface measures.* (i) The group must report on the first 248 consecutively ranked beneficiaries in the sample for each measure or module. If the sample of eligible assigned beneficiaries is less than 248, then the group must report on 100 percent of assigned beneficiaries.

(ii) [Reserved]

(2) [Reserved]

■ 30. Section 414.1350 is revised to read as follows:

§ 414.1350 Cost performance category.

(a) *Specification of cost measures.* For purposes of assessing performance of MIPS eligible clinicians on the cost performance category, CMS specifies cost measures for a performance period.

(b) *Attribution.* (1) Cost measures are attributed at the TIN/NPI level.

(2) For the total per capita cost measure, beneficiaries are attributed using a method generally consistent with the method of assignment of beneficiaries under § 425.402 of this chapter.

(3) For the Medicare Spending per Beneficiary (MSPB) measure, an episode is attributed to the MIPS eligible clinician who submitted the plurality of claims (as measured by allowed charges) for Medicare Part B services rendered during an inpatient hospitalization that is an index admission for the MSPB measure during the applicable performance period.

(4) For the acute condition episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills at least 30 percent of inpatient evaluation and management (E&M) visits during the trigger event for the episode.

(5) For the procedural episode-based measures specified for the 2017 performance period, an episode is attributed to each MIPS eligible clinician who bills a Medicare Part B claim with a trigger code during the trigger event for the episode.

(6) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, an episode is attributed to each MIPS eligible clinician who bills inpatient E&M claim lines during a trigger inpatient hospitalization under a TIN that renders at least 30 percent of the inpatient E&M claim lines in that hospitalization.

(7) For the procedural episode-based measures specified beginning with the 2019 performance period, an episode is attributed to each MIPS eligible clinician who renders a trigger service as identified by HCPCS/CPT procedure codes.

(c) *Case minimums.* (1) For the total per capita cost measure, the case minimum is 20.

(2) For the Medicare spending per beneficiary measure, the case minimum is 35.

(3) For the episode-based measures specified for the 2017 performance period, the case minimum is 20.

(4) For the procedural episode-based measures specified beginning with the 2019 performance period, the case minimum is 10.

(5) For the acute inpatient medical condition episode-based measures specified beginning with the 2019 performance period, the case minimum is 20.

(d) *Scoring weight.* Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the cost performance category comprises:

(1) Zero percent of a MIPS eligible clinician's final score for MIPS payment year 2019.

(2) 10 percent of a MIPS eligible clinician's final score for MIPS payment year 2020.

(3) 15 percent of a MIPS eligible clinician's final score for MIPS payment year 2021.

■ 31. Section 414.1355 is amended by revising paragraphs (a), (b) introductory text, and (c) to read as follows:

§ 414.1355 Improvement activities performance category.

(a) For a MIPS payment year, CMS uses improvement activities included in the MIPS final inventory of improvement activities established by CMS through rulemaking to assess performance in the improvement activities performance category.

(b) Unless a different scoring weight is assigned by CMS under section 1848(q)(5)(F) of the Act, performance in the improvement activities performance category comprises:

* * * * *

(c) The following are the list of subcategories, of which, with the exception of Participation in an APM, include activities for selection by a MIPS eligible clinician or group:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of

individuals to provide timely health care interventions or participation in a QCDR.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients or other clinicians, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision making mechanisms.

(5) Patient safety and practice assessment, such as through the use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an APM.

(7) Achieving health equity, such as for MIPS eligible clinicians that achieve high quality for underserved populations, including persons with behavioral health conditions, racial and ethnic minorities, sexual and gender minorities, people with disabilities, people living in rural areas, and people in geographic HPSAs.

(8) Emergency preparedness and response, such as measuring MIPS eligible clinician participation in the Medical Reserve Corps, measuring registration in the Emergency System for Advance Registration of Volunteer Health Professionals, measuring relevant reserve and active duty uniformed services MIPS eligible clinician activities, and measuring MIPS eligible clinician volunteer participation in domestic or international humanitarian medical relief work.

(9) Integrated behavioral and mental health, such as measuring or evaluating such practices as: Co-location of behavioral health and primary care services; shared/integrated behavioral health and primary care records; cross training of MIPS eligible clinicians, and integrating behavioral health with primary care to address substance use disorders or other behavioral health conditions, as well as integrating mental health with primary care.

■ 32. Section 414.1360 is amended by revising paragraph (a)(1) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(1) *Via direct, login and upload, and login and attest.* For the applicable performance period, submit a yes response for each improvement activity that is performed for at least a continuous 90-day period during the applicable performance period.

* * * * *

§ 414.1365 [Removed]

■ 33. Section 414.1365 is removed.

■ 34. Section 414.1370 is amended by revising paragraphs (b)(3), (f)(2), (g)(4), (h)(4) introductory heading, (h)(5)(i)(A) and (B), and (h)(5)(ii) introductory text.

The revisions read as follows:

§ 414.1370 APM scoring standard under MIPS.

* * * * *

(b) * * *

(3) The APM bases payment on quality measures and cost/utilization; and

* * * * *

(f) * * *

(2) MIPS eligible clinicians who participate in a group or have elected to participate in a virtual group and who are also on a MIPS APM Participation List will be included in the assessment under MIPS for purposes of producing a group or virtual group score and under the APM scoring standard for purposes of producing an APM Entity score. The MIPS payment adjustment for these eligible clinicians is based solely on their APM Entity score; if the APM Entity group is exempt from MIPS all eligible clinicians within that APM Entity group are also exempt from MIPS.

(g) * * *

(4) *Promoting Interoperability.* (i) For the 2019 and 2020 MIPS payment years, each Shared Savings Program ACO participant TIN must report data on the Promoting Interoperability performance category separately from the ACO, as specified in § 414.1375(b)(2). The ACO participant TIN scores are weighted according to the number of MIPS eligible clinicians in each TIN as a proportion of the total number of MIPS eligible clinicians in the APM Entity group, and then aggregated to determine an APM Entity score for the ACI performance category.

(ii) For the 2019 and 2020 MIPS payment years, for APM Entities in MIPS APMs other than the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. Beginning with the 2021 MIPS payment year, for APM Entities in MIPS APMs including the Shared Savings Program, CMS uses one score for each MIPS eligible clinician in the APM Entity group to derive a single average APM Entity score for the Promoting Interoperability performance category. The score for each MIPS eligible clinician is the higher of either:

(A) A group score based on the measure data for the Promoting Interoperability performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups; or

(B) An individual score based on the measure data for the Promoting Interoperability performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician participating in a MIPS APM receives an exception from the Promoting Interoperability performance category reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's Promoting Interoperability performance category score under the APM scoring standard.

(A) If all MIPS eligible clinicians in an APM Entity have been excepted from reporting the Promoting Interoperability performance category, the performance category weight will be reweighted to zero for the APM Entity for that MIPS performance period.

(B) [Reserved]

(h) * * *

(4) *Promoting Interoperability.* * * *

(5) * * *

(i) * * *

(A) In 2017, the improvement activities performance category is reweighted to 25 percent and the Promoting Interoperability performance category is reweighted to 75 percent; and

(B) Beginning in 2018, the Promoting Interoperability performance category is reweighted to 75 percent and the improvement activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to zero percent:

* * * * *

■ 35. Section 414.1375 is amended by revising the section heading, paragraphs (a), (b) introductory text, and (b)(2) to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

(a) *Final score.* Unless a different scoring weight is assigned by CMS under sections 1848(o)(2)(D), 1848(q)(5)(E)(ii), or 1848(q)(5)(F) of the Act, performance in the Promoting Interoperability performance category comprises 25 percent of a MIPS eligible clinician's final score for each MIPS payment year.

(b) *Reporting for the Promoting Interoperability performance category.* To earn a performance category score for the Promoting Interoperability performance category for inclusion in the final score, a MIPS eligible clinician must:

* * * * *

(2) *Report MIPS—Promoting Interoperability objectives and measures.* Report on the objectives and associated measures as specified by CMS for the Promoting Interoperability performance category for the performance period as follows:

(i) For the 2019 and 2020 MIPS payment years: For each base score measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or claim an exclusion for each measure that includes an option for an exclusion; and

(ii) For the 2021 and 2022 MIPS payment years:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs; and

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion.

* * * * *

■ 36. Section 414.1380 is revised to read as follows:

§ 414.1380 Scoring.

(a) *General.* MIPS eligible clinicians are scored under MIPS based on their performance on measures and activities in four performance categories. MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, composed of their performance category scores, and calculated according to the final score methodology.

(1) *Performance standards.* (i) For the quality performance category, measures are scored between zero and 10 measure achievement points. Performance is measured against benchmarks. Measure bonus points are available for submitting high-priority measures, submitting measures using end-to-end electronic reporting, and in small practices that submit data on at least 1 quality measure. Beginning with the 2020 MIPS payment year, improvement scoring is available in the quality performance category.

(ii) For the cost performance category, measures are scored between 1 and 10 points. Performance is measured against a benchmark. Starting with the 2024 MIPS payment year, improvement scoring is available in the cost performance category.

(iii) For the improvement activities performance category, each improvement activity is assigned a certain number of points. The points for all submitted activities are summed and scored against a total potential performance category score of 40 points.

(iv) For the Promoting Interoperability performance category, each measure is scored against a maximum number of points. The points for all submitted measures are summed and scored against a total potential performance category score of 100 points.

(2) [Reserved]

(b) *Performance categories.* MIPS eligible clinicians are scored under MIPS in four performance categories.

(1) *Quality performance category.* (i) *Measure achievement points.* For the 2019, 2020, and 2021 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) *Lack of benchmark or case minimum.* (*1*) Except as provided in paragraph (b)(1)(i)(A)(*2*) of this section, for the 2019, 2020, and 2021 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

(*2*) The following measures are excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points:

(*i*) Each submitted CMS Web Interface-based measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement, or is redesignated as pay-for-reporting for all Shared Savings Program accountable care organizations by the Shared Savings Program; and

(*ii*) Each administrative claims-based measure that does not have a benchmark or meet the case minimum requirement.

(B) *Lack of complete data.* (*1*) Except as provided in paragraph (b)(1)(i)(B)(*2*) of this section, for each submitted measure that does not meet the data completeness requirement:

(*i*) For the 2019 MIPS payment year, MIPS eligible clinicians receive 3 measure achievement points;

(*ii*) For the 2020 and 2021 MIPS payment years, MIPS eligible clinicians other than small practices receive 1 measure achievement point, and small practices receive 3 measure achievement points; and

(*iii*) Beginning with the 2022 MIPS payment year, MIPS eligible clinicians other than small practices receive zero measure achievement points, and small practices receive 3 measure achievement points.

(*2*) MIPS eligible clinicians receive zero measure achievement points for each submitted CMS Web Interface-based measure that does not meet the data completeness requirement.

(ii) *Benchmarks.* Benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

(A) Each benchmark must have a minimum of 20 individual clinicians or groups who reported the measure meeting the case minimum requirement at paragraph (b)(1)(iii) of this section and the data completeness requirement at § 414.1340 and having a performance rate that is greater than zero.

(B) CMS Web Interface collection type uses benchmarks from the corresponding reporting year of the Shared Savings Program.

(iii) *Minimum case requirements.* Except for the all-cause hospital readmission measure, the minimum case requirement is 20 cases. For the all-cause hospital readmission measure, the minimum case requirement is 200 cases.

(iv) *Topped out measures.* CMS will identify topped out measures in the benchmarks published for each Quality Payment Program year.

(A) For the 2020 MIPS payment year, each topped out measure specified by CMS through rulemaking receives no more than 7 measure achievement points, provided that the benchmark for the applicable collection type is identified as topped out in the benchmarks published for the 2018 MIPS performance period.

(B) Beginning with the 2021 MIPS payment year, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(v) *Measure bonus points.* MIPS eligible clinicians receive measure bonus points for the following measures, except as otherwise required under § 414.1335, regardless of whether the measure is included in the MIPS eligible clinician's total measure achievement points.

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures.

(*1*) *Limitations.* (*i*) Each high priority measure must have a benchmark at paragraph (b)(1)(ii) of this section, meet the case minimum requirement at (b)(1)(iii) of this section, meet the data completeness requirement at § 414.1340, and have a performance rate that is greater than zero.

(*ii*) For the 2019, 2020, and 2021 MIPS payment years, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(*iii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(*1*) of this section, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(*1*) *Limitations.* (*i*) For the 2019, 2020, and 2021 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

(*ii*) Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that collect data in accordance with § 414.1325 on a single measure via multiple collection types receive measure bonus points only once.

(C) *Small practices.* Beginning with the 2021 MIPS payment year, MIPS eligible clinicians in small practices receive 6 measure bonus points if they submit data to MIPS on at least 1 quality measure.

(vi) *Improvement scoring.* Improvement scoring is available to MIPS eligible clinicians that demonstrate improvement in performance in the current MIPS performance period compared to performance in the performance period immediately prior to the current MIPS performance period based on measure achievement points.

(A) Improvement scoring is available when the data sufficiency standard is met, which means when data are available and a MIPS eligible clinician has a quality performance category achievement percent score for the previous performance period and the current performance period.

(*1*) Data must be comparable to meet the requirement of data sufficiency which means that the quality performance category achievement percent score is available for the current performance period and the previous performance period and quality performance category achievement percent scores can be compared.

(*2*) Quality performance category achievement percent scores are comparable when submissions are received from the same identifier for two consecutive performance periods.

(*3*) If the identifier is not the same for 2 consecutive performance periods, then for individual submissions, the comparable quality performance category achievement percent score is the highest available quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for the individual. For group, virtual group, and APM Entity submissions, the comparable quality performance category achievement percent score is the average of the quality performance category achievement percent score associated with the final score from the prior performance period that will be used for payment for each of the individuals in the group.

(*4*) Improvement scoring is not available for clinicians who were scored under facility-based measurement in the performance period immediately prior to the current MIPS performance period.

(B) The improvement percent score may not total more than 10 percentage points.

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category percent score as described in paragraph (b)(1)(vii) of this section.

(*1*) The improvement percent score is awarded based on the rate of increase in the quality performance category achievement percent score of MIPS eligible clinicians from the previous performance period to the current performance period.

(*2*) An improvement percent score is calculated by dividing the increase in the quality performance category achievement percent score from the prior performance period to the current performance period by the prior performance period quality performance category achievement percent score multiplied by 10 percent.

(*3*) An improvement percent score cannot be lower than zero percentage points.

(*4*) For the 2020 and 2021 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

(*5*) The improvement percent score is zero if the MIPS eligible clinician did not fully participate in the quality performance category for the current performance period.

(D) For the purpose of improvement scoring methodology, the term ''quality performance category achievement percent score'' means the total measure achievement points divided by the total available measure achievement points, without consideration of measure bonus points or improvement percent score.

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category percent score as described in paragraph (b)(1)(vii) of this section.

(F) For the purpose of improvement scoring methodology, the term ''fully participate'' means the MIPS eligible

clinician met all requirements in §§ 414.1335 and 414.1340.

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category percent score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category percent score cannot exceed 100 percentage points.

(A) Beginning with the 2021 MIPS payment year, for each measure that a MIPS eligible clinician submits that is significantly impacted by clinical guideline changes or other changes that CMS believes may result in patient harm or misleading results, the total available measure achievement points are reduced by 10 points.

(B) Beginning with the 2021 MIPS payment year, for groups that submit 5 or fewer measures and register for the CAHPS for MIPS survey but do not meet the minimum beneficiary sampling requirements, the total available measure achievement points are reduced by 10 points.

(viii) *ICD–10 updates.* Beginning with the 2018 MIPS performance period, measures significantly impacted by ICD–10 updates, as determined by CMS, will be assessed based only on the first 9 months of the 12-month performance period. For purposes of this paragraph (b)(1)(viii), CMS will make a determination as to whether a measure is significantly impacted by ICD–10 coding changes during the performance period. CMS will publish on the CMS website which measures require a 9-month assessment process by October 1st of the performance period if technically feasible, but by no later than the beginning of the data submission period at § 414.1325(f)(1).

(2) *Cost performance category.* For each cost measure attributed to a MIPS eligible clinician, the clinician receives one to ten achievement points based on the clinician's performance on the measure during the performance period compared to the measure's benchmark. Achievement points are awarded based on which benchmark decile range the MIPS eligible clinician's performance on the measure is between. CMS assigns partial points based on the percentile distribution.

(i) Cost measure benchmarks are determined by CMS based on cost measure performance during the performance period. At least 20 MIPS eligible clinicians or groups must meet the minimum case volume specified under § 414.1350(c) for a cost measure in order for a benchmark to be determined for the measure. If a benchmark is not determined for a cost measure, the measure will not be scored.

(ii) A MIPS eligible clinician must meet the minimum case volume specified under § 414.1350(c) to be scored on a cost measure.

(iii) The cost performance category percent score is the sum of the following, not to exceed 100 percent:

(A) The total number of achievement points earned by the MIPS eligible clinician divided by the total number of available achievement points; and

(B) The cost improvement score, as determined under paragraph (b)(2)(iv) of this section.

(iv) The cost improvement score is determined for a MIPS eligible clinician that demonstrates improvement in performance in the current MIPS performance period compared to their performance in the immediately preceding MIPS performance period.

(A) The cost improvement score is determined at the measure level for the cost performance category.

(B) The cost improvement score is calculated only when data sufficient to measure improvement is available. Sufficient data is available when a MIPS eligible clinician or group participates in MIPS using the same identifier in 2 consecutive performance periods and is scored on the same cost measure(s) for 2 consecutive performance periods. If the cost improvement score cannot be calculated because sufficient data is not available, then the cost improvement score is zero.

(C) The cost improvement score is determined by comparing the number of measures with a statistically significant change (improvement or decline) in performance; a change is determined to be significant based on application of a t-test. The number of cost measures with a significant decline is subtracted from the number of cost measures with a significant improvement, with the result divided by the number of cost measures for which the MIPS eligible clinician or group was scored for 2 consecutive performance periods. The resulting fraction is then multiplied by the maximum cost improvement score.

(D) The cost improvement score cannot be lower than zero percentage points.

(E) The maximum cost improvement score for the 2020, 2021, 2022, and 2023 MIPS payment years is zero percentage points.

(v) A cost performance category percent score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(3) *Improvement activities performance category.* Subject to paragraphs (b)(3)(i) and (ii) of this section, the improvement activities performance category score equals the total points for all submitted improvement activities divided by 40 points, multiplied by 100 percent. MIPS eligible clinicians (except for non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs) receive 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325. Non-patient facing MIPS eligible clinicians, small practices, and practices located in rural areas and geographic HPSAs receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325.

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

(ii) For MIPS eligible clinicians in a practice that is certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, the improvement activities performance category score is 100 percent. For the 2019 MIPS payment year, at least one practice site within a group's TIN must be certified or recognized as a patient-centered medical home or comparable specialty practice. For the 2020 MIPS payment year and future years, at least 50 percent of the practice sites within a group's TIN must be recognized as a patient-centered medical home or comparable specialty practice. MIPS eligible clinicians that wish to claim this status for purposes of receiving full credit in the improvement activities performance category must attest to their status as a patient-centered medical home or comparable specialty practice in order to receive this credit. A practice is certified or recognized as

a patient-centered medical home if it meets any of the following criteria:

(A) The practice has received accreditation from one of four accreditation organizations that are nationally recognized;

(*1*) The Accreditation Association for Ambulatory Health Care;

(*2*) The National Committee for Quality Assurance (NCQA);

(*3*) The Joint Commission; or

(*4*) The Utilization Review Accreditation Commission (URAC).

(B) The practice is participating in a Medicaid Medical Home Model or Medical Home Model.

(C) The practice is a comparable specialty practice that has received the NCQA Patient-Centered Specialty Recognition.

(D) The practice has received accreditation from other certifying bodies that have certified a large number of medical organizations and meet national guidelines, as determined by the Secretary. The Secretary must determine that these certifying bodies must have 500 or more certified member practices, and require practices to include the following:

(*1*) Have a personal physician/clinician in a team-based practice.

(*2*) Have a whole-person orientation.

(*3*) Provide coordination or integrated care.

(*4*) Focus on quality and safety.

(*5*) Provide enhanced access.

(4) *Promoting Interoperability performance category.* (i) For the 2019 and 2020 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the base score, performance score, and any applicable bonus scores, not to exceed 100 percentage points. A MIPS eligible clinician cannot earn a performance score or bonus score unless they have earned a base score.

(A) A MIPS eligible clinician earns a base score by reporting for each base score measure, as applicable: The numerator (of at least one) and denominator, or a yes/no statement, or an exclusion.

(B) A MIPS eligible clinician earns a performance score by reporting on the performance score measures specified by CMS. A MIPS eligible clinician may earn up to 10 or 20 percentage points as specified by CMS for each performance score measure reported.

(C) A MIPS eligible clinician may earn the following bonus scores:

(*1*) A bonus score of 5 percentage points for reporting to one or more additional public health agencies or clinical data registries.

(*2*) A bonus score of 10 percentage points for attesting to completing one or more improvement activities specified by CMS using CEHRT.

(*3*) For the 2020 MIPS payment year, a bonus score of 10 percentage points for submitting data for the measures for the base score and the performance score generated solely from CEHRT as defined in § 414.1305 for 2019 and subsequent years.

(ii) For the 2021 and 2022 MIPS payment years, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the six required measures and any applicable bonus scores, not to exceed 100 points.

(A) A MIPS eligible clinician earns a score for each measure by reporting, as applicable: the numerator (of at least one) and denominator, or a yes/no statement. If an exclusion is reported for a measure, the points available for that measure are redistributed to another measure(s).

(B) Each required measure is worth 10, 20, or 40 points, as specified by CMS.

(C) Each optional measure is worth five bonus points.

(c) *Final score calculation.* Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year calculated as follows. If a MIPS eligible clinician is scored on fewer than 2 performance categories, he or she receives a final score equal to the performance threshold.

For the 2019 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.

For the 2020 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.

Beginning with the 2021 MIPS payment year:

Final score = [(quality performance category percent score × quality performance category weight) + (cost performance category percent score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

(1) *Performance category weights.* The weights of the performance categories in the final score are as follows, unless a different scoring weight is assigned under paragraph (c)(2) of this section:

(i) Quality performance category weight is defined under § 414.1330(b).

(ii) Cost performance category weight is defined under § 414.1350(d).

(iii) Improvement activities performance category weight is defined under § 414.1355(b).

(iv) Promoting Interoperability performance category weight is defined under § 414.1375(a).

(2) *Reweighting the performance categories.* (i) In accordance with paragraph (c)(2)(ii) of this section, a scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, in the following circumstances:

(A) CMS determines based on the following circumstances that there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act.

(*1*) For the quality performance category, CMS cannot calculate a score for the MIPS eligible clinician because there is not at least one quality measure applicable and available to the clinician.

(*2*) For the cost performance category, CMS cannot reliably calculate a score for the cost measures that adequately captures and reflects the performance of the MIPS eligible clinician.

(*3*) Beginning with the 2021 MIPS payment year, for the quality, cost, improvement activities, and Promoting

Interoperability performance categories, the MIPS eligible clinician joins an existing practice during the final 3 months of the performance period year that is not participating in MIPS as a group or joins a practice that is newly formed during the final 3 months of the performance period year.

(*4*) For the Promoting Interoperability performance category beginning with the 2021 MIPS payment year, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*5*) For the Promoting Interoperability performance category for the 2019, 2020, and 2021 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*6*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that prevented the clinician from collecting information that the clinician would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time. Beginning with the 2021 MIPS payment year, in the event that a MIPS eligible clinician submits data for the quality, cost, or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*7*) For the 2019 MIPS payment year, for the quality and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for a performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*8*) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS. In the event that a MIPS eligible clinician submits data for the quality or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(B) Under section 1848(q)(5)(E)(ii) of the Act, CMS estimates that the proportion of MIPS eligible clinicians who are physicians as defined in section 1861(r) of the Act and earn a Promoting Interoperability performance category score of at least 75 percent is 75 percent or greater. The estimation is based on data from the performance period that occurs four years before the MIPS payment year and does not include physicians for whom the Promoting Interoperability performance category is weighted at zero percent.

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*1*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they lacked sufficient internet access during the performance period, and insurmountable barriers prevented the clinician from obtaining sufficient internet access.

(*2*) The MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that caused their CEHRT to be unavailable.

(*3*) The MIPS eligible clinician was located in an area affected by extreme and uncontrollable circumstances as identified by CMS.

(*4*) The MIPS eligible clinician demonstrates through an application submitted to CMS that 50 percent or more of their outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.

(*5*) The MIPS eligible clinician is a non-patient facing MIPS eligible clinician as defined in § 414.1305.

(*6*) The MIPS eligible clinician is a hospital-based MIPS eligible clinician as defined in § 414.1305.

(*7*) The MIPS eligible clinician is an ASC-based MIPS eligible clinician as defined in § 414.1305.

(*8*) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that their CEHRT was decertified either during the performance period for the MIPS payment year or during the calendar year preceding the performance period for the MIPS payment year, and the MIPS eligible clinician made a good faith effort to adopt and implement another CEHRT in advance of the performance period. In no case may a MIPS eligible clinician be granted this exception for more than 5 years.

(*9*) Beginning with the 2020 MIPS payment year, the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in § 414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category.

(ii) A scoring weight different from the weights specified in paragraph (c)(1) of this section will be assigned to a performance category, and its weight as specified in paragraph (c)(1) of this section will be redistributed to another performance category or categories, as follows:

(A) For the 2019 MIPS payment year:

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category percent score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category percent score (%)	Reweight scenario if no improvement activities performance category score (%)
Promoting Interoperability	25	0	50	25

(B) For the 2020 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	50	10	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	75	10	15	0
—No Quality	0	10	45	45
—No Improvement Activities	65	10	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	10	90	0
—No Promoting Interoperability and no Improvement Activities	90	10	0	0
—No Quality and no Improvement Activities	0	10	0	90

(C) For the 2021 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting interoperability (%)
No Reweighting Needed:				
—Scores for all four performance categories	45	15	15	25
Reweight One Performance Category:				
—No Cost	60	0	15	25
—No Promoting Interoperability	70	15	15	0
—No Quality	0	15	40	45
—No Improvement Activities	60	15	0	25
Reweight Two Performance Categories:				
—No Cost and no Promoting Interoperability	85	0	15	0
—No Cost and no Quality	0	0	50	50
—No Cost and no Improvement Activities	75	0	0	25
—No Promoting Interoperability and no Quality	0	15	85	0
—No Promoting Interoperability and no Improvement Activities	85	15	0	0
—No Quality and no Improvement Activities	0	15	0	85

(iii) For MIPS eligible clinicians submitting data as a group or virtual group, in order for the Promoting Interoperability performance category to be reweighted in accordance with paragraph (c)(2)(ii) of this section, all of the MIPS eligible clinicians in the group must qualify for reweighting based on the circumstances described in paragraph (c)(2)(i) of this section.

(3) *Complex patient bonus.* For the 2020 and 2021 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

(i) For MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5].

(ii) For APM entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively, × 5].

(iii) The complex patient bonus cannot exceed 5.0.

(4) *Small practice bonus.* A small practice bonus of 5 points will be added to the final score for the 2020 MIPS payment year for MIPS eligible clinicians, groups, virtual groups, and APM Entities that meet the definition of a small practice as defined at § 414.1305 and participate in MIPS by submitting

data on at least one performance category in the 2018 MIPS performance period.

(d) *Scoring for APM Entities.* MIPS eligible clinicians in APM Entities that are subject to the APM scoring standard are scored using the methodology under § 414.1370.

(e) *Scoring for facility-based measurement.* For the payment in 2021 MIPS payment year and subsequent years and subject to paragraph (e)(6)(vi) of this section, a MIPS eligible clinician or group will be scored under the quality and cost performance categories using the methodology described in this paragraph (e).

(1) *General.* The facility-based measurement scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified as meeting the requirements in paragraph (e)(2) of this section.

(i) The measures used for facility-based measurement are the measure set finalized for the fiscal year value-based purchasing program for which payment begins during the applicable MIPS performance period.

(ii) Beginning with the 2021 MIPS payment year, the scoring methodology applicable for MIPS eligible clinicians scored with facility-based measurement is the Total Performance Score methodology adopted for the Hospital VBP Program, for the fiscal year for which payment begins during the applicable MIPS performance period.

(2) *Eligibility for facility-based measurement.* MIPS eligible clinicians are eligible for facility-based measurement for a MIPS payment year if they are determined to be facility-based as an individual clinician or as part of a group, as follows:

(i) *Facility-based individual determination.* A MIPS eligible clinician is facility-based if the clinician meets all of the following criteria:

(A) Furnishes 75 percent or more of his or her covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out.

(B) Furnishes at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting.

(C) Can be attributed, under the methodology specified in paragraph (e)(5) of this section, to a facility with a value-based purchasing score for the applicable period.

(ii) *Facility-based group determination.* A facility-based group is a group in which 75 percent or more of its eligible clinician NPIs billing under the group's TIN meet the requirements under paragraph (e)(2)(i) of this section.

(3) [Reserved]

(4) *Data submission for facility-based measurement.* There are no data submission requirements for individual clinicians to be scored under facility-based measurement. A group must submit data in the improvement activities or Promoting Interoperability performance categories in order to be scored as a facility-based group.

(5) *Determination of applicable facility score.* (i) A facility-based clinician is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the clinician provided services to the most Medicare beneficiaries during the period the claims are drawn from in paragraph (e)(2) of this section. If there is an equal number of Medicare beneficiaries treated at more than one facility, the value-based purchasing score for the highest scoring facility is used.

(ii) A facility-based group is scored with facility-based measurement using the score derived from the value-based purchasing score for the facility at which the plurality of clinicians identified as facility-based would have had their score determined under paragraph (e)(5)(i) of this section.

(6) *MIPS performance category scoring under the facility-based measurement scoring standard*—(i) *Measures.* The quality and cost measures are those adopted under the value-based purchasing program of the facility for the year described in paragraph (e)(1)(i) of this section.

(ii) *Benchmarks.* The benchmarks are those adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iii) *Performance period.* The performance period for facility-based measurement is the performance period for the measures adopted under the value-based purchasing program of the facility program for the year described in paragraph (e)(1) of this section.

(iv) *Quality.* The quality performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category percent score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category

(v) *Cost.* The cost performance category percent score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category percent score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost category.

(A) *Other cost measures.* MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless a clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

■ 37. Section 414.1395 is amended by revising paragraphs (b) and (c) to read as follows:

§ 414.1395 Public reporting.

* * * * *

(b) *Maintain existing public reporting standards.* With the exception of data that must be mandatorily reported on Physician Compare, for each program year, CMS relies on established public reporting standards to guide the information available for inclusion on Physician Compare. The public reporting standards require data included on Physician Compare to be statistically valid, reliable, and accurate; comparable across collection types; and meet the reliability threshold. And, to be included on the public facing profile pages, the data must also resonate with website users, as determined by CMS.

(c) *First year measures.* For each program year, CMS does not publicly report any first year measure for the first 2 years, meaning any measure in its first 2 years of use in the quality and cost performance categories. After the first 2 years, CMS reevaluates measures to determine when and if they are suitable for public reporting.

* * * * *

■ 38. Section 414.1400 is revised to read as follows:

§ 414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, or virtual group by any of the following third party intermediaries:

(i) A QCDR;

(ii) A qualified registry;

(iii) A health IT vendor; or

(iv) A CMS-approved survey vendor.

(2) QCDRs, qualified registries, and health IT vendors may submit MIPS data for any of the following MIPS performance categories:

(i) Quality, except for data on the CAHPS for MIPS survey;

(ii) Improvement activities; or

(iii) Promoting Interoperability, if the MIPS eligible clinician, group, or virtual group is using CEHRT.

(3) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(4) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(i) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(ii) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(iii) All data must be submitted in the form and manner specified by CMS.

(iv) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(5) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(b) *QCDR approval criteria*—(1) *QCDR self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a QCDR must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing QCDRs that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(2) *Establishment of a QCDR entity.* (i) Beginning with the 2022 MIPS Payment Year, the QCDR must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If the entity uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(3) *QCDR measures for the quality performance category.* (i) For purposes of QCDRs submitting data for the MIPS quality performance category, CMS considers the following types of quality measures to be QCDR measures:

(A) Measures that are not included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year; and

(B) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

(ii) For the 2020 MIPS payment year and future years, an entity seeking to become a QCDR must submit specifications for each measure, activity, and objective that the entity intends to submit to for MIPS (including the information described in paragraphs (b)(3)(ii)(A) and (B) of this section) at the time of self-nomination. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for each QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

(A) For QCDR measures, the entity must submit the measure specifications for each QCDR measure, including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms.

(B) For MIPS quality measures, the entity must submit the MIPS measure IDs and specialty-specific measure sets, as applicable.

(iii) A QCDR must include the CMS-assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(c) *Qualified registry approval criteria*—(1) *Qualified registry self-nomination.* For the 2020 and 2021 MIPS payment years, entities seeking to qualify as a qualified registry must self-nominate from September 1 until November 1 of the CY preceding the applicable performance period. For the 2022 MIPS payment year and future years, entities seeking to qualify as a qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2021 MIPS payment year and future years, existing qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(2) *Establishment of a qualified registry entity.* Beginning with the 2022 MIPS Payment Year, the qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(d) *Health IT vendor approval criteria.* Health IT vendors must meet the criteria specified at paragraph (a)(4) of this section.

(e) *CMS-approved survey vendor approval criteria.* Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for

which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(1) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect date), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(2) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(3) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(4) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(5) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(6) The entity has sent an interim survey data file to CMS that establishes the entity's ability to accurately report CAHPS data.

(f) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, or has submitted data that is inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) to CMS to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. The CAP must be submitted to CMS by a date specified by CMS.

(ii) Publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(2) CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time period or the CAP is not accepted by CMS; or

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(3) For purposes of paragraph (f) of this section, CMS may determine that submitted data is inaccurate, unusable, or otherwise compromised if the submitted data:

(i) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies; and

(ii) Affects more than 3 percent of the total number of MIPS eligible clinicians or group for which data was submitted by the third party intermediary.

(g) *Auditing of entities submitting MIPS data.* Any third party intermediary must comply with the following procedures as a condition of its qualification and approval to participate in MIPS as a third party intermediary.

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email.

(2) The entity must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(3) For the purposes of auditing, CMS may request any records or data retained for the purposes of MIPS for up to 6 years from the end of the MIPS performance period.

■ 39. Section 414.1405 is amended by—

■ a. Adding paragraphs (b)(6) and (d)(5);

■ b. Revising paragraph (e); and

■ c. Adding paragraph (f).

The additions and revision read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(6) The performance threshold for the 2021 MIPS payment year is 30 points.

* * * * *

(d) * * *

(5) The additional performance threshold for the 2021 MIPS payment year is 75 points.

(e) *Application of adjustments to payments.* Except as specified in paragraph (f) of this section, in the case of covered professional services (as defined in section 1848(k)(3)(A) of the Act) furnished by a MIPS eligible clinician during a MIPS payment year beginning with 2019, the amount otherwise paid under Part B with respect to such covered professional services and MIPS eligible clinician for such year, is multiplied by 1, plus the sum of the MIPS payment adjustment factor divided by 100, and as applicable, the additional MIPS payment adjustment factor divided by 100.

(f) *Exception to application of MIPS payment adjustment factors to model-specific payments under section 1115A APMs.* Effective for the 2019 MIPS payment year, the payment adjustment factors specified under paragraph (e) of this section are not applicable to payments that meet all of the following conditions:

(1) Are made only to participants in a model tested under section 1115A of the Act;

(2) Would otherwise be subject to the requirement to apply the MIPS payment adjustment factors if the payment is made with respect to a MIPS eligible clinician participating in a section 1115A model; and

(3) Either have a specified payment amount or are paid according to a methodology for calculating a model-specific payment that is applied in a consistent manner to all model participants, such that application of the MIPS payment adjustment factors would potentially interfere with CMS's ability to effectively evaluate the impact of the APM.

■ 40. Section 414.1415 is amended, effective January 1, 2019, by revising paragraphs (a)(1)(i) and (ii), (b)(1), (c) introductory text, (c)(3)(i)(A), and (c)(6) to read as follows:

§ 414.1415 Advanced APM criteria.

(a) * * *

(1) * * *

(i) Require at least 50 percent, or for QP Performance Periods beginning in 2019, 75 percent of eligible clinicians in each participating APM Entity group, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or health care providers; or

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity.

(b) * * *

(1) To be an Advanced APM, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.

* * * * *

(c) *Financial risk.* To be an Advanced APM, except as described in paragraph (c)(6) of this section, an APM must either meet the financial risk standard under paragraph (c)(1) or (2) of this section and the nominal amount standard under paragraph (c)(3) or (4) of this section or be an expanded Medical Home Model under section 1115A(c) of the Act.

* * * * *

(3) * * *

(i) * * *

(A) For QP Performance Periods beginning in 2017, through 2024, 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in participating APM Entities; or

* * * * *

(6) *Capitation.* A full capitation arrangement meets this Advanced APM criterion. For purposes of this part, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses incurred or savings earned by the APM Entity. Arrangements between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (c)(6).

* * * * *

■ 41. Section 414.1415 is further amended (effective January 1, 2010) by revising paragraphs (b)(2) and (3) to read as follows:

§ 414.1415 Advanced APM criteria.

* * * * *

(b) * * *

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (b)(1) of this section must:

(i) For QP Performance Periods before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) In addition to the quality measure described under paragraph (b)(2) of this section, the quality measures upon which an Advanced APM bases the payment in paragraph (b)(1) of this section must include at least one additional measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Beginning January 1, 2020, the included outcome measure must satisfy the criteria in paragraph (b)(2) of this section.

* * * * *

■ 42. Section 414.1420 is amended effective January 1, 2019, by revising paragraphs (d) introductory text, (d)(3)(i), and (d)(7) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(d) *Financial risk.* To be an Other Payer Advanced APM, except as described in paragraph (d)(7) of this section, a payment arrangement must meet either the financial risk standard under paragraph (d)(1) or (2) of this section and the nominal amount standard under paragraph (d)(3) or (4) of this section, or be a Medicaid Medical Home Model with criteria comparable to an expanded Medical Home Model under section 1115A(c) of the Act.

* * * * *

(3) * * *

(i) For QP Performance Periods 2019 through 2024, 8 percent of the total combined revenues from the payer to providers and other entities under the payment arrangement if financial risk is expressly defined in terms of revenue; or, 3 percent of the expected expenditures for which an APM Entity is responsible under the payment arrangement.

* * * * *

(7) *Capitation.* A full capitation arrangement meets this Other Payer Advanced APM criterion. For purposes of paragraph (d)(3) of this section, a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the payment arrangement for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed for the purpose of reconciling or sharing losses incurred or savings earned by the participant. Arrangements made directly between CMS and Medicare Advantage Organizations under the Medicare Advantage program (42 U.S.C. 422) are not considered capitation arrangements for purposes of this paragraph (c)(7).

* * * * *

■ 43. Section 414.1420 is further amended (effective January 1, 2020) by revising paragraphs (b), (c)(2) and (3) to read as follows:

§ 414.1420 Other payer advanced APM criteria.

* * * * *

(b) *Use of CEHRT.* To be an Other Payer Advanced APM, CEHRT must be used by at least 50 percent, or for QP Performance Periods on or after January 1, 2020, 75 percent of participants in each participating APM Entity group, or each hospital if hospitals are the APM Entities, in the other payer arrangement to document and communicate clinical care.

(c) * * *

(2) At least one of the quality measures used in the payment arrangement as specified in paragraph (c)(1) of this section must:

(i) For QP Performance Period before January 1, 2020, have an evidence-based focus, be reliable and valid, and meet at least one of the following criteria:

(A) Used in the MIPS quality performance category, as described in § 414.1330;

(B) Endorsed by a consensus-based entity;

(C) Developed under section 1848(s) of the Act;

(D) Submitted in response to the MIPS Call for Quality Measures under section 1848(q)(2)(D)(ii) of the Act; or

(E) Any other quality measures that CMS determines to have an evidence-based focus and to be reliable and valid; and

(ii) For QP Performance Periods beginning on or after January 1, 2020, be:

(A) Finalized on the MIPS final list of measures, as described in § 414.1330;

(B) Endorsed by a consensus-based entity; or

(C) Determined by CMS to be evidenced-based, reliable, and valid.

(3) To meet the quality measure use criterion under paragraph (c)(1) of this section, a payment arrangement must:

(i) For QP Performance Periods before January 1, 2020, use an outcome measure if there is an applicable outcome measure on the MIPS quality measure list. This criterion also applies for payment arrangements determined to be Other Payer Advanced APMs on or before January 1, 2020, but only for the Other Payer Advanced APM determination made with respect to the arrangement for the CY 2020 QP Performance Period (regardless of whether that determination is a single- or multi-year determination).

(ii) For QP Performance Periods on or after January 1, 2020, in addition to the quality measure described under paragraph (c)(2) of this section, use at least one additional measure that is an outcome measure and meets the criteria in paragraph (c)(2)(ii) of this section if there is such an applicable outcome measure on the MIPS quality measure list.

* * * * *

■ 44. Section 414.1440 is amended by revising paragraphs (d)(1) through (3) to read as follows:

§ 414.1440 Qualifying APM participant determination: All-payer combination option.

* * * * *

(d) * * *

(1) CMS performs QP determinations following the QP Performance Period using payment amount and/or patient count information submitted from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31. CMS will use data for the same time periods for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. CMS will use the payment amount or patient count method, applying the more advantageous of the two for both the Medicare and other payer portions of the Threshold score calculation, regardless of the method used for the Medicare Threshold Score calculation.

(2) An APM Entity may request that CMS make QP determinations at the APM Entity level, an eligible clinician may request that CMS make QP determinations at the eligible clinician level, and an eligible clinician or an APM Entity may request that CMS makes QP determinations at the TIN-level in instances where all clinicians who reassigned billing rights to the TIN are participating in a single APM Entity. CMS makes QP determinations at either the APM Entity, eligible clinician, or TIN level. Eligible clinicians assessed at the eligible clinician level under the Medicare Option at § 414.1425(b)(2) will be assessed at the eligible clinician level only under the All-Payer Combination Option. Eligible Clinicians may meet the Medicare and the All-Payer Combination Option thresholds using the payment amount method for both thresholds, the patient account method for both thresholds, or the payment amount method for one threshold and the patient account method for the other threshold.

(3) CMS uses data at the same level for the Medicare and other payer portions of Threshold Score calculations under the All-Payer Combination Option. When QP determinations are made at the eligible clinician or, at the TIN level when all clinicians who have reassigned billing rights to the TIN are included in a single APM Entity; and if the Medicare Threshold score for the APM Entity group is higher than when calculated for the eligible clinician or TIN, CMS makes QP determinations using a weighted Medicare Threshold Score that is factored into an All-Payer Combination Option Threshold Score.

* * * * *

■ 45. Section 414.1445 is amended by revising paragraph (b)(1), adding paragraph (c)(2)(i), and reserving paragraph (c)(2)(ii) to read as follows:

§ 414.1445 Determination of other payer advanced APMs.

* * * * *

(b) * * *

(1) *Payer initiated Other Payer Advanced APM determination process.* Beginning in 2018, and each year thereafter, at a time determined by CMS a payer with a Medicare Health Plan payment arrangement may request, in a form and manner specified by CMS, that CMS determine whether a Medicare Health Plan payment arrangement meets the Other Payer Advanced APM criteria set forth in § 414.1420. A payer with a Medicare Health Plan payment arrangement must submit its requests by the annual Medicare Advantage bid deadline of the year prior to the relevant QP Performance Period. A Medicare Health Plan is a Medicare Advantage plan, a section 1876 cost plan, a PACE organization operated under section 1894, and any similar plan which provides Medicare benefits under demonstration or waiver authority (other than an APM as defined in section 1833(z)(3)(C) of the Act).

* * * * *

(c) * * *

(2) * * *

(i) Based on the submission by an eligible clinician or payer of evidence that CMS determines sufficiently demonstrates that CEHRT is used as specified in § 414.1420(b) by participants in the payment arrangement, CMS will consider the CEHRT criterion in § 414.1420(b) is satisfied for that payment arrangement.

(ii) [Reserved]

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 46. The authority citation for part 415 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 47. Section 415.172 is amended by revising paragraph (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

* * * * *

(b) *Documentation.* Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

* * * * *

■ 48. Section 415.174 is amended—
■ a. In paragraph (a)(3)(iii) by removing ''; '' and adding in its place ''; and'';
■ b. In paragraph (a)(3)(iv) by removing ''; and'' and adding in its place ''.'';
■ c. By removing paragraph (a)(3)(v); and
■ d. By adding paragraph (a)(6).

The addition reads as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) * * *

(6) The medical records must document the extent of the teaching physician's participation in the review and direction of services furnished to each beneficiary. The extent of the teaching physician's participation may be demonstrated by the notes in the medical records made by a physician, resident, or nurse.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 49. The authority citation for part 425 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 50. Section 425.20 is amended—
■ a. By revising the definition of ''Agreement period'';
■ b. By adding in alphabetical order definitions for ''Certified Electronic Health Record Technology (CEHRT)'' and ''Eligible clinician''; and
■ c. By revising the definition of ''Performance year''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Agreement period means the term of the participation agreement.

* * * * *

Certified Electronic Health Record Technology (CEHRT) has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Eligible clinician has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement.

* * * * *

§ 425.100 [Amended]

■ 51. Section 425.100 is amended—
■ a. In paragraph (b) by removing the phrase ''under § 425.604, § 425.606 or § 425.610'' and adding in its place the phrase ''under § 425.604, § 425.606, § 425.609 or § 425.610''; and
■ b. In paragraph (c) by removing the phrase ''under § 425.606 or § 425.610'' and adding in its place the phrase ''under § 425.606, § 425.609 or § 425.610''.

■ 52. Section 425.200 is amended—
■ a. By revising paragraph (a);
■ b. By revising the heading of paragraph (b);
■ c. By removing paragraph (b)(2) introductory text, adding a heading for paragraph (b)(2), and revising paragraph (b)(2)(ii); and
■ d. By removing paragraph (b)(3) introductory text, adding a heading for paragraph (b)(3); and
■ e. By revising paragraphs (c) and (d).

The revisions and additions read as follows:

§ 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.** * *

(2) *For 2013 and through 2016.** * *

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(*1*) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(*2*) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(3) *For 2017 and all subsequent years.* * * *

(c) *Performance year.* The ACO's performance year under the participation agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) For an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c), and as applicable according to §§ 425.608 and 425.609.

* * * * *

§ 425.221 [Amended]

■ 53. Section 425.221 is amended—
■ a. In paragraph (b)(1)(i) by removing the phrase ''December 31st of such performance year'' and adding in its place the phrase ''the last calendar day of the performance year''; and
■ b. In paragraph (b)(2) by removing the phrase ''December 31 of a performance year'' and adding in its place the phrase ''the last calendar day of a performance year''.

■ 54. Section 425.302 is amended—
■ a. In paragraph (a)(3)(i) by removing the phrase ''requirements; and'' and adding in its place the phrase ''requirements;'';
■ b. In paragraph (a)(3)(ii) by removing the phrase ''owed to CMS.'' and adding in its place the phrase ''owed to CMS; and''; and
■ c. Adding paragraph (a)(3)(iii).

The addition reads as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) That the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

§ 425.315 [Amended]

■ 55. Section 425.315 is amended in paragraph (a)(1)(ii) by removing the phrase ''§ 425.604(f), § 425.606(h) or § 425.610(h)'' and adding in its place the phrase ''§ 425.604(f), § 425.606(h), § 425.609(e) or § 425.610(h)''.

■ 56. Section 425.400 is amended by—
■ a. Revising paragraph (a)(1)(ii);
■ b. Revising paragraphs (c)(1)(iv) introductory text, (c)(1)(iv)(A), (c)(1)(iv)(B) introductory text, and (c)(1)(iv)(B)(*5*); and
■ c. Adding paragraphs (c)(1)(iv)(B)(*6*) and (*7*).

The revisions and additions read as follows:

§ 425.400 General.

(a)(1) * * *

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO professional during each performance year for which shared savings are to be determined and, with respect to ACOs participating in a 6-month performance year during CY 2019, during the entirety of CY 2019 as specified in § 425.609.

* * * * *

(c) * * *

(1) * * *

(iv) For performance years starting on January 1, 2019, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*2*) 99304 through 99318 (codes for professional services furnished in a nursing facility; services identified by these codes furnished in a SNF are excluded).

(*3*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*4*) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(*5*) 99487, 99489 and 99490 (codes for chronic care management).

(*6*) 99495 and 99496 (codes for transitional care management services).

(*7*) 99497 and 99498 (codes for advance care planning).

(*8*) 96160 and 96161 (codes for administration of health risk assessment).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(B) HCPCS codes:

* * * * *

(*5*) G0444 (codes for annual depression screening service).

(*6*) G0442 (code for alcohol misuse screening service).

(*7*) G0443 (code for alcohol misuse counseling service).

■ 57. Section 425.401 is amended by revising paragraph (b) introductory text to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

* * * * *

(b) A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii), if the beneficiary meets any of the following criteria during the performance or benchmark year:

* * * * *

■ 58. Section 425.402 is amended by revising paragraph (e)(2) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(2) Beneficiaries are added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) For performance year 2018:

(A) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(B) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(C) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(D) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary is not added to the ACO's list of assigned beneficiaries under the assignment methodology in paragraph (b) of this section.

(ii) For performance years starting on January 1, 2019, and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year or the ACO's list of assigned beneficiaries for a 6-month performance year, which is based on the entire CY 2019 as provided in § 425.609.

(D) The beneficiary is not assigned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model.

* * * * *

§ 425.404 [Amended]

■ 59. Section 425.404 is amended in paragraph (b) by removing the phrase ''For performance year 2019 and subsequent performance years'' and adding in its place the phrase ''For performance years starting on January 1, 2019, and subsequent performance years''.

■ 60. Section 425.502 is amended—

■ a. In paragraph (e)(4)(vi) by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ b. By adding a new paragraph (e)(4)(vii);

■ c. By revising paragraph (f) introductory text;

■ d. By redesignating paragraphs (f)(1) and (2) as paragraphs (f)(2)(i) and (ii);
■ e. By adding a new paragraph (f)(1);
■ f. By adding a new paragraph (f)(2) introductory text;
■ g. In newly redesignated paragraph (f)(2)(i) by removing the phrase ''for performance year 2017'' and adding in its place the phrase ''for the relevant performance year'';
■ h. By removing paragraph (f)(4); and
■ i. By redesignating paragraph (f)(5) as paragraph (f)(4).

The revisions and additions read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(e) * * *

(4) * * *

(vii) For performance year 2017 and subsequent performance years, if an ACO receives the mean Shared Savings Program ACO quality score under paragraph (f) of this section, in the next performance year for which the ACO receives a quality performance score based on its own quality reporting, quality improvement is measured based on a comparison between the performance in that year and the most recently available prior performance year in which the ACO reported quality.

(f) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, including the applicable quality data reporting period for the performance year if the quality reporting period is not extended, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraphs (a) through (e) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination for performance year 2017, CMS uses the final list of beneficiaries assigned to the ACO for the performance year. For performance year 2018 and subsequent performance years, CMS uses the list of assigned beneficiaries used to generate the Web Interface quality reporting sample.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (f)(1) of this section, CMS calculates the ACO's quality score as follows:

* * * * *

■ 61. Section 425.506 is amended—
■ a. In paragraph (b) by removing the phrase ''As part of the quality performance score'' and adding in its place the phrase ''For performance years 2012 through 2018, as part of the quality performance score'';
■ b. In paragraph (c) by removing the phrase ''Performance on this measure'' and adding in its place the phrase ''For performance years 2012 through 2018, performance on this measure'';
■ c. In paragraph (e) introductory text by removing the phrase ''For 2017 and subsequent years'' and adding in its place the phrase ''For 2017 and 2018''; and
■ d. By adding paragraph (f).

The addition reads as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track that—

(1) Does not meet the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or

(2) Meets the financial risk standard to be an Advanced APM must certify annually that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under § 414.1415(a)(1)(i) of this chapter.

■ 62. Section 425.602 is amended by adding paragraph (c) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period.

* * * * *

(c) *January 1, 2019 through June 30, 2019 performance year.* In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(9) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 63. Section 425.603 is amended by adding paragraph (g) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period.

* * * * *

(g) In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (c)(10) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (d) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 64. Section 425.604 is amended by adding paragraph (g) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(g) *January 1, 2019 through June 30, 2019 performance year.* Shared savings for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 65. Section 425.606 is amended—
■ a. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';
■ b. In paragraph (i)(1) remove the phrase ''2017''; and
■ c. By adding paragraph (j).

The addition reads as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(j) *January 1, 2019 through June 30, 2019.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 66. Section 425.609 is added to read as follows:

§ 425.609 Determining performance for a 6-month performance year during CY 2019.

(a) *General.* An ACO's financial and quality performance for a 6-month performance year during 2019 are determined as described in this section.

(b) *January 2019 through June 2019.* For ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), CMS reconciles the ACO for the period from January 1, 2019, through June 30, 2019, after the conclusion of CY 2019, based on the 12-month calendar year and pro-rates shared savings or shared losses to reflect the ACO's participation from January 1, 2019, through June 30, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning January 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400.

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) Medicare fee-for-service beneficiaries are prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502. The ACO's latest certified ACO participant list is used to determine the quality reporting samples for the 2019 reporting year for an ACO that extends its participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B).

(3) Uses the methodology for calculating shared savings or shared losses applicable to the ACO under the terms of the participation agreement that was in effect on January 1, 2019.

(i) The ACO's historical benchmark is determined according to either § 425.602 (first agreement period) or § 425.603 (second agreement period) except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.602(b), § 425.603(b), or § 425.603(d), based on whether the ACO is in its first or second agreement period, and for an ACO in a second agreement period, the date on which that agreement period began.

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section.

(B) Expenditures calculated in paragraph (b)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (b)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section is used to determine the MSR for Track 1 ACOs and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. For two-sided model ACOs that selected a fixed MSR/MLR at the start of the ACO's agreement period, this fixed MSR/MLR is applied. In the event an ACO's performance year assigned population identified in paragraph (b)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined according to § 425.110(b).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (b)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive a shared savings payment under paragraph (b)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS pro-rates any shared savings amount determined under paragraph (b)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(E) For an ACO responsible for shared losses under paragraph (b)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.606 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (b)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (b)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the period from January 1, 2019, through June 30, 2019.

(c) [Reserved]

(d) *Extreme and uncontrollable circumstances.* For ACOs affected by extreme and uncontrollable circumstances during CY 2019—

(1) In calculating the amount of shared losses owed, CMS makes adjustments to the amount determined in paragraph (b)(3)(ii)(E)(*1*) of this section, as specified in § 425.606(i) or § 425.610(i), as applicable; and

(2) In determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(e) *Notification of savings and losses.* CMS notifies the ACO of shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year, consistent with the notification requirements specified in §§ 425.604(f), 425.606(h), and 425.610(h), as applicable:

(1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

■ 67. Section 425.610 is amended—

■ a. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ b. In paragraph (i)(1) by removing the phrase ''2017''; and

■ c. By adding paragraph (j).

The addition reads as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

* * * * *

(j) *January 1, 2019 through June 30, 2019 performance year.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 68. Section 425.702 is amended by adding paragraph (d) to read as follows:

§ 425.702 Aggregate reports.

* * * * *

(d) For an ACO eligible to be reconciled under § 425.609(b), CMS shares with the ACO quarterly aggregate reports as provided in paragraphs (b) and (c)(1)(ii) of this section for CY 2019.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 69. The authority citation for part 495 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 70. Section 495.4 is amended in the definition of ''EHR reporting period'' by adding paragraph (1)(v) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period. * * *

(1) * * *

(v) Under the Medicaid Promoting Interoperability Program, for the CY 2021 payment year:

(A) For the EP first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within CY 2021 that ends before October 31, 2021, or that ends before an earlier date in CY 2021 that is specified by the state and approved by CMS in the State Medicaid HIT plan described at § 495.332.

(B) For the EP who has successfully demonstrated he or she is a meaningful EHR user in any prior year, any continuous 90-day period within CY 2021 that ends before October 31, 2021, or that ends before an earlier date in CY 2021 that is specified by the state and approved by CMS in the State Medicaid HIT plan described at § 495.332.

* * * * *

■ 71. Section 495.24 is amended by revising paragraphs (d)(6)(i)(B) and (d)(8)(i)(B)(*2*) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(d) * * *

(6) * * *

(i) * * *

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(6)(i)(B)(*1*) through (*3*) of this section except those measures for which an EP qualifies for an exclusion under paragraph (a)(3) of this section.

(*1*) During the EHR reporting period, more than 5 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and do either of the following:

(*i*) View, download or transmit to a third party their health information;

(*ii*) Access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's CEHRT; or

(*iii*) A combination of paragraphs (d)(6)(i)(B)(*1*)(*i*) and (*ii*) of this section.

(*2*) A secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient, for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

(*3*) Patient generated health data or data from a nonclinical setting is incorporated into the CEHRT for more than 5 percent of all unique patients seen by the EP during the EHR reporting period.

* * * * *

(8) * * *

(i) * * *

(B) * * *

(*2*) *Syndromic surveillance reporting.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting, or from any other setting from which ambulatory syndromic surveillance data are collected by the state or a local public health agency.

* * * * *

■ 72. Section 495.332 is amended by adding paragraphs (f)(3), (4), and (5) to read as follows:

§ 495.332 State Medicaid health information technology (HIT) plan requirements.

* * * * *

(f) * * *

(3) An alternative date within CY 2021 by which all ''EHR reporting periods'' (as defined under § 495.4) for the CY 2021 payment year for Medicaid EPs demonstrating they are meaningful EHR users must end. The alternative date selected by the state must be earlier than October 31, 2021, and must not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

(4) An alternative date within CY 2021 by which all clinical quality measure reporting periods for the CY 2021 payment year for Medicaid EPs demonstrating they are meaningful EHR users must end. The alternative date selected by the state must be earlier than October 31, 2021, and must not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state.

(5) For the CY 2019 payment year and beyond, a state-specific listing of which clinical quality measures selected by CMS are considered to be high priority measures for purposes of Medicaid EP clinical quality measure reporting.

* * * * *

Dated: October 26, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 30, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Appendix 1: Finalized MIPS Quality Measures

Note: Except as otherwise finalized in this final rule, previously finalized measures and specialty measure sets will continue to apply for the 2021 MIPS payment year and future years.

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TABLE Group A: Finalized New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years

A.1. Continuity of Pharmacotherapy for Opioid Use Disorder

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	468
Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.
Measure Steward:	University of Southern California
Numerator:	Adults in the denominator who have at least 180 days of continuous pharmacotherapy with a medication prescribed for OUD without a gap of more than 7 days.
Denominator:	Adults aged 18 years and older who had a diagnosis of OUD.
Exclusions:	Pharmacotherapy for OUD initiated after June 30th of performance period.
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High Priority Measure:	Yes (Appropriate Use and Opioid-Related)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because the opioid epidemic is immensely affecting the nation and it is imperative to measure opioid use. This clinical concept is currently not represented within MIPS. There are three existing opioid use related measures for MIPS but none cover the topic of pharmacotherapy. This measure captures patients diagnosed with opioid use disorder (OUD) who are receiving and adhering to the prescribed therapy. The performance data provided by the measure steward supports there is opportunity for improvement. Based on the measure steward research, only about a quarter to a third of individuals with commercial insurance or Medicaid coverage taking medication for OUD remained on the medication for at least 180 days without a gap of more than 7 days. The MAP acknowledged the public health importance of measures that address opioid use disorder and noted the gap in this area. However, the MAP recognized that the current measure is specified and tested at the health plan and state level and recommended the measure be refined and resubmitted prior to rulemaking because the measure has not been tested or endorsed at the clinician or clinician group level. While we agree that the measure should be tested at the clinician level, we believe there is an urgent need for measures that address the opioid epidemic affecting the nation. We believe that the health plan level version of the measure can be adapted to the clinician level by revising the measure analytics to assess the proportion of patients with opioid use disorder that achieve continuity of pharmacotherapy aggregated at the clinician level. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported adoption of new measure Q468: Continuity of Pharmacotherapy for Opioid Use Disorder, but has concerns about the potential for confounders in the measure data sources. The commenter urged CMS to consider, and account for the possibilities of confounders as the agency determines whether and how to adopt this measure.

Response: We thank the commenter for their support. We will work with the measure steward to consider accounting for confounders when implementing this measure, but maintain the notion that the measure is appropriate for implementation. This measure also addresses an at-risk population not addressed within MIPS measures which outweighs the risk of potential variables.

FINAL ACTION: We are finalizing the *Continuity of Pharmacotherapy for Opioid Use Disorder* measure as proposed for the 2019 Performance Period and future years.

A.2. Average Change in Functional Status Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	2643
Quality #:	469
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to 1 year (9 to 15 months) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	The average change (preoperative to 1 year post-operative) in functional status for all patients in the denominator. There is not a traditional numerator for this measure; the measure calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. For example: Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI 1 year post-op 26.4 points on a 100 point scale
Denominator:	Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively. *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed
Exclusions:	The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. The commenter stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Another commenter is pleased this measure emphasizes the change in functional status.

Response: We thank the commenters for their support.

Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oswestry Disability Index (ODI) as the functional status assessment basis for this quality measure.

Response: The measure steward has developed and tested this measure using the ODI tool to assess the change in functional status. We do not believe that the PROMIS scale will add value to this quality measure. Rather, we believe that the addition of the PROMIS scale introduces variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools.

Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF

Category	Description
	endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. The Oswestry Disability Index is a standardized tool that will allow eligible clinicians to track the progress of their patient's functional improvement. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance. **FINAL ACTION:** We are finalizing the *Average Change in Functional Status Following Lumbar Spine Fusion Surgery* measure as proposed for the 2019 Performance Period and future years.

A.3. Average Change in Functional Status Following Total Knee Replacement Surgery

Category	Description
NQF #:	2653
Quality #:	470
Description:	For patients age 18 and older undergoing total knee replacement surgery, the average change from pre-operative functional status to 1 year (9 to 15 months) post-operative functional status using the Oxford Knee Score (OKS) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative OKS score. For example: The average change in knee function was an increase of 15.9 points 1 year post-operatively on a 48 point scale. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account patients who have an improvement and patients whose function decreases post-operatively. For example: Patient Pre-op OKS:I Postop OKS:I Change in OKS Patient A: I 33 :I 45 :I 12 Patient B: I 17 :I 39 :I 22 Patient C: I 16 :I 31 :I 15 Patient D: I 23 :I 40 :I 17 Patient E: I 34 :I 42 :I 8 Patient F: I 10 :I 42 :I 32 Patient G: I 14 :I 44 :I 30 Patient H: I 32 :I 44 :I 12 Patient I: I 19 :I 45 :I 26 Patient J: I 26 :I 19 :I -7 Patient K: I 24 :I 43 :I 19 Patient L: I 29 :I 34 :I 5 Patient M : I 23 :I 39 :I 16 Patient N: I 29 :I 45 :I 16 Patient O: I 29 :I 45 :I 16 Patient P: I 34 :I 41 :I 7 Patient Q: I 11 :I 14 :I 3 Patient R: I 13 :I 39 :I 26 Patient S: I18 :I 45 :I 27 Average change in OKS 1 year post-op 15.9 points on a 48 point scale
Denominator:	Eligible Population: Patients with total knee replacement procedures (Primary TKR Value Set, Revision TKR Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose functional status was measured by the Oxford Knee Score within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed
Exclusions:	None
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. Results can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP supported this measure for rulemaking and recognized that improvement in functional status is an important outcome to patients and was encouraged by the potential addition of more patient-reported outcome measures to the MIPS set. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. They stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Several commenters are pleased this measure emphasizes the change in functional status and said that CMS should consider development of additional short and long-term outcomes measures for total joint procedures.

Response: We thank the commenters for their support.

Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oxford Knee Score (OKS) as the functional status assessment basis for this quality measure. A second commenter expressed concern that the OKS is a proprietary tool and that there are a number of validated tools available. Another commenter recommended the use of KOOS Jr and other potential measuring surveys to be available for use. The commenter also stated that KOOS Jr. and HOOS Jr. tools were selected as the preferred measurement instruments by the national orthopaedic specialty societies due to the ease of the tools.

Response: We thank the commenters for their input. The measure steward has developed and tested this measure using the OKS tool to assess the change in functional status. We do not believe that the introduction of additional tools (PROMIS, KOOS Jr, HOOS Jr.) will add value to this quality measure. Rather, we believe that the addition tools introduce variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools. In addition, it would not be appropriate to include the

Category	Description
HOOS Jr. survey since the patient population within this measure includes patients that have had a total knee replacement procedure. The HOOS Jr. is used to assess hip injuries and osteoarthritis. **Comment:** One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain. **Response:** Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance. **FINAL ACTION:** We are finalizing the *Average Change in Functional Status Following Total Knee Replacement Surgery* measure as proposed for the 2019 Performance Period and future years.	

A.4. Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	471
Description:	For patients age 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to 3 months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	The average change (preoperative to 3 months post-operative) in functional status for all patients in the denominator. There is not a traditional numerator for this measure; the measure is calculating the average change in functional status score from pre-operative to post-operative functional status score. The measure is NOT aiming for a numerator target value for a post-operative ODI score. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose function decreases post-operatively. For example: Patient Pre-op ODI :I Post-op ODI :I Change in ODI Patient A: I 47 :I 18 :I 29 Patient B: I 45 :I 52 :I -7 Patient C: I 56 :I 12 :I 44 Patient D: I 62 :I 25 :I 37 Patient E: I 42 :I 57 :I -15 Patient F: I 51 :I 10 :I 41 Patient G: I 62 :I 25 :I 37 Patient H: I 43 :I 20 :I 23 Patient I: I 74 :I 35 :I 39 Patient J: I 59 :I 23 :I 36 Average change in ODI 3 months post-op 26.4 points on a 100-point scale
Denominator:	Eligible Population: Patients with lumbar discectomy laminotomy procedure (Single Disc-Lami Value Set) for a diagnosis of disc herniation (Disc Herniation Value Set)) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose functional status was measured by the Oswestry Disability Index, version 2.1a (ODI, v2.1a) within 3 months preoperatively AND at 3 months (6 to 20 weeks) postoperatively. *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed.
Exclusions:	The following exclusions must be applied to the eligible population: Patient had any additional spine procedures performed on the same date as the lumbar discectomy laminotomy.
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High Priority Measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it measures an important patient reported outcome evaluating the functional status change from pre- to post-operative. The results of the measure can be used by clinicians in evaluating whether the patient's functional status has improved post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. They stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning). Another commenter is pleased this measure emphasizes the change in functional status.

Response: We thank the commenters for their support.

Comment: One commenter recommended using the Patient-Reported Outcome Measurement Information System (PROMIS) as an alternative to the Oswestry Disability Index (ODI) as the functional status assessment basis for this quality measure.

Response: The measure steward has developed and tested this measure using the ODI tool to assess the change in functional status. We do not believe that the PROMIS scale will add value to this quality measure. Rather, we believe that the addition of the PROMIS scale introduces variability and would not provide a standardized tool to assess functional status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools.

Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Category	Description
Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance. **FINAL ACTION:** We are finalizing the *Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery* measure as proposed for the 2019 Performance Period and future years.	

A.5. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	472
Description:	Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Female patients who received an order for at least one DXA scan in the measurement period.
Denominator:	Female patients ages 50 to 64 years with an encounter during the measurement period.
Exclusions:	Exclude from the denominator patients with a combination of risk factors (as determined by age) or one of the independent risk factors: • Ages: 50-54 (>=4 combo risk factors) or 1 independent risk factor • Ages: 55-59 (>=3 combo risk factors) or 1 independent risk factor • Ages: 60-64 (>=2 combo risk factors) or 1 independent risk factor Combination risk factors (The following risk factors are all combination risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur any time in the patient's history but must be active during the measurement period: • White (race) • BMI <= 20 kg/m2 (must be the first BMI of the measurement period) • Smoker (current during the measurement period) • Alcohol consumption (> two units per day (one unit is 12 oz. of beer, 4 oz. of wine, or 1 oz. of liquor)) The following risk factor may occur any time in the patient's history and must not start during the measurement period: • Osteopenia The following risk factors may occur at any time in the patient's history or during the measurement period: • Rheumatoid arthritis • Hyperthyroidism • Malabsorption syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption • Chronic liver disease • Chronic malnutrition The following risk factors may occur any time in the patient's history and do not need to be active at the start of the measurement period: • Documentation of history of hip fracture in parent • Osteoporotic fracture • Glucocorticoids (>= 5 mg/per day) [cumulative medication duration >= 90 days] Independent risk factors (The following risk factors are all independent risk factors; they are grouped by when they occur in relation to the measurement period): The following risk factors may occur at any time in the patient's history and must not start during the measurement period: • Osteoporosis The following risk factors may occur at any time in the patient's history prior to the start of the measurement period, but do not need to be active during the measurement period: • Gastric bypass • FRAX[R] 10-year probability of all major osteoporosis related fracture >= 9.3 percent • Aromatase inhibitors The following risk factors may occur at any time in the patient's history or during the measurement period: • Type I diabetes • End stage renal disease • Osteogenesis imperfecta • Ankylosing spondylitis • Psoriatic arthritis • Ehlers-Danlos syndrome • Cushing's syndrome • Hyperparathyroidism • Marfan syndrome • Lupus
Measure Type:	Process
Measure Domain:	Efficiency and Cost Reduction
High Priority measure:	Yes (Appropriate Use)
Collection Type:	eCQM Specifications
Rationale:	We are adopting this measure because it will serve as a counterbalance to the existing measure of appropriate use (that is, Screening for Osteoporosis for Women Aged 65-85 Years of Age (Quality ID #039)). This measure addresses the inappropriate use of DXA scans for

Category	Description
	women age 50 – 64 years without risk factors for osteoporosis. The MAP recognized the need for early detection of osteoporosis but reiterated the importance of appropriate use of this screening technique and noted this measure could be complementary to the existing osteoporosis screening measure (Quality ID #039). The MAP recognized the potential need for a balancing measure to prevent the potential underuse of DXA scans. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported the addition of this measure.

Response: We thank the commenter for their support.

Comment: One commenter expressed that clinicians may not be aware of the distinction between screening DXA scans and those appropriately performed as medically necessary follow-up care in a diagnosed individual to ascertain response to pharmacological interventions. The commenter urged CMS to clarify this distinction within its final rule and consider augmenting the pharmacologic therapy quality measure with a subpart that captures appropriate DXA re-testing to ascertain response to treatment. A second commenter urged CMS to defer implementing any quality measures that might deter osteoporosis screening until most men and women who are at heightened risk of fragility fractures receive testing and pharmacotherapy within the standard of care.

Response: Thank you for your comment and support of the DXA screening measure. We affirm that the intent of this measure is to encourage screening in the population at greatest risk for osteoporosis and assess progress toward appropriate screening. We appreciate your suggestion for an additional measure on appropriate screening as a follow-up to pharmacologic therapy in the treatment of osteoporosis and will give consideration to developing such a measure. This measure includes a number of applicable risk factors that would remove the at-risk patient from the denominator. The intended patient population is not considered high risk where a DXA scan is not appropriate. This measure does not deter appropriate osteoporotic screening for patients that meet the risks factors.

FINAL ACTION: We are finalizing the *Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture* measure as proposed for the 2019 Performance Period and future years.

A.6. Average Change in Leg Pain Following Lumbar Spine Fusion Surgery

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	473
Description:	For patients age 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to 1 year (9 to 15 months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.
Measure Steward:	Minnesota Community Measurement
Numerator:	The average change (preoperative to 1 year post-operative) in leg pain for all patients in the denominator. There is not a traditional numerator for this measure; the measure is calculating the average change in leg pain score from pre-operative to post-operative leg pain score. The measure is NOT aiming for a numerator target value for a post-operative pain score. The average change is calculated as follows: Change is first calculated for each patient and then changed scores are summed and then an average is determined. Measure calculation takes into account those patients that have an improvement and those patients whose pain increases post-operatively. For example: Patient I: Pre-op VAS I: Post-op VAS I:(Pre-op minus Post-op) Patient A: I: 8.5 I: 3.5 I: 5.0 Patient F I: 7.5 I: 1.5 I: 6.0 Patient B: I: 9.0 I: 2.5 I: 6.5 Patient G I: 9.0 I: 4.5 I: 4.5 Patient C: I: 7.0 I: 0.5 I: 6.5 Patient H I: 5.5 I: 7.5 I: -2.0 Patient D: I: 6.5 I: 8.0 I: -1.5 Patient I I: 9.0 I: 5.0 I: 4.0 Patient E I: 8.5 I: 2.0 I: 6.5 Patient J I: 7.0 I: 2.5 I: 4.5 Average change in VAS points 4.0 Average change in leg pain 1 year post-op 4.0 points on a 10 point scale.
Denominator:	Eligible Population: Patients with lumbar spine fusion procedures (Arthrodesis Value Set) occurring during a 12-month period for patients age 18 and older at the start of that period. Denominator: Patients within the eligible population whose leg pain was measured by the Visual Analog Scale (VAS) within 3 months preoperatively AND at 1 year (+/- 3 months) postoperatively. *The measure of average change in function can only be calculated if both a pre-operative and post-operative PRO assessment are completed
Exclusions:	The following exclusions must be applied to the eligible population: Patient had cancer (Spine Cancer Value Set), fracture (Spine Fracture Value Set) or infection (Spine Infection Value Set) related to the spine. Patient had idiopathic or congenital scoliosis (Congenital Scoliosis Value Set)
Measure Type:	Patient Reported Outcome
Measure Domain:	Person and Caregiver-Centered Experience and Outcomes
High priority measure:	Yes (Patient Reported Outcome)
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because it evaluates the management of pain from pre- to post-operative, which represents an important patient reported outcome. The results can be used by clinicians in evaluating whether the patient's pain has reduced post-operatively. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter supported this new measure and applauded CMS for proposing to adopt four patient-reported outcome measures. The commenter stated that patient-reported outcomes reflect issues that are important to patients and provide a valuable perspective on care that cannot be obtained from other data sources (for example, severity of pain, physical functioning).

Response: We thank the commenter for their support.

Comment: One commenter did not support the addition of this measure, stating that the validity, reliability, and informativeness of PROMs are uncertain.

Response: Although we agree PROMs can be challenging to implement, the measure steward has fully tested this measure for validity and reliability to obtain NQF endorsement. PROMs have been deemed one of our priorities as it is important to ensure patients are engaged in their care and are an important component in evaluating outcomes. Therefore, we respectfully disagree that PROMs are not informative for improving patient outcomes and clinician quality performance.

FINAL ACTION: We are finalizing the *Average Change in Leg Pain Following Lumbar Spine Fusion Surgery* measure as proposed for the 2019 Performance Period and future years.

A.7. Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	Not Applicable (N/A)
Description:	The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and were on daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.
Measure Steward:	Minnesota Community Measurement
Numerator:	Denominator patients with documentation that the patient was on daily aspirin or anti-platelet medication during the measurement period, unless allowed contraindications or exceptions are present.
Denominator:	18 years or older at the start of the measurement period AND less than 76 years at the end of the measurement period. AND Patient had a diagnosis of ischemic vascular disease (Ischemic Vascular Disease Value Set) with any contact during the current or prior measurement period OR had ischemic vascular disease (Ischemic Vascular Disease Value Set) present on an active problem list at any time during the measurement period. AND At least one established patient office visit (Established Pt Diabetes & Vasc Value Set) for any reason during the measurement period
Exclusions:	The following exclusions are allowed to be applied to the eligible population: • Patient was a permanent nursing home resident at any time during the measurement period. • Patient was in hospice or receiving palliative care at any time during the measurement period. • Patient died prior to the end of the measurement period. • Patient had only urgent care visits during the measurement period.
Measure Type:	Process
Measure Domain:	Effective Clinical Care
High priority measure:	No
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Rationale:	We proposed this measure because the measure exclusions are more appropriate than those in the currently adopted Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204) measure. The measure accounts for history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or anti-platelets, or use of non-steroidal anti-inflammatory agents. The MAP acknowledged both that clinicians may still report Aspirin or Anti-platelet Medication measures separately from the composite to drive quality improvement. The MAP conditionally supported this measure with the condition that there are no competing measures in the program. We refer readers to Table C where we are removing Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic (Quality ID #204). Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: A commenter recommended utilizing the Core Quality Measure Collaborative (CQMC) to evaluate both the Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet measure and the measure CMS proposed to replace it with a new measure: Ischemic Vascular Disease: Use of Aspirin or Antiplatelet Medication, during their maintenance review of the ACO/PMH/PC Core Measure Set. This will allow payers, clinicians, and other stakeholders to weigh in on the measures' exclusion criteria and other characteristics. Another commenter encouraged CMS to continue alignment of the MIPS measure set with those recommended by the CQMC. Another commenter opposed the proposed adoption of this measure because they believe that it is already captured in the Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) measure and recommended not including such a measure in the program where it could displace reporting of the higher-value composite measure.

Response: We appreciate the suggestion to allow stakeholders to weigh in on the exclusion criteria; however, we do not steward either of the measures and may not have the flexibility to revise the measures based on payers, clinicians or other stakeholders' feedback. Engaging the CQMC is beneficial to obtaining stakeholder feedback, but we encourage the commenter to provide this feedback to the CQMC. We are aware that this new measure is captured in the composite measure Q441 and that the composite measure is more robust. Although we believe Q441 may be burdensome to some eligible clinicians, we also believe it is a more meaningful measure than this new IVD measure. Therefore, to be consistent with our policy to remove measures that are duplicative to other measures and to ensure measures are more meaningful, we have decided to not finalize inclusion of this new IVD measure.

FINAL ACTION: We are not finalizing the *Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication* measure as proposed for the 2019 Performance Period.

A.8. Zoster (Shingles) Vaccination

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	474
Description:	The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.
Measure Steward:	PPRNet
Numerator:	Patients with a shingles vaccine ever recorded.
Denominator:	Patients 50 years of age and older.
Exclusions:	None
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	MIPS CQMs Specifications
Rationale:	We are adopting this measure because there are no measures currently in MIPS that address shingles vaccination for patients 50 years and older as recommended by the CDC. The MAP concluded that this measure would address the important topic of adult immunization. It discussed the new guidelines under development for the Zoster vaccination that could impact the amount of doses, the age of administration, and the specific vaccine that is used, but also noted that guidelines are constantly evolving and measures should be routinely updated based on changing guidelines. The MAP conditionally supported this measure pending NQF endorsement, and specifically requested evaluating the measure to ensure it has appropriate exclusions and reflects the most current CDC guidelines given the concerns about the cost of the vaccine and potential concerns about administering to immunocompromised patients. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter did not support the proposed adoption of this measure because it needs to be updated to reflect the most recent clinical guidelines.

Response: The measure steward has aligned this measure with the most current clinical guidelines and it will be implemented as such. As indicated in our rationale, the measure will address the impacts to the amount of doses, the age of administration and the specific vaccine utilized. This measure addresses an important gap in adult immunization.

Comment: Several commenters noted that the proposed rule rationale of "60 years and older" should be "50 years and older."

Response: We thank the commenters for their concerns regarding the age criteria with the rationale. The correct age was included in the description and denominator within the proposed rule, but did not align with the rationale. We agree with the denominator including patients over the age of 50 years and aligned the rationale with the measure's age criteria.

Comment: One commenter supported the proposed new measure for Zoster (Shingles) Vaccination. The commenter also supported broader adoption of a herpes zoster measure across specialty sets to reduce the number of missed immunization opportunities for this debilitating condition. The commenter supported the alignment of reporting mechanisms and believed doing so will strengthen and enhance the development and implementation of adult immunization quality measures.

Response: We thank the commenter for their support of the new measure, Zoster (Shingles) Vaccination.

FINAL ACTION: We are finalizing the *Zoster (Shingles) Vaccination* measure as proposed for the 2019 Performance Period and future years. The rationale is updated to state "patients 50 years and older" which aligns with the description and denominator age criteria.

A.9. HIV Screening

Category	Description
NQF #:	Not Applicable (NA)
Quality #:	475
Description:	Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).
Measure Steward:	Centers for Disease Control and Prevention
Numerator:	Patients with documentation of the occurrence of an HIV test between their 15th and 66th birthdays and before the end of the measurement period.
Denominator:	Patients 15 to 65 years of age who had an outpatient visit during the measurement period.
Exclusions:	Patients diagnosed with HIV prior to the start of the measurement period.
Measure Type:	Process
Measure Domain:	Community/Population Health
High priority measure:	No
Collection Type:	eCQM Specifications
Rationale:	We are adopting this measure because HIV screening is a national and global priority. While there are three currently adopted HIV measures in MIPS, they do not include screening the general population. The MAP acknowledged the importance of HIV screening from a population health perspective, but also questioned whether encouraging HIV screening through the MIPS program is the most effective strategy for improving this population health goal. It also expressed concern about how this measure under consideration identified individuals who may have a HIV screening in the community. Additionally, several MAP members expressed concern regarding the specifications requiring one time lifetime screening. The MAP conditionally supported this measure pending NQF endorsement. While we agree with MAP that NQF endorsement of measures is preferred, it is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure is evidence-based and is an important patient reported outcome. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Comment: One commenter did not support the proposed adoption of this measure because they stated that there is no demonstrated performance gap (measure testing results showed very high performance overall) and the measure still needs to be tested at the clinician-level.

Response: We believe it is important to implement an HIV screening measure as it addresses an important national and global priority. This measure has been developed as an eCQM Specification and should have little burden in the submission of this measure. The version of this measure proposed has been tested at the clinician-level. The measure steward developed and tested a previous version of this measure at the community center-level. The NQF Health and Well-Being 2015-2017 Committee reviewed this facility-level version of the measure and voted to pass the measure on evidence and performance gap, but decided the measure did not meet the scientific acceptability criteria. The NQF standing committee noted that when this previous version of the measure was tested at the facility-level a performance gap was demonstrated, performance at four community health centers ranged from 20.6 to 31.1 percent and performance at a fifth community health center serving a high-risk population was 65.3 percent (NQF, Health and Well-Being 2015-2017: Technical Report, April 17, 2017, http://www.qualityforum.org/Projects/h/Health_and_Well_Being_2015-2017/Final_Report.aspx). Since then, the measure steward modified the measure and tested it at the clinician-level. As we indicated in our proposal, the MAP reviewed this clinician-level version of the measure in 2018 and conditionally supported it pending NQF review and endorsement. The steward plans to seek NQF endorsement on this clinician-level measure. We believe implementing this measure at the clinician-level will raise awareness and improve patient care leading to improvement in population health.

FINAL ACTION: We are finalizing the *HIV Screening* measure as proposed for the 2019 Performance Period and future years.

A.10. Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls

Category	Description
NQF #:	0101
Quality #:	Not Applicable (N/A)
Description:	This is a clinical process measure that assesses falls prevention in older adults. The measure has three rates: **Screening for Future Fall Risk:** Percentage of patients aged 65 years and older who were screened for future fall risk at least once within 12 months. **Falls Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months. **Plan of Care for Falls:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.
Measure Steward:	National Committee for Quality Assurance
Numerator:	This measure has three rates. The numerators for the three rates are as follows: A) Screening for Future Fall Risk: Patients who were screened for future fall* risk** at last once within 12 months. B) Falls Risk Assessment: Patients who had a risk assessment*** for falls completed within 12 months. C) Plan of Care for Falls: Patients with a plan of care**** for falls documented within 12 months. *A fall is defined as a sudden, unintentional change in position causing an individual to land at a lower level, on an object, the floor, or the ground, other than as a consequence of a sudden onset of paralysis, epileptic seizure, or overwhelming external force. **Risk of future falls is defined as having had had 2 or more falls in the past year or any fall with injury in the past year. ***Risk assessment is comprised of balance/gait assessment AND one or more of the following assessments: postural blood pressure, vision, home fall hazards, and documentation on whether medications are a contributing factor or not to falls within the past 12 months. ****Plan of care must include consideration of vitamin D supplementation AND balance, strength and gait training.
Denominator:	A) Screening for Future Fall Risk: All patients aged 65 years and older seen by an eligible provider in the past year. B & C) Falls Risk Assessment & Plan of Care for Falls: All patients aged 65 years and older seen by an eligible provider in the past year with a history of falls (history of falls is defined as 2 or more falls in the past year or any fall with injury in the past year).
Exclusions:	Patients who have documentation of medical reason(s) for not screening for future fall risk, undergoing a risk-assessment or having a plan of care (for example, patient is not ambulatory) are excluded from this measure.
Measure Type:	Process
Measure Domain:	Patient Safety
High Priority Measure:	Yes
Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Rationale:	We are adopting this measure because it is a combined version of three of the currently adopted measures 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk. The new combined Falls measure (based on specifications in NQF 0101) is more robust and will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care which creates a more comprehensive screening measure. As noted in Table C, we are proposing to remove 154: Falls: Risk Assessment, 155: Falls: Plan of Care and 318: Falls: Screening for Future Fall Risk because they will be subsumed by this new measure. While we note that has not been put forth through the MAP for consideration in MIPS, the three individual measures have been NQF endorsed as one measure.

Comment: We received a number of comments opposing the new composite measure. Comments included a need for more clinical review, that vendors need time to develop and certify the respective replacement measures, and that CMS does not describe a benchmark for the composite measure.
Several commenters were in support of the new composite measure stating that that it is a more robust and more comprehensive screening measure.

Response: We thank all of the commenters for expressing the opposition of combining three measures to create a composite measure. We agree with the feedback provided and will postpone the implementation of the Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls measure until the measure can be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population.

FINAL ACTION: We are not finalizing the *Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls* measure for the 2019 Performance Period.

TABLE Group B: Finalized New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years

Note: In the CY 2019 PFS proposed rule (83 FR 35704), we proposed to modify the specialty measure sets below based upon review of updates made to existing quality measure specifications, the proposal of adding new measures for inclusion in MIPS, and the feedback provided by specialty societies. In the first column, existing measures with substantive changes are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§) and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to fully represent the regulatory definition of high priority measures.

As discussed in section III.I.3.h.(2)(b)(i) of this final rule, we are amending the definition of high priority at §414.1305 to include opioid-related measures. We define high priority measure to mean an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. Outcome measures include outcome, intermediate outcome, and patient reported outcome. A high priority indicator (an exclamation point (!)) in the Indicator column has been added for all opioid-related measures.

The following specialty measure sets have been excluded from this final rule, because we did not propose any changes to these sets: Allergy/Immunology, Electro-Physiology Cardiac Specialist, Plastic Surgery, Interventional Radiology, Dentistry and Hospitalists. Therefore, we refer readers to these finalized specialty sets in the CY 2018 Quality Payment Program final rule (82 FR 53976 through 54146). Note: In the proposed rule, we inadvertently included the Dentistry specialty set even though no changes were proposed for this specialty set; therefore, we removed the Dentistry specialty set from this final rule because we did not receive any comments specific to the Dentistry specialty set from previous final rules or the proposed rule.

B.1. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Anesthesiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 426 and 427.

B.1. Anesthesiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0236	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	2681	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
! (Patient Safety)	N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	American Society of Anesthesiologists
	N/A	463	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years of age, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Anesthesiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.1. Anesthesiology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, the following measure(s) are removed from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	426	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU or other non-ICU location in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future."
N/A	427	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Anesthesiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.2. Cardiology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Cardiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 204 and 373.

B.2. Cardiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0081	005	CMS135 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40** percent**):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	CMS144 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan	National Committee for Quality Assurance
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: ACE Inhibitor or ARB Therapy--Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
*	0421	128	CMS69v	Medicare Part	Process	Community/	**Preventive Care and Screening: Body Mass**	Centers for

B.2. Cardiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§			7	B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications		Population Health	**Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022	238	CMS156 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

B.2. Cardiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP).	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period.	American College of Cardiology
! (Efficiency)	N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology
! (Efficiency)	N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified	American Heart Association

B.2. Cardiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications			thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism.	
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery**.**	Society for Vascular Surgeons
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communicati on and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
	N/A	438	CMS347 v2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermedi ate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must	Wisconsin Collaborativ e for Healthcare Quality

B.2. Cardiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	(WCHQ)
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for 6 months after discharge.	National Committee for Quality Assurance

Comment: One commenter supported the inclusion of measure Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting measure in this measure set. The commenter noted that the inclusion of the performance measure, in the MIPS Cardiology Specialty Measure Sets is a first and important step in improving physician referral habits; however, the commenter stated that it will also be important to include the corresponding measure, Cardiac Rehabilitation Patient Referral from an Inpatient Setting as well.

Response: We encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process to include the measure related to the inpatient setting.

FINAL ACTION: We are finalizing the *Cardiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication. We are no longer finalizing the inclusion of this measure as it is duplicative of a component within Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control).

B.2. Cardiology

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0068	204	CMS164v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is removed from the 2019 program based on the detailed below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	373	CMS65v8	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Cardiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.3. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Gastroenterology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we are not finalizing our proposal to remove Quality ID: 185 (MIPS CQMs Specifications) from the specialty set, but we are finalizing our proposal to remove Quality ID: 185 (Medicare Part B Claims Measure Specifications). Therefore, Q185 is now included in this measure set table for the final rule with MIPS CQMs Specifications as the collection type.

B.3. Gastroenterology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§ !	0659	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
§	0028	226	CMS138v7	Medicare Part B Claims Measure	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:**	Physician Consortium for

B.3. Gastroenterology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications			a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Performance Improvement Foundation (PCPI®)
§	N/A	271	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. Individuals who received an assessment for bone loss during the prior or current year are considered adequately screened.	American Gastro-enterological Association
§	N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastro-enterological Association
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroentero logical Association
§ ! (Outcome)	N/A	343	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or	American Society for Gastrointesti

B.3. Gastroenterology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy.	nal Endoscopy
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroentero logical Association
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroentero logical Association
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointesti nal Endoscopy
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening	Physician Consortium for Performance Improvement Foundation

B.3. Gastroenterology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	(PCPI®)
§ ! (Efficiency)	N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	American Gastroenterological Association

Comment: A few commenters did not support removal of measure Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use. One commenter noted that updated guidelines on the appropriate follow-up interval for patients with a history of adenomatous polyps are set to be released in the near future. This commenter noted that it is likely that the measure specifications will be updated at that point, which may alter clinician performance. This commenter recommended that CMS retain the measure in MIPS until it is able to review other stakeholder concerns about measure performance, and that CMS work with the measure developer to update the MIPS measure specifications when new guidelines are released.

Response: We agree that updated guidelines could affect the performance of this measure causing the measure to have a substantive change, and therefore, may no longer have a benchmark that is considered to be topped out. We note this measure shows a 97.7 percent average performance for Medicare Part B Claims Measure Specifications while the MIPS CQMs Specification (registry) version shows less than 97 percent average performance rate. Based on our extremely topped out measure removal policy, we are only finalizing the removal of this measure from the Medicare Part B Claims Measure Specification collection type for the 2019 performance period. We will not finalize the removal of MIPS CQM s Specification collection type. We will work with the measure steward to update for the new clinical guidelines once they are released and continue to monitor the performance of the MIPS CQM Measure Specification in the future.

Comment: One commenter expressed concern about the scoring methodology of measure Q343: Screening Colonoscopy Adenoma Detection Rate as a performance rate near 100 percent would not indicate better care. The commenter stated that in a typical population about 25 percent of colonoscopies should find an adenoma to set a benchmark of 25 percent for all populations. From a clinical and performance measure perspective, while it may be true that a 0 percent or 5 percent rate would be worrisome, the commenter stated there is no reason to believe that a rate of 20 percent is worse than 30 percent or that 40 percent is better than 35 percent or 45 percent. A rate of 90 percent would be suspicious.

Response: We will explore options to alter the scoring methodology to assign higher deciles to the 25th to 35th percentiles or consider removing the measure in future rulemaking. We encourage measure stewards to explore options that address appropriate adenoma detection and submit measures for consideration to the annual Call for Measures.

Comment: One commenter indicated that the measure steward listed in the proposed rule for measure Q343: Screening Colonoscopy Adenoma Detection Rate is incorrect and asked that the measure steward be corrected.

Response: We agree with the commenter that the measure steward was incorrectly listed as the American Gastroenterological Association. This has been updated to the American Society for Gastrointestinal Endoscopy.

FINAL ACTION: We are finalizing the *Gastroenterology Specialty Measure Set* as proposed for the 2019 Performance Period and future years. As noted above, we are not finalizing the removal of measure Q185 (MIPS CQM specification) from the *Gastroenterology Specialty Measure Set* for the 2019 Performance Period and future years; therefore, measure Q185 has been added back into this measure specialty set.

B.4. Dermatology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Dermatology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measure from the specialty set: Quality ID: 224.

B.4. Dermatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patients visits, regardless of age, with a new occurrence of melanoma, who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within 1 month of diagnosis.	American Academy of Dermatology
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Care Coordination)	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology

B.4. Dermatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic therapy who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment	American Academy of Dermatology
! (Care Coordination)	N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma: Biopsy Reporting Time – Pathologist to Clinician:** Basal Cell Carcinoma (BCC)/Squamous Cell Carcinoma (SCC): Biopsy Reporting Time – Pathologist to Clinician: Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

Comment: One commenter was pleased this measure set includes measures Q337: Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier and Q410: Psoriasis Clinical Response to Systemic Medication. Inclusion of these measures will advance psoriatic disease care and help to ensure that clinicians are accountable for meaningful measures that have the greatest impact on patient care.

A second commenter appreciated that CMS accepted its recommendations to update the description and expand the measure numerator and denominator.

Response: We thank the commenter for their support of these measures.

FINAL ACTION: We are finalizing the *Dermatology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.4 Dermatology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	224	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Melanoma: Avoidance of Overutilization of Imaging Studies:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Dermatology Measure Set* as proposed for the 2019 Performance Period and future years.

B.5. Family Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Family Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 163, 204, 334, 373, and 447.

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122 v7	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
§	0081	005	CMS135 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	CMS144 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0105	009	CMS128 v7	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment.	National Committee for Quality Assurance

B.5. Family Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriate Use)	0069	065	CMS154v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	066	CMS146v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an	National Committee for Quality Assurance

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							antibiotic and received a group A streptococcus (strep) test for the episode.	
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology - Head and Neck Surgery
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology - Head and Neck Surgery
	0104	107	CMS161 v7	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	2372	112	CMS125 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
§	0034	113	CMS130 v7	Medicare Part B Claims Measure	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality

B.5. Family Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications				Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
* §	0055	117	CMS131 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the	Centers for Medicare & Medicaid Services

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications			encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0022	238	CMS156v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care	0643	243	N/A	MIPS CQMs Specifications	Process	Communication and Care	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:**	American Heart

B.5. Family Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Coordination)						Coordination	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	Association
! (Opioid)	0004	305	CMS137 v7	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	0032	309	CMS124 v7	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	National Committee for Quality Assurance
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	CMS139 v7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 & 0006	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							• Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA- approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load	Health Resources and Services

B.5. Family Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							less than 200 copies/mL at last HIV viral load test during the measurement year.	Administration
! (Outcome)	N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710	370	CMS159 v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	0712	371	CMS160 v7	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	377	CMS90v 8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	1407	394	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three	Minnesota Community Measurement

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							age appropriate patient reported outcome tools.	
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the 6 months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the 6 months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least	Physician Consortium for Performance Improvement Foundation

B.5. Family Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	(PCPI®)
	N/A	438	CMS347 v2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for 6 months after discharge.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75 percent of their	National Committee for Quality Assurance

B.5. Family Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							treatment period.	
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Appropriate Use)	N/A	472	CMS249 v1	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	N/A	475	CMS349 v1	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

Comment: One commenter indicated that opportunities to assess the immunization status of Medicare beneficiaries for should be done by the range of clinicians who care for them, including primary care and specialty clinicians. Taking advantage of each and every patient encounter to ensure that counseling and education on vaccines, based on their age and health status, and a strong clinician recommendation have been found to improve the likelihood of a patient being immunized. The commenter supported the inclusion of measure Q110: Preventive Care and Screening Influenza Immunization and measure Q111: Pneumococcal Vaccination Status for Older Adults into a number of primary care and specialty quality measure sets. Prioritizing quality measures around immunizations will help close existing measure gaps, improve upon immunization rates and health outcomes for the millions of Medicare beneficiaries. A second commenter supported inclusion of measures Q110, Q111, Q394: Immunizations for Adolescents.

Response: We thank the commenters for their support of measures Q110, Q111, and Q394.

FINAL ACTION: We are finalizing the *Family Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future year with the exception of the following newly proposed measures: Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication and Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of this IVD measure as it is duplicative of a component within Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control). We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q048, Q154, Q155, and Q318 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.

B.5. Family Medicine

MEASURES FINALIZED FOR REMOVAL

Note: In this this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0056	163	CMS123 v7	eCQM Specifications	Process	Effective Clinical Care	**Comprehensive Diabetes Care: Foot Exam:** The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
0068	204	CMS164 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.	National Committee for Quality Assurance	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology-Otolaryngology- Head and Neck Surgery	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	373	CMS65v 8	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Chlamydia Screening and Follow Up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	This measure is removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Family Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future years. However, as noted in our responses to public comments in Table C, we are not finalizing the following measures for removal from this measure set: Q048, Q154, Q155, and Q318.

B.6. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Internal Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 163, 204, 276, 278, 334, 373, and 447.

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
§	0081	005	CMS135v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Stable Coronary Artery Disease: Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy—Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have prior MI OR a current or prior LVEF < 40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	0083	008	CMS144v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvement
	0105	009	CMS128v7	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on	National Committee for Quality Assurance

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	
! (Care Coord-ination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordinatio n)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
! (Appropriat e Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology -Head and Neck Surgery
! (Appropriat	0654	093	N/A	Medicare Part B Claims	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of**	American Academy of

B.6. Internal Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
e Use)				Measure Specifications, MIPS CQMs Specifications			**Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	Otolaryngology -Head and Neck Surgery
	0041	110	CMS147v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine	National Committee for Quality Assurance
§ ! (Appropriat e Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription	National Committee for Quality Assurance
* §	0055	117	CMS131v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§	0062	119	CMS134v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165v7	Medicare Part B Claims Measure	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose	National Committee for Quality

B.6. Internal Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications			blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	Assurance
! (Patient Safety)	0022	238	CMS156v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordinatio n)	0643	243	N/A	MIPS CQMs Specifications	Process	Communicatio n and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/ diagnosis who were referred to a CR program.	American Heart Association
	N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
! (Opioid)	0004	305	CMS137v 7	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment within 14 days of the diagnosis. • Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit.	National Committee for Quality Assurance
§	0032	309	CMS124v 7	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria:	National Committee for Quality Assurance

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							• Women age 21–64 who had cervical cytology performed every 3 years • Women age 30–64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.	
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	CMS139v 7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) •• Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ) Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA- approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery
!	N/A	332	N/A	MIPS CQMs	Process	Efficiency and	**Adult Sinusitis: Appropriate Choice of**	American

B.6. Internal Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
(Appropriate Use)				Specifications		Cost Reduction	**Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	Academy of Otolaryngology -Head and Neck Surgery
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery
	N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test	American Academy of Dermatology
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* § ! (Outcome)	0710	370	CMS159v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	MN Community Measurement
*	0712	371	CMS160v7	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A	377	CMS90v8	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	Health Services Advisory Group
	N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Outcome)	N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools.	Minnesota Community Measurement
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association/ American Society for Gastro-intestinal Endoscopy/ American College of Gastro-enterology
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.6. Internal Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	0053	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the 6 months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the 6 months after the fracture.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	438	CMS347v 2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients: all considered at high risk of cardiovascular events who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease(ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.6. Internal Medicine

MEASURES FINALIZED FOR INCLUSION								
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							measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated.	
§	0071	442	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Persistent Beta Blocker Treatment After a Heart Attack:** The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received were prescribed persistent beta-blocker treatment for 6 months after discharge.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma (MMA):** The percentage of patients 5-64 years of age during the measurement year who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75 percent of their treatment period.	National Committee for Quality Assurance
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
! (Appropriate Use)	N/A	472	CMS249v1	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients aged 50 to 64 without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	N/A	475	CMS349v1	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

Comment: One commenter supported measure Q277: Sleep Apnea: Severity Assessment at Initial Diagnosis and measure Q279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy in this measure set.

Response: We thank the commenter for their support.

FINAL ACTION: We are finalizing the *Internal Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future year with the exception of the following newly proposed measures: Ischemic Vascular Disease Use of Aspirin or Anti-platelet Medication and Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of this IVD measure as it is duplicative of a component within Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control). We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q048, Q154, Q155, and Q318 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years. Please note that measures Q468, Q472, Q474, and Q475 were included in the proposed rule for this specialty set; however, they did not have Quality # IDs at the time they were published in the proposed rule because they were new measures. They were included at the beginning of this specialty measure set table in the proposed rule with "TBD" as the Quality # IDs. Therefore, in this final rule, we replaced "TBD" with the assigned Quality # IDs Q468, Q472, Q474, and Q475, which were established for these new measures subsequent to the proposed rule publication and included these measures at the end of this measure set table in ascending order.

B.14. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Physical Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may re-assess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.14. Physical Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons
* §	0421	128	CMS69 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
!	0101	155	N/A	Medicare Part	Process	Communication	**Falls: Plan of Care:**	National

B.14. Physical Medicine

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
(Care Coordination)				B Claims Measure Specifications, MIPS CQMs Specifications		and Care Coordination	Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	Committee for Quality Assurance
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
§	0028	226	CMS13 8v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	CMS22 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the	American Academy of Neurology

B.14. Physical Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							medical record.	
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example, Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Physical Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q154 and Q155 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.								

B.15. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Preventive Medicine specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 014.

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122 v7	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	109	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs	Process	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain.	American Academy of Orthopedic Surgeons

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications				
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	2372	112	CMS125 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 51 - 74 years of age who had a mammogram to screen for breast cancer.	National Committee for Quality Assurance
§	0034	113	CMS130 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance
§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.15. Preventive Medicine

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							identified as a tobacco user.	
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	438	CMS347v2	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	/Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
	N/A	475	CMS349v1	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention

We did not receive specific comments regarding the measures included in this specialty measure set.

FINAL ACTION: We are finalizing the *Preventive Medicine Specialty Measure Set* as proposed for the 2019 Performance Period and future years. However, as noted in our responses to public comments in Table C, we are not finalizing the following measures for removal from this measure set: Q048. Q154, Q155. Therefore, measures Q048. Q154, Q155 are retained for the 2019 Performance Period and future years. These measures were previously included within the 2018 specialty measure set and therefore they will continue to be included in this measure set. To this end, we have deleted the Removal table in this final rule.

B.16. Neurology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Neurology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.16. Neurology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	NA	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims	Process	Community/ Population	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:**	Physician Consortium

B.16. Neurology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications		Health	a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	for Performance Improvement Foundation (PCPI®)
		268	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year.	American Academy of Neurology
	2872	281	CMS149 v7	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Psychiatric Association and American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others; and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association and American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12-month period.	American Psychiatric Association and American Academy of Neurology

B.16. Neurology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.	American Academy of Neurology
	N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.	American Academy of Neurology
!	N/A	293	N/A	Registry	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (for example, physical, occupational, or speech therapy) discussed in the last 12 months.	American Academy of Neurology
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP).	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
!	N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (for example, advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology

B.16. Neurology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example, Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
! (Efficiency) *	N/A	419	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI)
! (Outcome)	N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved	American Academy of Neurology

Comment: One commenter supported the inclusion of measure Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan. Comorbid depression is a frequent concern for patients with neurologic conditions.

Response: We thank the commenter for their support of measure Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan.

Comment: Two commenters do not support removal of Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences from this measure set. The commenters appreciated the effort to decrease redundancy between this measure and the Q047 Advance Care Plan measure. While these measures do overlap, the commenters noted that ALS measure specification recognizes the likely earlier age of onset of this devastating diagnosis and the need to have earlier planning conversations around palliative and end of life care by having no minimum age requirement. For this reason, the commenter believed the measure should be retained.

Response: We agree with the commenters concerns about removing measure Q386 and will not finalize this measure for removal. Specifically, we agree that patients with ALS are often younger than those in the denominator for measure Q047, which includes patients age 65 and older. For this reason, we concur with commenters that a separate measure applying to all patients with a diagnosis of ALS is clinically indicated.

Comment: One commenter requested that CMS consider adding the measure Q370: Depression Remission at Twelve Months to this measure set because they stated that comorbid depression is a frequent concern for patients with neurologic conditions.

Response: We note that this measure set does include Q134, which screens for depression and would address the commenter's concern of identifying comorbid depression. Prior to rulemaking, we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. The suggestion to add the measure to the Neurology specialty measure set was not provided as part of the feedback received from specialty stakeholders for the 2019 performance period. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking.

FINAL ACTION: We are finalizing the *Neurology Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q154, Q155, and Q386 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.

B.17. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Mental/Behavioral Health specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measure from the specialty set: Quality ID: 367.

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0105	009	CMS128 v7	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on antidepressant medication treatment. Two rates are reported: a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
	0104	107	CMS161 v7	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.	Physician Consortium for Performance Improvement
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	0418	134	CMS2v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs	Process	Community / Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications				
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder mal-treatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	2872	281	CMS149 v7	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Psychiatric Association and American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others; and (2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association and American Academy of Neurology
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association and American Academy of Neurology
	N/A	317	CMS22v7	Medicare Part B Claims	Process	Community /	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up**	Centers for Medicare &

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Measure Specifications, eCQM Specifications, MIPS CQMs Specifications		Population Health	**Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Medicaid Services
! (Care Coordination)	N/A	325	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by another clinician with communication to the clinician treating the comorbid condition.	American Psychiatric Association
	0108	366	CMS136 v8	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710	370	CMS159 v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	0712	371	CMS160 v7	eCQM Specifications	Process	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period.	MN Community Measurement
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	1365	382	CMS177 v7	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	1879	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).	National Committee for Quality Assurance
! (Care Coordination)	0576	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days of discharge. ● The percentage of discharges for which the patient received follow-up within 7 days of discharge.	National Committee for Quality Assurance
	N/A	402	NA	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	0711	411	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Six Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 6 months (+/- 60 days) after an index event date.	MN Community Measurement
	2152	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
! (Opioid)	N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder:** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

Comment: One commenter stated that the Mental/Behavioral Health Specialty Measure Set too narrowly defines the measures' denominator populations. This type of highly detailed specification inappropriately limits the users' abilities to apply otherwise applicable and useful measures to a larger percentage of patients. The commenter also stated that considering the frequency of medical comorbidity diagnoses and the fragmented health care delivery for serious mental illness (SMI) patients, it requested that CMS include more cross-cutting measures that address commonly diagnosed medical comorbidities among patients with SMI into the Mental/Behavioral Health Specialty Measure Set. Due to the nature of the encounter, the eligible clinician-psychiatrist might not utilize otherwise appropriate measures because it might be therapeutically inappropriate. The decision to employ a quality measure for all specialties must be made on a case-by-case basis.

Response: Prior to rulemaking, we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking. In addition, eligible clinicians are not limited to selecting measures from their specialty measure set, but have the opportunity to select any of the MIPS measure that are applicable to their practice and workflow. We encourage the commenter to collaborate with measure developers to create robust measures that address patient with serious mental illnesses with comorbidities. Once fully tested, we request the measure be submitted to the Call for Measures process for consideration.

Comment: One commenter stated that behavioral health clinicians (psychiatrists, clinical psychologists), while eligible for MIPS, may not have received the direction and

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**

attention that has been focused on other specialties. The commenter requested that CMS provide background on the development of its measures for these behavioral health clinicians and solicit input from these clinicians as to the appropriateness of those measures.

Response: The measures included within the measure specialty set have been reviewed and developed by specialty societies. Prior to rulemaking, we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking. Each of the measures included in the specialty measure sets is developed and stewarded by various measure stewards as indicated in the table. The measure steward revises the quality measure during the annual revision cycle based on their technical expert panel input and direction.

Comment: One commenter did not agree that new measures must be developed to specifically address patients with mental or substance use disorders and medical comorbidities. Measures that already exist for the general population would be adequate to use to monitor these conditions.

Response: We disagree and believe there is a gap in measurement that addresses mental and substance use disorders. Measures applicable to the general population are not appropriate to promote appropriate or adherence of treatment for patient with mental and substance use disorders with comorbidities.

Comment: One commenter requested that CMS test the measure Q105: Anti-Depressant Medication Management at the clinician-level before its continued use in MIPS.

Response: This measure has been in use at the clinician-level for several years without incident so we believe that its continued use in MIPS is appropriate until clinician-level testing is conducted by the steward. We will continue to encourage the steward to expand testing for this measure at the clinician-level.

Comment: One commenter was concerned about the denominator for measure Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment. As currently specified, the denominator limits screening for suicide to patients with new onset or recurrent episodes of Major Depressive Disorder (MDD), instead of applying it to patients with mood disorders, as supported by the measure's rationale and evidence to measure (part of the National Quality Forum's 2018 Spring Behavioral Health Measure Endorsement Cycle). Current evidence supports suicide risk assessments for an even broader population, like patients with other mental illnesses who present an increased safety risk. This measure would be better specified by including patients with comorbid-multiple psychiatric illnesses paired with increased substance use and medical conditions (that is, chronic pain). The commenter requested that CMS work with the measure's developers to also provide a definition of the term "assessment to avoid issues with the measure's reliability and to provide clarity to those clinicians who do not possess expertise in suicide risk assessments. In addition, the commenter recommended that measure Q107 include references on the use of validated rating scales designed for suicide screening and assessment.

Response: This measure was originally developed as part of a suite of measures to improve care for adults with major depressive disorder and was specified and tested for that population. We will give consideration to this suggestion in future updates of the measure. A change in the measure intent as suggested would require additional testing to understand the impact on measure performance, feasibility, reliability, and validity of the measure. A "suicide risk assessment" is defined more explicitly in the Numerator Details section in the human readable format of this measure's technical specifications. The clinical guideline statement also makes reference to key components of a complete assessment. Clinical guidance on how to address and manage patients who screen positive for suicidal ideation is provided in the human readable format of this measure's technical specifications. Use of a standardized tool or instrument to assess suicide risk will meet numerator performance, and can be mapped to a general SNOMED CT code: "Suicide risk assessment (procedure)". We encourage mapping to this concept in order to ensure that the suicide risk assessment was performed. We will work with the measure steward to consider reference to specific suicide risk assessment tools for clinician guidance in future updates of this measure.

Comment: One commenter stated that measure Q105: Anti-Depressant Medication Management consists of a limited denominator. Antidepressants may be prescribed to individuals who do not meet criteria for an MDD diagnosis. According to current evidence, various mental illnesses may be treated with antidepressants; as such, adherence to antidepressants result in more positive health outcomes for those for whom they are appropriately prescribed. Therefore, the commenter requested that CMS engage with the measure's developers and discuss widening the measure's population to consist of anyone prescribed antidepressants as guided by current evidence. Thus, this measure should not be considered for use in the MIPS quality performance category until it is tested and demonstrates valid and reliable measurement characteristics.

Response: This measure is focused on treating patients with major depression disorder. Expanding the denominator to include all patients taking antidepressants would change the intent of this measure. We will give consideration to this suggestion in future updates of the measure. A change in the measure intent as suggested would require additional testing to understand the impact on measure performance, feasibility, reliability, and validity of the measure.

Comment: One commenter appreciated that measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions remains in this measure set. The commenter interpreted the lack of the "Individual Measures List" proposed within the rule to mean that CMS solely supports quality measures as part of specialty measure sets, and the commenter concluded that clinicians would be required to select measures from one of the 33 specialty sets to meet the 6-measure (including one outcome or high priority measure) criteria.

Response: We thank the commenter for their support of measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions. Previously finalized measure sets were not republished in the proposed rule and remain available for applicable specialties.

FINAL ACTION: We are finalizing the *Mental/Behavioral Health Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.17. Mental/Behavioral Health

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	367	CMS169 v7	eCQM Specifications	Process	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter did not support removal of measure Q367: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use. The commenter stated that removal would make this measure set lack measures that address unhealthy substance use. The commenter did not agree that measure Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling is duplicative or superior to measure Q367. If the developers were to update the denominator to include the general population and the numerator to include data capture of the follow-up actions related to the appraisal, this measure would be more useful in MIPS than is measure Q431.

Response: Currently, Q367 does not include follow-up actions when there is identified alcohol or substance abuse. The measure steward has not currently specified this for Q367 and although they could add it in the future, it would not be in enough time to implement for the 2019 performance period. Q431 is currently more robust as it includes the requirement of a follow-up action in identified alcohol or substance abuse patients. We agree with the commenter that a measure with a broader denominator to include the general population and the numerator to include data capture of the follow-up actions related to the appraisal would be appropriate. These revisions would require a new measure to be submitted to the Call for Measures process. We encourage the commenter to collaborate with measure developers to create a measure as suggested.

FINAL ACTION: We are finalizing the removal of measures from the *Mental/Behavioral Health Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.18. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Diagnostic Radiology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 359 and 363.

B.18. Diagnostic Radiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Efficiency)	0508	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign."	American College of Radiology
! (Care Coordination)	N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (for example, x-ray, MRI, CT, etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
	0507	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
!	0509	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology
! (Patient Safety)	N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Patient Safety)	N/A	361	N/A	MIPS CQMs Specifications	Structure	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age,	American College of Radiology

B.18. Diagnostic Radiology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							that are reported to a radiation dose index registry that is capable of collecting at a minimum selected data elements.	
!	N/A	362	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study.	American College of Radiology
* ! (Appropriate Use)	N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (for example, type of imaging or biopsy) or for no follow-up, and source of recommendations (for example, guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology
! (Appropriate Use)	N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for abdominal imaging studies for asymptomatic patients aged 18 years and older with one or more of the following noted incidentally with follow-up imaging recommended: • Liver lesion ≤ 0.5 cm. • Cystic kidney lesion < 1.0 cm. • Adrenal lesion ≤ 1.0 cm.	American College of Radiology
! (Appropriate Use)	N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck or ultrasound of the neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing CT with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.18. Diagnostic Radiology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**

Comment: One commenter noted on measure Q436: Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques that there is equivalency of a site-based attestation and an attestation included in the individual radiology report. In practice, these generic attestations included in the report are not dictated case-by-case, but rather automatically added to all CT templates in order to satisfy the measure. Adding additional generic comments necessarily lengthens our reports, making it less likely that the requesting clinician will read the entire report or identify the clinically relevant information. The commenter suggested the following: Site-based attestations be sufficient to meet measure Q436, without requiring documentation in each individual adult CT report.

Response: This measure does not require detailed comments that would lengthen a report, but requires general attestation statement in the final report; however, there would need to be a written policy in place describing the process that ensures dose optimization techniques are used appropriately per instrument/room, as well as a method for validating that their use occurs for each patient. This may include periodic audits.

FINAL ACTION: We are finalizing the *Diagnostic Radiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.18. Diagnostic Radiology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	359	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	363	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.	American College of Radiology	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter did not support removal of measure Q359: Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging. The commenter also did not support the removal of measure Q363: Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive. The commenter indicated that the number of radiology measures is limited, and that additional measures should be added before additional measures are removed, and CMS should also encourage clinicians to take greater advantage of existing studies as a means of reducing unnecessary duplicative exams.

Response: We encourage measure developers to submit additional radiology measures through the Call for Measures process. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

FINAL ACTION: We are finalizing the removal of measures from the *Diagnostic Radiology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.19. Nephrology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Nephrology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 122 and 327.

B.19. Nephrology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0059	001	CMS122 v7	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications, eCQM Specifications.	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0 percent during the measurement period.	National Committee for Quality Assurance
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (for example hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs	Process	Community / Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.19. Nephrology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				Specifications				
§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordinat ion)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communica tion and Care Coordinatio n	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
	0101	318	CMS139 v7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Outcome)	1667	328	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/dL:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL.	Renal Physicians Association
!	N/A	330	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Adult Kidney Disease: Catheter Use for Greater Than or Equal to 90 Days:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving maintenance hemodialysis for greater than or equal to 90 days whose mode of vascular access is a catheter.	Renal Physicians Association
§	N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-	Physician Consortium for Performance Improvement

B.19. Nephrology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							time screening for hepatitis C virus (HCV) infection.	
! (Patient Experience)	N/A	403	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of ESRD who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care.	Renal Physicians Association
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Nephrology Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measure Q386 is not finalized for removal from this measure set as proposed; therefore, it will be retained in this measure set for the 2019 Performance Period and future years.								

B.19. Nephrology (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	122	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.	Renal Physicians Association	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	327	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.	Renal Physicians Association	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the proposed removal of measures from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Nephrology Specialty Measure Set* as proposed for the 2019 Performance Period and future years. However, as noted in our responses to public comments in Table C, we are not finalizing the following measure proposed for removal from this measure set: Q318.

B.20. General Surgery

In addition to the considerations discussed in the introductory language of Table B in this final rule, the General Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.20. General Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (for example, hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years of age and older seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is submitted as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	CMS69 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25	Centers for Medicare & Medicaid Services

B.20. General Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							kg/m2.	
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	CMS13 8v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
	N/A	317	CMS22 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30-day postoperative period.	American College of Surgeons
! (Outcome)	N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care	N/A	374	CMS50 v7	eCQM Specifications,	Process	Communication and Care	**Closing the Referral Loop:** Receipt of Specialist Report	Centers for Medicare &

B.20. General Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Coordination)				MIPS CQMs Specifications		Coordination	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

Comment: One commenter noted the inclusion of measure Q264: Sentinel Lymph Node Biopsy for Invasive Breast Cancer measure as a new measure in this measure set in the 2019 performance year. They support the inclusion of this measure in this measure set.

Response: We thank the commenter for their support.

FINAL ACTION: We are finalizing the *General Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years. Note: Measure Q263 was incorrectly attributed to this measure set and proposed as a removal from this measure set in the proposed rule; therefore, the removal table that included measure 263 has been deleted from this final rule.

B.21. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Vascular Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 257 and 423.

B.21. Vascular Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138	Medicare Part	Process	Community/	**Preventive Care and Screening: Tobacco Use:**	Physician

B.21. Vascular Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
			v7	B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications		Population Health	**Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Outcome)	0018	236	CMS165 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Elective Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged at Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services

B.21. Vascular Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1534	347	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) Who Are Discharged Alive:** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
! (Outcome)	N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	1523	417	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) who are discharged alive.	Society for Vascular Surgeons
! (Outcome)	N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report	Society of Interventional Radiology

B.21. Vascular Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							an improvement on a disease specific patient reported outcome survey instrument after treatment.	
! (Outcome)	N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Vascular Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.21. Vascular Surgery (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
1519	257	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge.	Society for Vascular Surgeons	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
0465	423	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery.	Society for Vascular Surgeons	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter stated that measure Q257: Statin Therapy at Discharge after Lower Extremity Bypass (LEB) is not duplicative of the new measure for Ischemic Vascular Disease – Use of Aspirin or Anti-platelet Medication proposed for 2019. An important part of this measure is its timeframe. In many institutions, anti-platelet agents are stopped 7 days prior to any procedure/operation. Ensuring that the patient stays on the antiplatelet agent in the pre-operative period often requires extra effort and coordination so the commenter believed measure Q257 should be maintained for 2019. The benefit of statins has been well-documented.

Response: We agree with the commenter that it is not duplicative of a proposed measure Ischemic Vascular Disease – Use of Aspirin or Anti-platelet Medication. We cited that this measure was duplicative of measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.

FINAL ACTION: We are finalizing the removal of measures from the *Vascular Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.22. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Thoracic Surgery specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 043, 236, and 441.

B.22. Thoracic Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Outcome)	0129	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0130	165	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or	Society of Thoracic Surgeons

B.22. Thoracic Surgery

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							mediastinum requiring operative intervention	
! (Outcome)	0131	166	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (that is, any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population	**Tobacco Use and Help with Quitting Among Adolescents:**	National Committee for

B.22. Thoracic Surgery

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
						Health	The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	Quality Assurance
§ !	0119	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

Comment: One commenter noted that the correct measure steward for the following measures should be the "Society of Thoracic Surgeons": Q164: CABG: Prolonged Intubation; Q165: CABG: Deep Sternal Wound Infection Rate; Q166: CABG: Stroke; Q167: CABG: PostOp Renal Failure

Response: We have updated the measure steward for these measures accordingly.

Comment: The commenter stated that measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented is not appropriate for the Thoracic Surgery Specialty Set and requested its removal for CY 2019. The commenter noted that blood pressure management is outside of the scope of practice of cardiothoracic surgeons.

Response: We do not agree to remove the measure from the Thoracic Surgery specialty set because if the patient has an elevated blood pressure at post-op, it is within the thoracic surgeon's scope to recommend a follow-up with the patient's PCP. In addition, we believe that if the thoracic surgeon should assess a patient at pre-operatively or post-operatively, there should be blood pressure screening.

Comment: One commenter supported inclusion of measures Q358: Patient-Centered Surgical Risk Assessment and Communication.

Response: We thank the commenter for their support of measure Q358: Patient-Centered Surgical Risk Assessment and Communication.

FINAL ACTION: We are finalizing the *Thoracic Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.22. Thoracic Surgery (continued)

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, CMS removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0134	043	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
0018	236	CMS165 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance	We agree with specialty society feedback to remove this measure from this specialty set because blood pressure control is managed by care team members other than the cardiothoracic surgeon. Blood pressure outcomes are more likely attributed to the primary care provider or cardiologist. These eligible clinicians are part of the core treatment team that is responsible for the ongoing hypertension therapy.
N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg; and • Most recent tobacco status is Tobacco Free; and • Daily Aspirin or Other Antiplatelet Unless Contraindicated; and • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)	We agree with specialty society feedback to remove this measure from this specialty set because the outcomes and medications within the measure are managed by care team members other than the cardiothoracic surgeon. Blood pressure and tobacco cessation outcomes are more likely attributed to the primary care provider or cardiologist. These eligible clinicians are part of the core treatment team that is responsible for the ongoing ischemic vascular disease care.

Comment: One commenter opposed removal of measure Q043: CABG: Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery due to topped out status. The commenter stated that IMA use is so important to long-term graft patency and if CMS removes this life-saving measure from MIPS, there will be little incentive for clinicians to report it and thus, a natural tendency for performance to slip without anyone's knowledge. The commenter opposed the proposal to modify the existing topped-out measure policy to allow for the immediate removal of highly topped out measures.

Response: This measure leaves little room for improvement as reflected in the 2018 MIPS Benchmark Results as an average performance rate of 99 percent which supports the removal as it is a standard of care. The measure has limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying and restricts the creation of meaningful benchmarks. This provides little incentive for clinicians to report the measure since the performance data does not allow for maximum points to be awarded. We advise the commenter to collaborate with measure developers to submit more robust or outcome measures through

the Call for Measures process.

Comment: One commenter did not see that measure Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control) was in the removal table for Thoracic Surgery in the proposed rule, but supported its removal since not all of the four goals reflected in the measure are appropriate for acute surgical patients.

Response: We thank the commenter for feedback regarding the removal of this measure. We agree with the commenter's assessment that not all of the goals are applicable for this specialty. The measure was inadvertently not included in this specialty measure set tables but it was our intent to remove this measure from this specialty measure set based on similar feedback received prior to the public comment period.

Comment: Several commenters supported the removal of measure Q236: Controlling High Blood Pressure. Blood pressure control is managed by care team members other than the cardiothoracic surgeon.

Response: We thank the commenters for supporting the removal of measure Q236: Controlling High Blood Pressure.

FINAL ACTION: We are finalizing the removal of measures from the *Thoracic Surgery Specialty Measure Set* as proposed for the 2019 Performance Period and future years. Note: We are also including the removal of Q441 based on public comments above supporting removal.

B.23. Urology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Urology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set.

B.23. Urology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A	048	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Assessment of Presence or Absence Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389	102	CMS129 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0390	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

§	0062	119	CMS134 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
!	N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician.	American Academy of Dermatology
	N/A	317	CMS22v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by	American College of Surgeons

							their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	428	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation of stress urinary incontinence prior to pelvic organ prolapse surgery per ACOG/AUGS/AUA guidelines.	American Urogynecologic Society
! (Patient Safety)	N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
	2152	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement
! (Outcome)	N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing any surgery to repair pelvic organ prolapse who sustains an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
	N/A	462	CMS645 v2	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

Comment: One commenter noted that the proposed rule Urology Specialty Measure Set listed a measure for Benign Prostatic Hyperplasia and questioned its measure specifications.

Response: This measure was included in error and has been removed from the final rule. The measure will be reviewed for future consideration.

FINAL ACTION: We are finalizing the *Urology Specialty Measure Set* as proposed for the 2019 Performance Period and future years. Note: As noted in our responses to public comments in Table C, measure Q048 is not finalized for removal from this measure set as proposed; therefore, it is retained in this measure set for the 2019 Performance Period and future years.

B.24a. Oncology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Oncology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.24a. Oncology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389	102	CMS129v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0041	110	CMS147v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, andvitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0384	143	CMS157v	eCQM	Process	Person and	**Oncology: Medical and Radiation – Pain**	Physician

B.24a. Oncology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)			7	Specifications, MIPS CQMs Specifications		Caregiver Centered Experience and Outcome	**Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§	1853	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Population/ Community	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief**	Physician Consortium

B.24a. Oncology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							Counseling: Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	for Performance Improvement Foundation (PCPI)
§ ! (Appropriate Use)	1857	449	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies:** Percentage of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2) negative who are not administered HER2-targeted therapies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	1858	450	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Trastuzumab Received By Patients With AJCC Stage I (T1c) –III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy:** Proportion of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving trastuzumab.	American Society of Clinical Oncology
§	1859	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy::** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed.	American Society of Clinical Oncology
§ ! (Patient Safety)	1860	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	N/A	454	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer with More than One Emergency Department Visit in the Last 30 Days of Life (lower score – better):** Proportion of patients who died from cancer with more than one emergency room visit in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life**	American Society of Clinical

B.24a. Oncology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
)							**(lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	Oncology
§ ! (Appropriate Use)	0215	456	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Not Admitted To Hospice (lower score – better):** Proportion of patients who died from cancer not admitted to hospice.	American Society of Clinical Oncology
§ ! (Outcome)	0216	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
	N/A	462	CMS645v2	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Oncology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.24b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Radiation Oncology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measure from the specialty set: Quality ID: 156.

B.24b. Radiation Oncology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0389	102	CMS129 v8	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Physician Consortium for Performance Improvement Foundation (PCPI®)
§ ! (Patient Experience)	0384	143	CMS157 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* ! (Patient Experience)	0383	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain:** Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician.	American Society of Clinical Oncology

Comment: One commenter requested that its specialty be able to report the entire specialty specific measure set through a single collection type of their choice. The commenter was concerned that the eCQM reporting mechanism is not available for all three measures within the Radiation Oncology subspecialty measure set, which inhibits complete quality reporting of the subspecialty measure set via an EHR. The commenter urged CMS to continue to work with third-party measure stewards to allow EHR submission of each of the quality measures in the radiation oncology measure set and alleviate reporting burden.

Response: We regularly evaluate to identify measures that could be specified as an eCQM. There are some measures that are currently unable to be captured via an eCQM Specification but we will continue to work with the measure stewards to determine the future implementation of an eCQM Specification for measure Q144.

FINAL ACTION: We are finalizing the *Radiation Oncology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.24b. Radiation Oncology

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A	156	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	American Society for Radiation Oncology	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

We did not receive specific comments regarding the measures removed from this specialty measure set.

FINAL ACTION: We are finalizing the removal of measures from the *Radiation Oncology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.25. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Infectious Disease specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. In addition, as outlined at the end of this table, we removed the following quality measures from the specialty set: Quality IDs: 065, 066, 091, 093, 116, 128, 176, 226, 275, 331, 332, 333, 334, 337, 387, 390, 394, 400, 401, and 447.

B.25. Infectious Disease

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
§	0409	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection.	National Committee for Quality Assurance
§ ! (Outcome)	2082	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period, with a minimum of 60 days between medical	Health Resources and Services Administration

B.25. Infectious Disease

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							visits.	
! (Appropriate Use)	N/A	407	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment of Methicillin-Sensitive Staphylococcus Aureus (MSSA) Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (for example nafcillin, oxacillin or cefazolin) as definitive therapy.	Infectious Diseases Society of America
	N/A	475	CMS349 v1	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients 15-65 years of age who have ever been tested for human immunodeficiency virus (HIV).	Centers for Disease Control and Prevention
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency, and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Infectious Disease Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0069	065	CMS154 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months--18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for children with upper respiratory infections, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	066	CMS146 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate testing for children with pharyngitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology -Head and Neck Surgery	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care,

B.25. Infectious Disease

MEASURES FINALIZED FOR **REMOVAL** Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
								pediatricians, or other physicians to assess appropriate topical therapy treatment for patients with acute otitis externa. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate topical therapy treatment for patients with acute otitis externa, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis:** Percentage of adults 18-64 years of age with a diagnosis of acute bronchitis who were not dispensed an antibiotic prescription.	National Committee for Quality Assurance	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess the appropriate use of antibiotics for patients with acute bronchitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
								physicians only working within outpatient settings.
0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of routine preventive care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by rheumatologists or other physicians as part of disease management for rheumatoid arthritis for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation	Physician Consortium for Performance Improvement Foundation (PCPI®)	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of preventive care for patients. Most infectious disease physicians consult on

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
						intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.		patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastro-enterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by gastroenterologists or other physicians as part of inflammatory bowel disease management. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery	Most infectious disease physicians consult on patients in the inpatient setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin**	American Academy of Otolaryngology-	Most infectious disease physicians consult on patients in the inpatient

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
						With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use): Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	Head and Neck Surgery	setting. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis, hence this measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice. We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of Infectious Disease physicians only working within outpatient settings.
N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Otolaryngology - Head and Neck Surgery	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, otolaryngologists, or other physicians to assess appropriate treatment for patients diagnosed with acute sinusitis. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology - Otolaryngology - Head and Neck Surgery	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."
N/A	337	N/A	MIPS CQMs	Process	Effective	**Psoriasis: Tuberculosis (TB)**	American	We agree with specialty

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
			Specifications		Clinical Care	**Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier :** Percentage of patients, regardless of age, with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier whose providers are ensuring active tuberculosis prevention either through yearly negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	Academy of Dermatology	society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by dermatologists, rheumatologists, or other physicians to ensure appropriate testing prior to treatment with a biological immune response modifier. . Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	Physician Consortium for Performance Improvement	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians as part of screening process for a high risk patient population. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient.	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, gastroenterologists, or other physicians to promote shared decision making with patient with hepatitis C.

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
						To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.		Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
1407	394	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.	National Committee for Quality Assurance	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, pediatricians, or other physicians as part of well child care for patients. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We agree with specialty society feedback that this measure is neither an applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care or other physicians to assess the appropriate screening for a high-risk patient population. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with**	American Gastroenterological Association	We agree with specialty society feedback that this measure is neither an

B.25. Infectious Disease

MEASURES FINALIZED FOR REMOVAL

Note: In this final rule, we removed the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						Cirrhosis: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.		applicable nor a clinically relevant quality measure to assess the clinical performance of an Infectious Disease physician. This measure applies to the outpatient setting and is reported by primary care, gastroenterologists, or other physicians to ensure appropriate screening for patients with cirrhosis. Most infectious disease physicians consult on patients in the inpatient setting. This measure does not support the inpatient setting where the majority of eligible clinicians within this specialty practice.
N/A	447	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Chlamydia Screening and Follow Up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	This measure is being removed from the 2019 program based on the detailed rationale described below for this measure in "Table C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years."

Comment: One commenter supported removing measure Q065: Appropriate Treatment for Children with Upper Respiratory Infection, Appropriate Testing for Children with Pharyngitis and Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis from the Infectious Disease set. That set focuses on acute care while these measures focus on primary care.

Response: We thank the commenter for their support on removal of this measure.

Comment: One commenter noted that there will be a negative impact from the removal of measures Q130 and Q226 on quality reporting for Infectious Disease specialists and across all eligible medical specialties. They noted that according to the 2016 PQRS Experience Report the 41 MD/DO specialties listed in Table 14: Top Reported Individual Measures by Specialty or Provider Type (2016) in the 2016 PQRS Experience Report, Q130 was the top measure reported by 29 specialties (70 percent) and Q226 was reported the second most by 21 specialties (51 percent). In addition, across all medical specialties claims-based reporting was the most utilized method of reporting for the 2016 PQRS program. With the above rationale, the commenter asked CMS to consider retaining measure Q130 and Q226 as they would not only affect the opportunities to report for Infectious Disease physicians but most of medical specialties.

Response: To clarify, measure Q130 was not proposed for removal from the Infectious Disease specialty measure set nor from the 2019 Quality Payment Program as a whole, and therefore, will be retained for reporting. Also to clarify further, Q226 was not proposed for removal from the program in general but only proposed to be removed from the Infectious Disease specialty measure set. While we agree that Q226 is a highly reported measure that is applicable to many eligible clinicians, we received specific feedback from specialty societies that this measure was not applicable to most infectious disease physicians as they mostly consult in an inpatient setting. Q226 is specific to the outpatient setting and therefore would not be applicable to most infectious disease physicians.

FINAL ACTION: We are finalizing the removal of measures from the *Infectious Disease Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.26. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Neurosurgical specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.26. Neurosurgical

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0268	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
	N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within 2 hours of time last known well and for whom IV t-PA was initiated within 3 hours of time last known well.	American Heart Association
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.26. Neurosurgical

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	1543	345	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CAS who are stroke free while in the hospital or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	1540	346	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA) Who Are Stroke Free or Discharged Alive:** Percent of asymptomatic patients undergoing CEA who are stroke free or discharged alive following surgery.	Society for Vascular Surgeons
! (Outcome)	N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than 2 hours.	Society of Interventional Radiology
* ! (Outcome)	N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to 3 months postoperative) in back pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure.	MN Community Measurement
* ! (Outcome)	N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Back Pain Following Lumbar Fusion:** The average change (preoperative to 1 year postoperative) in back pain for patients 18 years of age or older who had lumbar spine fusion surgery.	MN Community Measurement
* ! (Outcome)	N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Discectomy and/or Laminotomy:** The average change (preoperative to 3 months postoperative) in leg pain for patients 18 years of age or older who had lumbar discectomy laminotomy procedure.	MN Community Measurement
! (Patient Experience)	2643	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Spine Fusion Surgery:** For patients aged 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative functional status to 1 year (9 to 15 months post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery:** For patients aged 18 and older undergoing lumbar discectomy laminotomy surgery, the average change from pre-operative functional status to 3 months (6 to 20 weeks) post-operative functional status using the Oswestry Disability Index (ODI version 2.1a) patient reported outcome tool.	Minnesota Community Measurement
! (Patient Experience)	N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Average Change in Leg Pain Following Lumbar Spine Fusion Surgery:** For patients aged 18 and older undergoing lumbar spine fusion surgery, the average change from pre-operative leg pain to 1 year (9 to 15 months) post-operative leg pain using the Visual Analog Scale (VAS) patient reported outcome tool.	Minnesota Community Measurement

B.26. Neurosurgical

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**

Comment: One commenter requested for measure Q023: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients) that the measure be changed to exclude unicompartmental/partial knee replacement in the denominator until the developer can consider the inclusion of ASA for acceptable prophylaxis consistent with current guidelines.

Response: We agree that the measure should align with current clinical guidelines. We will provide this suggestion to the measure steward for future consideration in the annual updates of the measure specifications.

Comment: One commenter supported measure Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy in this measure set. The commenter encouraged CMS to continue to consider measurement and payment of high quality, cost effective stroke care in all settings, including in the hospital inpatient setting.

Response: We thank the commenter for their support of measure Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy.

Comment: Once commenter expressed concern about the following new measures in this measure set: Q469: Average Change in Functional Status Following Lumbar Spine Fusion Surgery; Q471: Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery; and Q473: Average Change in Leg Pain Following Lumbar Spine Fusion Surgery. Although the commenter supported the measures in concept, they noted that the measures require the use of specific tools to capture pain (that is, Visual Analog Scale or VAS) and functional status (that is, Oswestry Disability Index or ODI) despite the existence of equally useful scoring systems. The commenter also noted these measures should provide more flexibility to clinicians by instead focusing more generically on "improvement on a validated pain or disability patient-reported outcome tool." The commenter further expressed concern that they were never consulted about the appropriateness of these measures and would have appreciated an earlier opportunity to provide feedback.

Response: The measure steward has developed and tested these measures using the VAS and ODI tools to assess the change in status. We do not own this measure and encourage the commenter to collaborate with the measure steward to expand the assessment tools. With regard to concerns about measure selection input for this specialty set, prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking.

FINAL ACTION: We are finalizing the *Neurosurgical Specialty Measure Set* as proposed for the 2019 Performance Period and future years.

B.27. Podiatry

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Podiatry specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.27. Podiatry

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention- Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	0421	128	CMS69v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
§	0028	226	CMS138v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	Physician Consortium for Performance Improvement Foundation (PCPI®)
	0101	318	CMS139v7	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.27. Podiatry

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Podiatry Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. In addition, as noted in our responses to public comments in Table C, measures Q154, Q155, and Q318 are not finalized for removal from this measure set as proposed; therefore, they will be retained in this measure set for the 2019 Performance Period and future years.								

B.28. Rheumatology

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Rheumatology specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This measure set does not have any measures removed from prior years.

B.28. Rheumatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N	024	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	CMS147 v8	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement Foundation (PCPI®)
*	N/A	111	CMS127 v7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0421	128	CMS69v 7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services

B.28. Rheumatology

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0419	130	CMS68v8	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
*	N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).	American College of Rheumatology
*	N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50 percent of encounters for RA for each patient during the measurement year.	American College of Rheumatology
	N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A	179	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months.	American College of Rheumatology
	N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
§	0028	226	CMS138v7	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications,	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were screened for tobacco use and identified as a tobacco user who received tobacco cessation	Physician Consortium for Performance Improvement Foundation (PCPI®)

B.28. Rheumatology

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				MIPS CQMs Specifications			intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	
§ !! (Outcome)	0018	236	CMS165 v7	Part B Claims Measure Specifications, eCQM Specifications, Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mmHg) during the measurement period	National Committee for Quality Assurance
! (Patient Safety)	0022	238	CMS156 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 6565 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	N/A	317	CMS22v 7	Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A	374	CMS50v 7	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
We did not receive specific comments regarding the measures included in this specialty measure set. **FINAL ACTION:** We are finalizing the *Rheumatology Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.29. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Physical Therapy/Occupational Therapy specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.29. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0421	128	CMS69v 7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m2.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0419	130	CMS68v 8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
! (Care Coordination)	2624	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
! (Outcome) *	0422	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure	Focus on Therapeutic Outcomes, Inc.

B.29. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	
! (Outcome) *	0423	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0424	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0425	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0426	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.).The measure	Focus on Therapeutic Outcomes, Inc.

B.29. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	
! (Outcome) *	0427	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.
! (Outcome) *	0428	223	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with General Orthopedic Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey).	Focus on Therapeutic Outcomes, Inc.

Comment: One commenter supported the creation of the Physical and Occupational Therapy Specialty Measure Set. The commenter encouraged CMS to make two additional measures available to physical therapists (Q126 Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation; and Q127 Diabetic Foot and Ankle Care, Ulcer Prevention Evaluation of Footwear) and three additional measures available to occupational therapists (Q134 Screening for Depression and Follow-Up Plan); Q181 Elder Maltreatment Screen and Follow-Up Plan); and Q226 Tobacco Use: Screening and Cessation Intervention).

Response: We will provide this recommendation to the measure steward for measures Q126 Diabetic Foot and Ankle Care, Peripheral Neuropathy: Neurological Evaluation, Q127 Diabetic Foot and Ankle Care, Ulcer Prevention Evaluation of Footwear, and Q226 Tobacco Use: Screening and Cessation Intervention. We will evaluate the commenter's request for inclusion for future revisions for measures Q134 Screening for Depression and Follow-Up Plan, Q181 Elder Maltreatment Screen and Follow-Up Plan. We maintain that the measures are still valid as currently specified which includes many clinical settings, but will thoroughly vet the request to include physical and occupational therapy.

FINAL ACTION: We are finalizing the *Physical Therapy/Occupational Therapy Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. .

B.30. Geriatrics

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Geriatrics specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.30. Geriatrics

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
§ ! (Care Coordination) *	0097	046	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (for example hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age. • Submission Criteria 2: 65 years and older. • Total Rate: All patients 18 years of age and older.	National Committee for Quality Assurance
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Experience)	N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
	0041	110	CMS147v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
*	N/A	111	CMS127v7	Medicare Part B Claims Measure Specifications,	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.30. Geriatrics

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				eCQM Specifications, MIPS CQMs Specifications				
! (Patient Safety)	0419	130	CMS68 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0022	238	CMS15 6v7	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in the Elderly:** Percentage of patients 6565 years of age and older who were ordered high-risk medications. Two rates are reported. a. Percentage of patients who were ordered at least one high-risk medication. b. Percentage of patients who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	2872	281	CMS14 9v7	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	Physician Consortium for Performance Improvement
	N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Academy of Neurology
	N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented symptoms screening for behavioral and psychiatric symptoms, including depression, AND for whom, if symptoms screening was positive, there was also documentation of recommendations for symptoms management in the last 12 months.	American Academy of Neurology
! (Patient Safety)	N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: (1) dangerousness to self or others; and (2)	American Academy of Neurology

B.30. Geriatrics

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	
! (Care Coordination)	N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Academy of Neurology
* § ! (Outcome)	0710	370	CMS159v7	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Opioid)	N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology
! (Opioid)	N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than 6 weeks duration evaluated for risk of opioid misuse using a brief validated instrument (for example Opioid Risk Tool, SOAPP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology
§ ! (Outcome)	0213	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet

Comment: One commenter recommended that this measure set be finalized. The commenter appreciated CMS' support of measures for the geriatrics population that CMS expends the most resources. The commenter noted that measure: Q474: Zoster (Shingles) Vaccination is not presently covered under Medicare Part B. The only Part B covered vaccines are influenza, hepatitis, and pneumococcal pneumonia. Because the Zoster (Shingles) vaccine is covered under Part D patients may incur cost-sharing obligations.

Response: This measure is being implemented as a MIPS CQM measure specification which allows all payer data. We appreciate the concern but believe this is a valuable measure that will promote the vaccination and open dialogue between the patient eligible clinician regarding the benefits of this vaccine.

FINAL ACTION: We are finalizing the *Geriatrics Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population.

B.31. Urgent Care

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Urgent Care specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.31. Urgent Care

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0069	065	CMS154 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months-18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.	National Committee for Quality Assurance
! (Appropriate Use)	N/A	066	CMS146 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.	National Committee for Quality Assurance
! (Appropriate Use)	0653	091	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Appropriate Use)	0654	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
§ ! (Appropriate Use)	0058	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis:** The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.	National Committee for Quality Assurance
! (Patient Safety)	0419	130	CMS68v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0420	131	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Pain Assessment and Follow-Up:** Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present.	Centers for Medicare & Medicaid Services
§	0028	226	CMS138 v7	Medicare Part B Claims Measure Specifications, eCQM Specifications,	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older	Physician Consortium for Performance Improvement

B.31. Urgent Care

MEASURES FINALIZED FOR **INCLUSION**								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
				CMS Web Interface Measure Specifications, MIPS CQMs Specifications			who were screened for tobacco use and identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user.	
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
! (Appropriate Use)	N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Appropriate Use)	N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
! (Appropriate Use)	N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)
	N/A	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2152	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.	Physician Consortium for Performance Improvement
! (Patient Safety)	0657	464	N/A	MIPS CQMs Specifications	Process	Patient Safety, Efficiency and Cost Reduction	**Otitis Media with Effusion (OME): Systemic Antimicrobials- Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAOHNSF)

B.31. Urgent Care

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Comment: One commenter thanked CMS for the creation of the Urgent Care specialty set that impacts many specialties. Delineation of a specialty measure set for urgent care medicine will assist physicians and other health care providers who practice in urgent care centers with measure selection, compliance with MIPS requirements, and, most importantly, practice improvement in a setting where tens of millions of patient visits occur annually. **Response:** We thank the commenter for their support of this new measure set. **FINAL ACTION:** We are finalizing the *Urgent Care Specialty Measure Set* as proposed for the 2019 Performance Period and future years.								

B.32. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B in this final rule, the Skilled Nursing Facility specialty set takes into consideration the following criteria, which includes, but is not limited to: the measure reflects current clinical guidelines and the coding of the measure includes the specialists. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. This is a new specialty set for 2019; therefore, we are not removing any measures from this specialty set.

B.32. Skilled Nursing Facility

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
§	0070	007	CMS145 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI OR a current or prior LVEF <40 percent who were prescribed beta-blocker therapy.	Physician Consortium for Performance Improvement
§	0083	008	CMS144 v7	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40 percent who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	Physician Consortium For Performance Improvemen
! (Care Coordination)	0326	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0041	110	CMS147 v8	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	Physician Consortium for Performance Improvement
§	0066	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40 percent who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
!	0101	154	N/A	Medicare Part	Process	Patient	**Falls: Risk Assessment:**	National

B.32. Skilled Nursing Facility

MEASURES FINALIZED FOR INCLUSION								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
(Patient Safety)				B Claims Measure Specifications, MIPS CQMs Specifications		Safety	Percentage of patients aged 65 years and older with a history of falls who had a risk assessment for falls completed within 12 months.	Committee for Quality Assurance
! (Care Coordination)	0101	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls who had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
	N/A	317	CMS22v7	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.	Centers for Medicare & Medicaid Services
§	1525	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
	N/A	474	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Zoster (Shingles) Vaccination:** The percentage of patients 50 years of age and older who have a Varicella Zoster (shingles) vaccination.	PPRNet

Comment: One commenter was pleased to see the new proposed Skilled Nursing Facility Specialty Measure Set. The commenter noted this is the first step to delineating the SNF/NF setting as an integral but different area of practice of medicine that deserves its own consideration within MIPS and APM programs. However, the commenter noted that while there are many "reportable" measures included in the MIPS program, some measures are counter to recommendations for the SNF/NF population. The commenter requested CMS consider the following measures for this measure set; Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy; Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy- Prior Myocardial Infraction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40 percent); Q047: Advance Care Plans; Q110: Preventive Care and Screening: Influenza Immunization; Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40 percent); Q154: Falls: Risk Assessment (Two part measure pair with Q155); Q155: Falls: Plan of Care (Two part measure- pair with Q154); Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented; and Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy. Other commenters were supportive of the addition of the Skilled Nursing Facility measure set.

Response: We agree that this specialty set will assist clinicians who provide care within SNFs to identify measures applicable to their patient population. All of the measures suggested by the commenter (except Q154 and Q155) were proposed for inclusion in this specialty measure set and we agree that they are applicable to Skilled Nursing Facilities. In addition, we agree with the commenter that measures Q154 and Q155 should be included in this measure set for the 2019 Performance Period and future years.

FINAL ACTION: We are finalizing the *Skilled Nursing Facility Specialty Measure Set* as proposed for the 2019 Performance Period and future years with the exception of the newly proposed composite measure: Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls. We are no longer finalizing the inclusion of the composite falls measure because it must be fully vetted to utilize standardized tools that would appropriately identify the at-risk patient population. However, based on public comments, we are finalizing the individual measures Q154: Falls: Risk Assessment and Q155: Falls: Plan of Care as additional measures in this measure set.

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

In this final rule, we removed 26 previously finalized quality measures from the MIPS Program for the 2021 MIPS payment year and future years. These measures are discussed in detail below. As discussed in section III.I.3.h.(2)(b) of the final rule, please note that our measure removal criteria considers the following:

- Whether the removal of the measure impacts the number of measures available to a specific specialty
- Whether the measure addresses a priority area of the Meaningful Measures Initiative
- Whether the measure is linked closely to improved outcomes in patients

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in section III.I.3.h.(2)(b) of this final rule, we applied additional criteria this year for the removal of measures, such as: extreme topped out measures, which means measures that are topped-out with an average (mean) performance rate between 98-100 percent.

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0088	018	CMS167v 7	eCQM Specifications	Process	Effective Clinical Care	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.	Physician Consortium for Performance Improvement Foundation (PCPI®)	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because it is duplicative both in concept and patient population as the currently adopted Measure 019: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (finalized in (81 FR 77558 through 77675)). Measure 019 is considered high priority because it promotes communication and care coordination with eligible clinicians managing diabetes care. The numerator of Measure 018 is considered the standard of care as it captures an assessment with no additional clinical action. Measure 018 neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
0134	043	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft.	Society of Thoracic Surgeons	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because there is no longer variation in performance for the measure to be able to evaluate improvement in performance making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. Therefore, we believe use of IMA has been widely accepted and implemented. The measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
N/A	099	N/A	Medicare Part B Claims Measure Specifications,	Process	Effective Clinical Care	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category**	College of American Pathologists	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because it is considered a standard of care that has

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
			MIPS CQMs Specifications			**(Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade		a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A0392	100	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	College of American Pathologists	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99.5 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas.
N/A	122	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care.	Renal Physicians Association	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the measure has neither been updated nor planned to be updated by the measure steward to reflect the current clinical guidelines as indicated by the measure steward.
0566	140	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were	American Academy of Ophthalmology	We proposed removal of this measure (finalized in (81 FR 77558 through 77675)) because the measure neither assesses a clinical outcome nor one of the defined MIPS high priority areas. The measure's quality action that only requires the provision of counseling of AREDS risk factors, but does not require discontinuation of

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						counseled within the 12-month performance period on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) 2 formulation for preventing progression of AMD.		AREDS if risks/adverse effects are identified.
N/A	156	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues.	American Society for Radiation Oncology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 97.5 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
0056	163	CMS123v7	eCQM Specifications	Process	Effective Clinical Care	**Comprehensive Diabetes Care: Foot Exam:** The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.	National Committee for Quality Assurance	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to the currently adopted Measure 126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (finalized in 81 FR 77558 through 77675). However, Measure 163 is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/CoreCQMs.html). Therefore, we specifically seek comments regarding the impact of removing this measure and replacing it with Measure 126. We strive to not duplicate measures in the program. We believe Measure 126 is a more appropriate measure because it targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.
0068	204	CMS164v7	Medicare Part B Claims Measure Specifications, eCQM Specifications,	Process	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:** Percentage of patients 18 years of age and older who were diagnosed with acute	National Committee for Quality Assurance	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it would be duplicative of a component within the existing measure Q441: Ischemic Vascular Disease: All or

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
			CMS Web Interface Measure Specifications, MIPS CQMs Specifications			myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) in the 12 months prior to the measurement period, or who had an active diagnosis of ischemic vascular disease (IVD) during the measurement period, and who had documentation of use of aspirin or another antiplatelet during the measurement period.		None Outcome Measure We strive to not duplicate measures in the program. In this case, we concluded that measure Q204 is captured within the more robust composite measure Q441.
N/A	224	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Melanoma: Avoidance of Overutilization of Imaging Studies:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered.	American Academy of Dermatology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99.5 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	251	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Effective Clinical Care	**Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer	College of American Pathologists	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 99 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure does not assess a clinical outcome or one of the defined MIPS high priority areas.
1519	257	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin	Society for Vascular Surgeons	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the clinical concept is captured within currently adopted Measure 438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (finalized in 81 FR 77558

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						medication at discharge.		through 77675). Measure 438 captures all patients that require statin therapy. Whereas Measure 257 only captures a subset of the patient population undergoing lower extremity bypass.
N/A	276	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness.	American Academy of Sleep Medicine	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to the currently adopted Measure 277: Sleep Apnea: Severity Assessment at Initial Diagnosis (finalized in 81 FR 77558 through 77675). Measure 276 only represents a quality action to assess for the sleep symptoms whereas Measure 277 includes the assessment along with the severity. This measure also lacks a quality action for positive assessments and does not indicate the use of a standardized tool. Also, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	278	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy.	American Academy of Sleep Medicine	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative to currently adopted Measure 279: Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy (finalized in 81 FR 77558 through 77675). Measure 279 is more robust and requires assessment of adherence to the therapy. Measure 278 does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	263	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method.	American Society of Breast Surgeons	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying. The average performance for this measure is 99.3 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip. In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	327	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month	Renal Physicians Association	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist.		improve clinical outcomes as it does not require a quality action if adequate volume management is not achieved. . In addition, the measure does not assess a clinical outcome nor one of the defined MIPS high priority areas.
N/A	334	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 1.6 percent (inverse measure where a lower score is better performance) based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	359	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems.	American College of Radiology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative of the currently adopted Measure 361: Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry (finalized in 81 FR 77558 through 77675). The use of standardized nomenclature within this measure is intended to enable reporting to Dose Index Registries to allow comparison across radiology sites. This measure does not require the submission to a Dose Index Registry as indicated in Measure 361, but merely using standard nomenclature. We will continue to maintain Measure 361 that represents a more robust quality action to submit standardized data elements to a Dose Index Registry.
N/A	363	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:**	American College of Radiology	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the quality action does not completely attribute to the radiologist submitting the measure. Often, the CT studies are ordered and completed by referring clinicians without opportunity to

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed.		complete the quality action by the radiologist. This allows their quality performance score to be impacted by other eligible clinicians. In addition, the measure does not require a quality action that links to improved outcomes when the search is completed prior to the study (that is, comparison).
N/A	367	CMS169v7	eCQM Specifications	Process	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use.	Center for Quality Assessment and Improvement in Mental Health	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the measure does not require a quality action that links to improved outcomes when assessed positive for alcohol or chemical substance use. The measure does not assess a clinical outcome or one of the defined MIPS high priority areas.
N/A	369	CMS158v7	eCQM Specifications	Process	Effective Clinical Care	**Pregnant women that had HBsAg testing:** This measure identifies pregnant women who had an HBsAg (hepatitis B) test during their pregnancy.	OptumInsight	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the measure steward is no longer maintaining the measure for continued utilization. Furthermore, the measure is evaluating a standard of care as this test would be part of the routine screening for women receiving prenatal care and does not evaluate for care with positive testing results.
N/A	373	CMS65v8	eCQM Specifications	Intermediate Outcome	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.	Centers for Medicare & Medicaid Services	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because a similar clinical concept is represented in Measure 236. It is our goal to ensure duplicate measures are not included in the program. In addition, Measure 236 may apply to a larger eligible clinician cohort and offers expanded data submission methods that are not offered by Measure 373.
0465	423	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:** Percentage of patients undergoing carotid endarterectomy (CEA) who are taking an anti-platelet agent within 48 hours prior to	Society for Vascular Surgeons	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because the clinical concept is captured within our proposed measure Ischemic Vascular Disease: Use of Aspirin or Anti-platelet Medication. We refer readers to Table A.7 where this measure is proposed. The

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
						surgery and are prescribed this medication at hospital discharge following surgery.		proposed measure captures all ischemic vascular disease patients that should be receiving an aspirin or anti-platelet medication. Whereas, Measure 423 only captures a subset of the patient population undergoing carotid endarterectomy.
N/A	426	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU or other non-ICU location in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	American Society of Anesthesiologists	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 97.7 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	427	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	American Society of Anesthesiologists	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is considered a standard of care that has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying making this measure extremely topped-out as discussed in section III.I.3.h.(2) of this final rule. The average performance for this measure is 97.9 percent based on the current MIPS benchmarking data available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Quality-Benchmarks.zip.
N/A	447	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Chlamydia Screening and Follow-up:** The percentage of female adolescents 16 years of age who had a chlamydia screening test with proper follow-up during the measurement period.	National Committee for Quality Assurance	We proposed removal of this measure (finalized in 81 FR 77558 through 77675) because it is duplicative of currently adopted Measure 310: Chlamydia Screening for Women (finalized in 81 FR 77558 through 77675). We strive to not duplicate in the program. This measure is designated as a core performance measure by the Core Quality Measures Collaborative (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html). Therefore, we

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
								specifically seek comments regarding the impact of removing this measure.

Comment: A commenter supported CMSs proposed removal of 26 MIPS measures and applauded CMS for beginning to use its "Meaningful Measures" framework to streamline the measures used in the MIPS.

Response: We thank the commenter for their support.

Comment: Several commenters opposed the removal of measure Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years. Removing the Urinary Incontinence measure will result in excluding up to half of women with urinary incontinence from quality measurement, resulting in loss of opportunity to improve outcomes. Commenters did not agree that measure Q048 is duplicative in concept and covers the same patient population as currently adopted measure Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older." Measure Q048 is intended to promote screening for urinary incontinence, recognizing that urinary incontinence is under-reported by patients and under-evaluated by clinicians; measure Q050 is intended to ensure that women who have identified as having urinary incontinence are the evaluated and offered treatment, based on literature showing that patients reporting urinary incontinence are often not evaluated for what is otherwise a treatable condition. The denominator for measure 048 is all women aged 65 years and older, whereas the denominator for measure Q050 is all eligible women already diagnosed with urinary incontinence. Relying on measure Q050 alone for quality measurement related to urinary incontinence will exclude nearly half of women over age 65 that have urinary incontinence but have not been diagnosed. Measures 048 and 050 go hand-in-hand because interventions to increase urinary incontinence screenings (as measured by measure Q048) results in higher numbers of women receiving urinary incontinence treatment (as measured by measure Q050). Having measure Q050 without measure Q048 undermines the purpose of improving outcomes for women with urinary incontinence.

Response: After further consideration, we agree with commenters that the denominator for Q050 is not duplicative of Q048 and would not capture the under diagnosis of urinary continence. Therefore, we will not finalize measure Q048 for removal as proposed.

Comment: One commenter opposed the CMS proposal to retire three of the eight current Pathology measures: Q099 – Breast Cancer Resection Pathology Reporting Measure, Q100 – Colorectal Cancer Resection Pathology Reporting Measure Q251 - Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients. Removal of these measures would leave pathologists with only five QPP measures whereas the CMS requirement is to report on a minimum of six quality measures. The commenter noted that would significantly hinder successful participation by pathologists in the Quality category.

Response: Although we acknowledge that removing these measures limits the number of measures specific to pathology available for reporting, we do believe removing these measures is consistent with our policy to remove measures that have an extremely high performance rate. Based on the 2018 MIPS Benchmark results reflect an average of 99 percent for Q99 and Q251, and 99.5 percent for Q100 which allows limited opportunity to improve clinical outcomes. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter supported the removal of measure Q122: Adult Kidney Disease: Blood Pressure Management because it cannot estimate the clinical impact based on the information provided by the measure developers and the measure lost NQF endorsement due to a lack of evidence. This measure does not conform to society guidelines and the measure specifications do not align with clinical recommendations on disease classification. Lastly, the denominator population is burdensome for clinicians to document a care plan for all patients classified as stage 3 and above without evidence to support the benefit of the intervention on clinical outcomes.

Response: We thank the commenter for their support to remove measure Q122: Adult Kidney Disease: Blood Pressure Management.

Comment: One commenter disagreed with the removal of measure Q122: Adult Kidney Disease: Blood Pressure Management The commenter stated removal would threaten patient care and disputes that the measure has not been updated nor is planned to be updated.

Response: We are continuously working with measure stewards to update the blood pressure values and were not updated in the annual revision cycle. We do not agree that the removal of this measure would threaten patient care. This clinical concept would also be captured in measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented.

Comment: One commenter opposed the removal of measure Q156: Oncology: Radiation Dose Limits to Normal Tissues stating, not only do oncology professionals continue to find value in this measure from a patient safety standpoint, they disagree with CMS' contention that it is truly topped out.

Response: This measure has a limited opportunity to improve clinical outcomes since performance on this measure is extremely high and unvarying. This does not allow meaningful benchmarks to be established. Based on the 2018 MIPS Benchmark Results, the average performance for this measure is 97.5 percent which does not allow ample opportunity to impact clinical outcomes.

Comment: One commenter supported the removal of measure Q163: Comprehensive Diabetes Care: Foot Exam measure from the from the CMS Web Interface collection type. Although the measure is included in the CQMC ACO Core Measure Set, the commenter recognized that measure sets used to evaluate different types of

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NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

clinicians may need to differ to some extent, and did not agree it necessary to use the exact same measures to evaluate clinicians/groups and ACOs. The commenter also noted that this measure is not used in other health plan reporting programs such as MA Star Ratings and the QRS, so its removal from MIPS will not cause misalignment with those programs.

Response: We thank the commenter for their support to remove measure Q163: Comprehensive Diabetes Care: Foot Exam from the CMS Web Interface collection type.

Comment: One commenter supported removal of measure Q163: Comprehensive Diabetes Care: Foot Care because this measure is duplicative with measure Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy-Neurological Evaluation. Measure Q126 is the preferred and appropriate measure as it targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines.

Response: We thank the commenter for supporting the removal of measure Q163.

Comment: One commenter did not support the removal of measure Q163: Comprehensive Diabetes Care: Foot Exam until NQF completes its pending comparison with it and the Diabetes Mellitus: Diabetic Foot and Ankle Care measure (which the proposed rule suggests it duplicates). NQF found no significant difference in the measures' ability to identify the at-risk population or in the components of clinical assessment specified in them. More than 10,000 clinicians in NCQA's Diabetes Recognition Program report Comprehensive Diabetes Care: Foot Exam. The measure also is in the Core Quality Measures Collaborative ACO/PCMH and Primary Care set, which CMS described as "a major step forward" for quality measure alignment" and a "framework upon which future efforts can be based."

Response: We agree with the commenter's statement indicating that both measures' ability to identify the at-risk population or in the components of clinical assessment specified in them. Both measures aim to promote appropriate foot examination to identify risk factors predictive of ulcers and amputations. However, measure Q126 requires the frequency of the exam to be increased if abnormalities are present. More frequent evaluation of the diabetic foot is recommended depending on risk category. It is through systematic examination and risk assessment, patient education, and timely referral that eligible clinicians may further reduce the unnecessarily high prevalence of lower-extremity morbidity in the diabetes population. We attempt to align with CQMC, but believe this is duplicative of a more robust measure. As MIPS moves forwards, we will continue to explore ways to align measurement across programs.

Comment: A commenter did not support removal of the Q185: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use measure. The commenter noted that updated guidelines on the appropriate follow-up interval for patients with a history of adenomatous polyps are set to be released in the near future. The commenter also noted that it is likely that the measure specifications will be updated at that point, which may alter clinician performance. The commenter recommended that CMS retain the measure in MIPS until it is able to review other stakeholder concerns about measure performance, and that CMS work with the measure developer to update the MIPS measure specifications when new guidelines are released.

Response: We agree that updated guidelines could affect the performance of this measure causing the measure to have a substantive change and therefore may no longer have a benchmark that is considered to be topped out. We note this measure shows a 97.7 percent average performance for Medicare Part B Claims Measure Specifications while the MIPS CQMs Specification (registry) version shows less than 97 percent average performance rate. Based on our extremely topped out measure removal policy, we intend to only remove this measure from the Medicare Part B Claims Measure Specification collection type for the 2019 performance period. We will not finalize the removal of MIPS CQM collection type. We will work with the measure steward to update for the new clinical guidelines once those are released and continue to monitor the performance of the MIPS CQM Measure Specification in the future.

Comment: Several commenters supported the proposed removal of the Q204: Ischemic Vascular Disease: Use of Aspirin or Another Anti-Platelet measure.

Response: We thank the commenters for their support to remove measure Q204: Ischemic Vascular Disease: Use of Aspirin or Another Anti-Platelet measure.

Comment: Several commenters were concerned about the removal of Q204: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet because its specialties have identified this measure as a high-priority measure, and therefore, requested the measure not be removed. Another commenter disagreed with removal of Q204 as the Million Hearts Campaign, Core Quality Measures Collaborative ACO/PCHM and Primary Care set and many other public and private programs use this measure.

Response: We originally proposed a replacement measure that included appropriate denominator exceptions, but ultimately decided it was duplicative of measure Q441: Ischemic Vascular Disease All or None Outcome Measure (Optimal Control). Therefore, to be consistent with our policy to remove measures that are duplicative to other measures and to ensure measures are more meaningful, we have decided to not finalize inclusion of this new IVD measure. In addition, it would introduce a measure that was not aligned with the Million Hearts Campaign, Core Quality Measures Collaborative ACO/PCHM and Primary Care set. We will finalize the proposal to remove Q204. Measure Q204 is duplicative and does not have appropriate denominator exceptions/exclusions to account for patients who are not appropriate for aspirin or antiplatelet therapy (that is, history of gastrointestinal bleeding, intracranial bleeding, bleeding disorder, allergy to aspirin or anti-platelets, or use of non-steroidal anti-inflammatory agents). We encourage the commenters to submit the outcome measure that addresses this concept.

Comment: One commenter expressed concern on the proposed removal of measures Q224: Melanoma: Avoidance of Overutilization of Imaging Studies and Q156: Oncology: Radiation Dose Limits to Normal Tissues without proposing new oncology-related measures to replace them. CMS should also be mindful of the need to ensure an adequate number of applicable measures for oncologists and other specialty groups when proceeding with decisions about measure removal.

Response: We refer the commenter to review the Oncology specialty measure set that provides a narrowed list of measures applicable to the oncology specialty. The specialty measure sets are reviewed annually by stakeholders to include applicable measures. The oncology measure set contains 24 quality measures.

Comment: Two commenters opposed the removal of measure Q276: Sleep Apnea: Assessment of Sleep Symptoms; and the adoption of measure Q277: Severity Assessment at Initial Diagnosis. One commenter noted that Q277 focuses on care provided to patients with a diagnosis of obstructive sleep apnea, and that many

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patients with neurologic disorders experience sleep disturbances and disorders other than obstructive sleep apnea. They also noted that removing Q276 would result in limited reporting options for neurologists specializing in sleep care. They stated also that while it may be easier to see the value in calculating the severity of sleep apnea, as required in measure Q277; that in accordance with evidence-based Clinical Practice Guideline for Diagnostic Testing for Obstructive Sleep Apnea, diagnostic testing for obstructive sleep apnea should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. One of the commenters noted that patients with untreated obstructive sleep apnea are also at an increased risk of being diagnosed with cardiovascular disease, difficult-to-control blood pressure, coronary artery disease, congestive heart failure, arrhythmias, and stroke. They stated further that sleep medicine professionals need relevant measures to report for participation in the MIPS program, and currently there are only four sleep medicine measures available.

Response: These measures address the same patient population; however, Q276, does not identify a standardized tool to assess sleep symptoms whereas Q277 defines a standard method of assessment. This allows clinicians a baseline to assess if the patient is being treated appropriately. A non-standardized assessment of daytime sleepiness may be circumstantial and may not be a reliable indicator of appropriate treatment. In addition, the measure Q276 does not have a quality action if the patient is experiencing daytime sleepiness. We agree with the commenters' suggestions that sleep apnea should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. The Q276 measure does not address the adequate follow-up component to mitigate the risks of cardiovascular disease, difficult-to-control blood pressure, coronary artery disease, congestive heart failure, arrhythmias, and stroke. We encourage the commenters to collaborate with measure developers to submit new measures that address sleep apnea in the Call for Measures process. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed removal of Q278 Sleep Apnea: Positive Airway Pressure Prescribed and requested that the measure be categorized as a high priority patient safety measure, given the overwhelming amount of evidence in the medical literature describing the negative effects of untreated sleep disorders. They noted that patients with untreated obstructive sleep apnea are also at an increased risk of being diagnosed with cardiovascular disease, difficult-to-control blood pressure, coronary artery disease, congestive heart failure, arrhythmias, and stroke. They stated further that sleep medicine professionals need relevant measures to report for participation in the MIPS program, and currently there are only four sleep medicine measures available.

Response: We are attempting to reduce reporting burden where measures are duplicative in concept or do not drive quality action by eligible clinician. We believe that this measure is low bar and choose to continue to implement measure Q279 is more robust and requires assessment of adherence to the therapy. Measure Q278 does not assess a clinical outcome nor one of the defined MIPS high priority areas. We encourage the commenters to collaborate with measure developers to submit new measures that address sleep apnea in the Call for Measures process. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed removal of measure Q327: Pediatric Kidney Disease: Adequacy of Volume Management. This measure meets several national quality strategy domains – clinical care, care coordination, and patient and caregiver experience and removal of this measure would leave only one MIPS measure for pediatric nephrologists. A second commenter also opposed the removal of measure Q327 because they noted that despite the small number of Medicare pediatric patients, many pediatric nephrologists do not meet the low volume threshold and are still required to participate in the Quality Payment Program. The commenter also noted also that very few measures exist that allow pediatric nephrologists to participate meaningfully. They requested CMS not to eliminate this or any other pediatric kidney disease measures from the Quality Payment Program unless and until they can be replaced with other measures specific to pediatric kidney disease.

Response: Although, we acknowledge that removing this measure limits the number of measures specific to pediatric nephrologists available for reporting, we do believe removing this measure is consistent with our policy to move towards more meaningful measures and decrease burden for eligible clinicians. This is a process measure that does not assess if there the patient had appropriate volume management, but whether the adequacy was assessed. As we move toward more outcome-based measures, we suggest the commenter to collaborate with measure stewards to develop an outcome measure that the patient aligns with the post dialysis weight. In addition, although there are not many specific measures available, there are cross-cutting measures that we believe would be applicable to pediatric nephrologists and could be submitted. This measure is only available by CQM Measure Specification, and therefore, in the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score may be adjusted through the measure validation process as applicable.

Comment: One commenter did not support the choice to remove the Q334: Adult Sinusitis CT scan measure because they noted that CMS did not follow the established process of utilizing a 4-year, step-down period for removing topped out measures. The commenter requested that CMS follow this process so that measure stewards are able to plan accordingly for other measure development before an existing measure is retired.

Response: By removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement. Additionally, this allows eligible clinicians to maximize their potential quality performance category score. Based on the 2018 Benchmark File, this measure only supported the creation of deciles 3 to 5, which would limit the score awarded for the measure.

Comment: One commenter opposed removal of measure Q359: Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging measure because they did not agree that it is duplicative of Q361: OPEIR - Reporting to a Dose Index Registry, which they noted is only intended to enable reporting to a dose index registry to allow comparison across radiology sites. They stated that removing this measure may affect some radiologists' ability to meet quality measure requirements.

Response: Standardized nomenclature permits data mining in order to participate in research projects, registries, and quality improvement efforts. This facilitates a first step toward structured reporting to Radiation Dose Index Registries, which would be captured in measure Q361: Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry. Even with the removal of this measure, the Radiology specialty measure set has more than 6 quality measures. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed the removal of measure Q363: Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive. The commenter respectfully suggested that CMS fails to appreciate the process upon which this measure has impact. It is correct that referring clinicians place orders, but radiologists would complete the exams. The measure quality action is that prior to performing the ordered exam, the radiologist would search existing image exchanges across institutions or geographic area for existing prior images for the patient. The potential improved outcome would be a reduction in patient exposure to radiation, as well as a substantial reduction when duplicative imaging procedures are avoided. Additionally, broader access to existing imaging studies, including relevant prior images used for comparative purposes of patient history (of lesions for example) could improve diagnostic specificity and accuracy for radiologists and potentially further minimize recommendations for follow-up studies. In addition, they stated that removing this measure may affect some radiologists' ability to meet quality measure requirements.

Response: While we appreciate the intent to review historical images and reduce radiation, the measure requires a finalized report of a CT study to be denominator eligible. Therefore, it would exclude instances where the duplicative CT was appropriately cancelled as they would no longer be denominator eligible. An eligible clinician can be numerator compliant if a CT was completed and had identified a prior CT exam. Therefore, it does not promote radiation reduction. Even with the removal of this measure, the Radiology specialty measure set has more than 6 quality measures. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process.

Comment: One commenter opposed removal of measure Q373: Hypertension: Improvement in Blood Pressure measure because of its impact on patient care and low reporting burden. They noted that the data is already documented in the EHR as part of standard workflows. One commenter agreed that measure Q373: Hypertension: Improvement in Blood Pressure provides no incremental benefit over measure Q236. However, the commenter expressed concern that a one-size-fits-all SBP goal of < 140/90 mm Hg may suggest to patients and their healthcare providers that their treatment is adequate if they reach this goal. In the future, as further evidence accumulates for other cohorts of patients, the commenter hoped a more comprehensive set of blood pressure control measures that are tailored to patients' cardiovascular risk will become available for CMS reporting.

Response: We are committed to our goal to remove measures that are duplicative to other measures and to be consistent with ensuring measures are more meaningful. As we indicated in our proposal, this measure is very similar in clinical concept to measure Q236: Controlling High Blood Pressure. We believe measure Q236 may apply to a larger eligible clinician cohort and offers expanded collection types that are not offered by measure Q373. Both measures are available via eCQM Specifications, and therefore, measure Q236 would have a low reporting burden since the data is already documented in the EHR as indicated by the commenter. In addition, we will continue to work with measure stewards to update the current blood pressure measures to align with clinical guidelines as appropriate or evaluate potential new measures to propose for the program.

Comment: One commenter expressed concerns about Appendix Table C and that it is premature to remove measures for which replacement measures are concurrently being proposed, (for example, Falls Screening and Functional Status Assessment for Total Knee Replacement), until vendors have had the necessary time to develop, certify and deploy their respective replacement measures.

Response: We provided a measure preview this year to allow for technical revisions, this also allowed vendors to gather preliminary implementation strategies. Additionally, all measure finalized will be posted on the CMS website prior to the start of the 2019 performance period. We also aim to reduce the number of duplicative measures. If we retain the Functional Status Assessment for Total Knee Replacement for the 2019 performance period, this would be duplicated measure concept of measure Q470: Average Change in Functional Status Following Total Knee Replacement Surgery.

Comment: Two commenters did not support removal of Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences from this measure set. The commenters appreciated the effort to decrease redundancy between this measure and the Q047 Advance Care Plan measure. While these measures do overlap, the commenters noted that ALS measure specification recognizes the likely earlier age of onset of this devastating diagnosis and the need to have earlier planning conversations around palliative and end of life care by having no minimum age requirement. For this reason, the commenter believed the measure should be retained.

Response: We agree with the commenters concerns about removing measure Q386 and will not finalize this measure for removal. Specifically, we agree that patients with ALS are often younger than those in the denominator for Measure 047, which includes patients age 65 and older. For this reason, we concur with commenters that a separate measure applying to all patients with a diagnosis of ALS is clinically indicated.

Comment: One commenter did not support the removal of measure Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and measure Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU). Their removal would jeopardize many anesthesiologists' opportunities to report the required six quality measures. The anesthesiology measure set currently includes seven anesthesia-specific measures and a handful of measures that are only reportable using evaluation and management codes–codes that are rarely reported by anesthesiologists. For anesthesiologists working in ambulatory settings and on surgeries lasting less than one hour, the number of applicable measures would be reduced to just one measure. In previous years, CMS correctly identified measures Q426 and Q427 as high-priority measures. The proposed removal of these measures would expose contradictions between CMS' intent to improve communication and care coordination with the removal of measures aimed at ensuring communication between clinicians. When considering Advanced Alternative Payment Models (APMs), and the need for entities to use measures comparable to MIPS, these two measures should be identified by those Advanced APMs as helping to reduce medical errors, adverse medication events, expedite recovery and reduce costs.

Response: Measures Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU) are being removed as they have limited opportunity to produce clinical outcomes as the performance rates are extremely topped out. By removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement. In the event an eligible clinician reports on less than 6 quality measures, because no other measures in the set are

TABLE C: Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years

NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process. We agree that promoting communication between clinician is important, the performance data does not support a gap in communication and drive quality improvement in this area. We encourage the commenter to work with measure developers to create a measure that promotes communication that addresses current gap in the anesthesia specialty.

Comment: Another commenter did not support removal of topped out measures: Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU). The commenter was concerned about removal of these measures as they relate to CRNAs. Without a concerted effort to expand measure specifications to include non-patient facing CPT codes, the commenter recommended that measures attributed to non-patient facing clinicians be excluded from the removal process to assure that CRNAs do not face additional burden by not having enough applicable measures to participate in MIPS.

Response: Measures Q426: Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU) and Q427: Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU) are being removed as they have limited opportunity to produce clinical outcomes as the performance rates are extremely topped out. By removing these extremely topped out measures, we are attempting to reduce reporting burden where there is little room for improvement. In the event a CRNA reports on less than 6 quality measures, because no other measures in the set are available or applicable to their scope of practice, the quality performance category score will be adjusted accordingly through the measure validation process. With the measure validation process in place, we do not agree with the commenter to maintain all non-patient facing measures.

Comment: Two commenters supported removal of the Q447: Chlamydia Screening and Follow-Up measure from the MIPS program. Although the measure proposed for removal is included in the CQMC OB/GYN Core Measure Set, the measure that CMS proposes to retain in MIPS, Q310: Chlamydia Screening in Women, is also a CQMC measure. The commenters agreed that the measure proposed to be retained provides more comprehensive quality information, as it includes a wider age range compared to the measure that would be remove and is limited to patients identified as sexually active.

Response: We thank the commenters for their support.

Comment: One commenter stated that they support CMS' outline of removal criteria to be considered when removing a measure. However, the commenter also requested that CMS evaluate measures for removal based on the collection type. For example, they noted that several eCQMs proposed for removal due to a duplicative measure being available; however, in most instances, that duplicative measure is not available as an eCQM. This would potentially force practices to maintain relationships and pay for reporting through multiple vendors to maintain their list of measures. Specifically, this affects the proposed removal of eCQMs Q163 (Comprehensive Diabetes Care: Foot Exam), Q204 (Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet), Q318 (Falls: Screening for Future Fall Risk), and Q375 (Functional Status Assessment for Total Knee Replacement: Changes to the measure description). Another commenter expressed similar concerns about removal of Q373: Hypertension: Improvement in Blood Pressure: Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period.

Response: In response to this concern, we conducted an analysis of the measures proposed for removal with an eCQM collection type. As a result of this analysis, we concluded that we will not finalize measures Q012, Q318, and Q375 for removal because there is not an eCQM collection type offered in the measures that we proposed as duplicative measures. With regard to updating the removal criteria to consider data collection type overall, we will take this into consideration as we refine future removal criteria.

FINAL ACTION: We are finalizing the removal of these measures as proposed for the 2019 Performance Period and future years with the exception of the following measures: Q012, Q048, Q154, Q155, Q185, Q318, Q375 and Q386. Our decisions to not finalize these measures for removal in this final rule are detailed in our responses above to the public comments for these measures. Note: The new measure "Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls" will not be finalized for inclusion in this final rule because the measure steward believes it is not implementable at this time. Therefore, the three falls measures (Q154, Q155, and Q318) will remain in the program for the 2019 performance period because they are important to evaluate for high-risk of falling.

TABLE Group D: Measures with Substantive Changes Finalized for the 2021 MIPS Payment Year and Future Years

D.1. Medication Reconciliation Post-Discharge

Category	Description
NQF #:	0097
Quality#:	046
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges from any inpatient facility (for example hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Submission Criteria 1: 18-64 years of age • Submission Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older
Substantive Change:	**Modified collection type**: Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This is a process measure, which promotes care coordination when transitioning from an inpatient facility to outpatient care. Removal of this measure from the CMS Web Interface supports our effort to move towards outcome and more meaningful measures within the CMS Web Interface. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements.

Comment: Commenters indicated that CMS should retain this measure because ensuring clinicians are reconciling patient medications limits the occurrence of adverse drug events for elderly patients with multiple co-morbidities and prescription medications.

Response: This is a process measure that promotes care coordination when transitioning from an inpatient facility to outpatient care. While we agree that medication reconciliation is an important aspect of care coordination and avoiding adverse drug events, we believe a more broadly applicable measure that does not just focus on medication reconciliation post discharge would more effectively promote care coordination. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. We do not believe removing this measure from one collection type, CMS Web Interface, will increase the occurrence of adverse drug events because eligible clinicians have the opportunity to report this measure as a Medicare Part B Claims Measure Specification or MIPS CQMs Specification.

Comment: In addition, several commenters expressed general concerns that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism. One commenter expressed concerns about removal of the CMS Web Interface and its impact on the Medicare Shared Savings Program and ACO participants that utilize this data collection method for this measure.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

FINAL ACTION: We are finalizing the changes to measure Q046 as proposed for the 2019 Performance Period and future years.

D.2. Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF #:	N/A
Quality#:	111
CMS eCQM ID:	CMS127v7
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This measure has lost NQF endorsement and no longer reflects the current guidelines. A new measure is under development to reflect current guidelines and may be proposed in the future. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements. We encourage stakeholders to submit a replacement measure for future consideration that is in alignment with the most current clinical guidelines.

Comment: Several commenters opposed the removal of the CMS Web Interface Measure Specifications collection type for this measure. The commenter recommended that CMS works toward immediately replacing the measure with another similar (and endorsed) measure which will lead to the capture of comprehensive care of elderly patients. They noted that complete removal and no replacement of this measure will lessen the incentive and urgency for ACOs to administer this life saving vaccination, resulting in fewer patients vaccinated, and leading to worsened outcomes and higher costs.

Response: We agree on the importance of a pneumonia vaccination measure. However, we believe the burden to submit this measure via the CMS Web Interface and the loss of NQF endorsement aligns with our goal to be less burdensome for clinicians and ensure measures are still supported by the current clinical guidelines. Furthermore, we acknowledge that pneumonia vaccination is an important preventive clinical intervention, but measure Q111 does not address current pneumonia vaccination guidelines. We believe maintaining the measure under other collection types to provide an option to select a measure that addresses important population health matter. However, until this measure can be replaced with a measure promoting pneumococcal vaccination, we believe it should not be required to be submitted via the CMS Web Interface. Eligible clinicians submitting Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications are able to select quality measures that are applicable to their specialty that are meaningful to their practice. In the CMS Web Interface, all measures are required; therefore, some eligible clinicians may believe the measure to be burdensome since it does not fully align with the current pneumococcal vaccination schedule.

Comment: A few commenters expressed concern that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. Specific to ACO participants, ACOs can track these additional metrics in order to participate in the Shared Savings Program and potentially earn shared savings. We note, however, that one of the advantages of clinician participation in a Shared Savings Program ACO is that the ACO reports quality on the clinicians' behalf, reducing clinician burden. We believe that this streamlined approach benefits ACOs in reducing program complexity and enables CMS to make meaningful comparisons on a consistent measure set, across ACOs who are eligible to share in any earned savings or may be responsible for any owed losses, based on that performance. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

Comment: One commenter stated that measure Q111: Pneumococcal Vaccination Status for Older Adults is aligned with the CMS Meaningful Measures Framework and is a high-impact measure. The commenter did not agree with CMS' concern that the measure is not aligned with ACIP pneumococcal vaccination recommendations. The commenter requested that CMS retain the current pneumococcal vaccination measure until such time as it can be updated with new measure(s).

Response: We agree that the measure addresses an important population health matter and encourage measure developers to submit an updated measure through the Call for Measures process. Please note that we are retaining this measure in the MIPS program and this substantive change only relates to the removal of the CMS Web Interface data collection method. The removal of the CMS Web Interface was proposed to reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. We maintain the concern that it is not in complete alignment with the ACIP recommendations. The measure specification only requires one dose ever documented, either the PCV13 or PPSV23 vaccine (or both). According to ACIP recommendations, patients should receive both vaccines. The order and timing of the vaccinations depends on certain patient characteristics, and are described in more detail in the ACIP recommendations.

Category	Description
FINAL ACTION: We are finalizing the changes to measure Q111 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS127v6" to "CMS127v7." The NQF# changed from "0043" to "N/A" due to loss of NQF endorsement. These changes were also applied to specialty measure sets in Table Group B where this measure was included.	

D.3. Diabetes: Eye Exam

Category	Description
NQF #:	0055
Quality #:	117
CMS eCQM ID:	CMS131v7
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal exam (no evidence of retinopathy) in the 12 months prior to the measurement period
Substantive Change:	**Modified collection type**: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This measure evaluates a process in the care for the patient. Removal of this measure from the CMS Web Interface Measure Specifications supports our effort to move towards outcome and meaningful measures. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements

Comment: One commenter opposed the elimination the CMS Web Interface Measure Specifications collection type for this measure as regular exams are vital to preventing unnecessary vision loss.

Response: We believe this measure would be burdensome to require all eligible clinicians using the CMS Web Interface to submit this measure. All measures included in the CMS Web Interface are required to be submitted even if the measure may not apply to a particular specialty. We are maintaining the measure under other collection types to provide an option to select a measure that addresses important process in diabetes care. Eligible clinicians submitting Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications are able to select quality measures that are applicable to their specialty that are meaningful to their practice. In the CMS Web Interface, all measures are required, therefore some eligible clinicians may believe the measure to be burdensome.

Comment: A few commenters expressed concern that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. Specific to ACO participants, ACOs can track these additional metrics in order to participate in the Shared Savings Program and potentially earn shared savings. We note, however, that one of the advantages of clinician participation in a Shared Savings Program ACO is that the ACO reports quality on the clinicians' behalf, reducing clinician burden. We believe that this streamlined approach benefits ACOs in reducing program complexity and enables CMS to make meaningful comparisons on a consistent measure set, across ACOs who are eligible to share in any earned savings or may be responsible for any owed losses, based on that performance. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

FINAL ACTION: We are finalizing measure Q117: *Diabetes: Eye Exam* as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS131v6" to "CMS131v7." These changes were also applied to specialty measure sets in Table Group B where this measure was included.

D.4. Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF #:	0421
Quality #:	128
CMS eCQM ID:	CMS69v7
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI => 18.5 and < 25 kg/m2.
Substantive Change:	**Modified collection type**: Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated the denominator exception logic:** for the eCQM Specifications collection type to allow medical reasons for not obtaining the BMI.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We removed the CMS Web Interface Measure Specifications collection type. This measure evaluates a process in the care for the patient. Removal of this measure from the CMS Web Interface Measure Specifications supports our effort to move towards outcome and meaningful measures. In addition, since clinicians are required to report all available CMS Web Interface measures, removing this measure from the CMS Web Interface will reduce the burden of the number of measures a clinician is required to report under the CMS Web Interface. This measure is broadly applicable to eligible clinicians participating in the MIPS program using the collection types of Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specifications. Retaining this measure through the Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications, and eCQM specification collection types allows clinicians to choose this measure as one of the six measures clinicians are generally required to report to meet the quality performance category requirements. We updated the denominator exception logic for the eCQM Specifications collection type to allow medical reasons for not obtaining the BMI. The Technical Expert Panel (TEP) convened by the measure steward recommended adding a medical reason as there could be valid medical reasons for not obtaining the BMI. We agree with the TEP to add a medical exception. There are valid medical reasons that may inhibit the eligible clinicians from obtaining a BMI. Specifically, CMS69v6 has denominator exceptions for medical reasons for not providing the follow-up plan. These exceptions are currently expressed as "Intervention, Order not done" and "Medication, Order not done". The updated measure, CMS69v7, adds an exception to remove patients from the denominator who have a medical reason for not having a BMI performed. This exception was added to account for patients for whom it may be physically difficult to conduct a BMI, such as patients who are unable to stand or for whom their weight exceeds scale limits. This update will provide eligible clinicians the opportunity to exclude patients when there is an appropriate medical reason documented.

Comment: One commenter suggested that BMI screening and follow-up is an important metric since weight loss and gain are symptoms of some mental health disorders and patients with serious mental illness face increased risks for obesity and early death from medical co-morbidities as a side-effect of psychotropic medications. One commenter supported the updates to this measure. Another commenter suggested that elimination of this measure would impact the long-term importance of assessing clinician performance related to population health.

Response: We agree that obesity-related care is important; however, we believe that this issue will continue to be addressed under several of the measures that remain in the CMS Web Interface and SSP measure set, for example the 30 day all-cause readmission measure, and the hypertension, statin, diabetes measures.

Comment: A few commenters expressed concern that the measures we proposed to remove from the CMS Web Interface would continue to be used in other programs or that they would remain available to report to MIPS via other reporting mechanisms, creating inconsistency in the available measure set by reporting mechanism.

Response: We acknowledge that measures proposed for removal from the CMS Web Interface may continue to be required by other programs and available by other collection types. However, removing them from the CMS Web Interface would reduce burden on MIPS groups and ACO participants by removing the requirement that they actively submit the measure performance data through the CMS Web Interface. Specific to ACO participants, ACOs can track these additional metrics in order to participate in the Shared Savings Program and potentially earn shared savings. We note, however, that one of the advantages of clinician participation in a Shared Savings Program ACO is that the ACO reports quality on the clinicians' behalf, reducing clinician burden. We believe that this streamlined approach benefits ACOs in reducing program complexity and enables CMS to make meaningful comparisons on a consistent measure set, across ACOs who are eligible to share in any earned savings or may be responsible for any owed losses, based on that performance. For MIPS groups, we are removing this measure to reduce burden of reporting the required measure set. However, we are retaining this measure through the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types to allow clinicians an opportunity to report this measure as one of the six measures to meet the quality performance category requirements.

FINAL ACTION: We are finalizing the changes to measure Q128 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS69v6" to "CMS69v7." These changes were also applied to specialty measure sets in Table Group B where this measure is included.

D.5. Oncology: Medical and Radiation – Plan of Care for Moderate to Severe Pain

Category	Description
NQF #:	0383
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having moderate to severe pain with a plan of care to address pain documented on or before the date of the second visit with a clinician
Substantive Change:	**The new numerator is revised to read**: Patients for whom a plan of care to address moderate to severe pain is documented on or before the date of the second visit with a clinician. Updated the denominator to clearly state that population for this measure would be limited to patients who had moderate to severe pain. **The new denominator is revised to read**: All patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having moderate to severe pain or All patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We modified the numerator to state that the plan of care for pain management should be documented in the first 2 visits (not at any point during the performance period). The current measure requires the plan of care to be documented at any time during the performance period. We modified the denominator to clearly state that the population for this measure would be limited to patients who had moderate to severe pain. Pain severity continues to remain largely unaddressed, especially in those patients who have moderate/severe pain. The edits to this measures numerator would ensure that the oncologist documents a plan of care early, so as to ensure that patients who have moderate to severe pain know what pain management options are available to them earlier on when receiving chemotherapy and radiation, and can become engaged early on in their healthcare decisions. The update to the numerator is based on American Society of Clinical Oncology feedback on the measure by Quality Oncology Practice Initiative registry users who realize that the measure should focus on this to ensure quality of life via pain management is improved in cancer patients.

Comment: One commenter supported the changes to this measure.

Response: We thank the commenter for their support.

FINAL ACTION: We are not finalizing the changes to measure Q144 as proposed for the 2019 Performance Period and future years because, upon reviewing the steward's test results for the proposed numerator and denominator changes, NQF determined that the measure steward's testing data was insufficient. As a result, the NQF has requested that the measure steward retest these changes with sufficient data. Therefore, we will retain the current 2018 numerator and denominator specifications for this measure, as follows:

Numerator: Patient visits that included a documented plan of care to address pain
Denominator: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain.

Please note that, although the proposed substantive changes are not finalized, the following technical changes were made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Medical and Radiation – Plan of Care for Pain" to "Medical and Radiation – Plan of Care for Moderate to Severe Pain." This change was applied to specialty measure sets in Table Group B where this measure is included.

D.6. Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF #:	N/A
Quality #:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD)
Substantive Change:	**The new description is revised to read:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD). **The new numerator is revised to read**: Patients for whom a TB screening was performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic DMARD.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We updated to the numerator to require the TB screening 12 months prior to the first biologic treatment rather than 6 months as currently stated. The measure steward believes this measure should be more in line with the specifications found in a similar measure developed by the American College of Rheumatology (ACR) and endorsed by the National Quality Forum (NQF). In creating its version of this measure, the ACR conducted an extensive development and review process. The measure was built by a panel of rheumatology experts, in conjunction with the ACR, based on quality of care guidelines and broad reviews of relevant research. Upon completion, the measure was shared with thousands of rheumatology clinicians across the U.S. for public comment. Following the comment period, the measure was updated appropriately based on the feedback received, then rigorously tested to ensure reliability and validity. The measure, along with the results of the testing, was submitted to the NQF for review and obtained trial endorsement. We typically prefer the use of NQF endorsed measures over measures that lack endorsement. However, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus. We believe this measure revision from tuberculosis screening from 6 months to 12 months can be supported by evidence and is an important measure to ensure proper tuberculosis screening for rheumatoid arthritis patients.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q176 as proposed for the 2019 Performance Period and future years.	

D.7. Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF #:	N/A
Quality #:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months.
Substantive Change:	**The new numerator is revised to read**: Patients with disease activity assessed by an ACR-endorsed rheumatoid arthritis disease activity measurement tool classified into one of the following categories: remission, low, moderate or high, at least >=50 percent of total number of outpatient RA encounters in the measurement year. **The new definition is revised to read**: Assessment and Classification of Disease Activity – Assesses if physicians are utilizing a standardized, systematic approach for evaluating the level of disease activity for each patient at least for >=50 percent of total number of outpatient RA encounters. The scales/instruments listed are the ACR-endorsed tools that should be used to define activity level and cut-off points: -Clinical Disease Activity Index (CDAI) -Disease Activity Score with 28-joint counts (erythrocyte sedimentation rate or C-reactive protein) (DAS-28) -Patient Activity Scale (PAS) -Patient Activity Score-II (PAS-II) -Routine Assessment of Patient Index Data with 3 measures (RAPID 3) -Simplified Disease Activity Index (SDAI) A result of any kind qualifies for meeting numerator performance.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We updated the numerator to change the requirement to assess disease activity from once a year to "≥ 50 percent of encounters in the measurement year" and to change the use of any standardized tool to only use ACR-endorsed tools. Currently, the measure is only required to be submitted once per performance period. The current measure identifies tools that are available, but allows eligible clinicians to utilize tools not listed within the specification. The changes add a considerable degree of specificity to quality measure 177 by (1) limiting options for disease activity measures to those that have been found to be valid through a rigorous ACR process, and (2) changing the frequency of assessment to include a majority of clinical encounters for RA, since this approach would be consistent with current guidelines regarding treating to a pre-specified target. The ACR developed recommendations for the use of RA disease activity measures in clinical practice. And after thorough evaluation of around 63 available measures, ACR recommends the following 6 measures: CDAI, DAS28 (ESR or CRP), PAS, PAS-II, RAPID-3, and SDAI as ACR-endorsed RA disease activity measures to be used in clinical practice. Many of these tools are available free of charge. The tools were selected to ensure a comprehensive and standardized approach to assess disease activity for rheumatoid arthritis. Given this evidence, the measure steward believes this measure should be updated to be more in line with the specifications found in similar measures developed by ACR and endorsed by NQF. We agree with the revision to promote utilization of the most current guidelines that have been developed by the panel of rheumatology experts. We typically prefer the use of NQF endorsed measures over measures that lack endorsement. Disease activity assessment is imperative to development of an appropriate treatment plan. Revising the numerator to require a more frequent assessment supports development of a more effective treatment plan. We support the use of standardized tools to assess disease activity so the score can be standardized and comparable among eligible clinicians.

Comment: One commenter supported the revisions to measure Q177: Rheumatoid Arthritis (RA) Periodic Assessment of Disease Activity as the changes would limit the measurement tools available to clinicians for assessing disease activity levels only to those that have been found to be valid through the American College of Rheumatology process. The change to increase the frequency of disease activity assessment from only once per year to "at least 50 percent or more of clinical encounters for RA" would be consistent with clinical guidelines for RA disease activity assessment and supported those changes. A narrower list of ACR-endorsed measurement tools will create measurement uniformity for clinicians, can help establish clinical consensus in how disease activity levels should be defined, and promotes consistent outcomes measurement across RA patients.

Response: We agree this would align would the current guideline and provide standardized approach to assess rheumatoid arthritis.

FINAL ACTION: We are finalizing the changes to measure Q177 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity at ≥50 percent of encounters for RA for each patient during the measurement year." These changes were also applied to specialty measure sets in Table Group B where this measure is included.

D.8. Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines

Category	Description
NQF #:	N/A
Quality #:	364
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (for example, follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors.
Substantive Change:	**Updated the denominator**: To patients 35 years and older. **Updated denominator exclusions**: Added heavy tobacco smokers **Updated denominator exceptions**: To include medical reasons. **Updated numerator**: Includes a recommended interval and modality for follow-up. **The new description is revised to read:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(for example, type of imaging or biopsy) or for no follow-up, and source of recommendations (for example, guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We updated the measure description and denominator from 18 years and older to 35 years and older. We also updated the numerator to include a recommended interval and modality for follow-up. The revised measure assesses final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up [(for example, type of imaging or biopsy) or for no follow-up, and source of recommendations (for example, guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians)]. The current measure specification does not allow a denominator exclusion for heavy smokers. A new denominator exclusion is included for heavy tobacco smokers who qualify for lung cancer screening. Furthermore, the current denominator exception does not account for the indication of a modality. A new denominator exception for medical reasons for not including a recommended interval and modality for follow-up. The changes add specificity to this measure and ensure the appropriate patient population is being targeted for this measure by: (1) updating the numerator quality action to specify a recommended interval and modality for follow-up; (2) specifying additional denominator exclusions and exceptions; and (3) changing the intended patient population (to 35 years and older) as supported by an update to clinical guidelines. We agree with the revision to promote utilization of the most current guidelines. It creates a more robust measure that defines the required clinical action to the narrowed patient population. We also agree with the addition specific denominator exceptions and denominator exclusions to promote consistent data among eligible clinicians.

We did not receive specific comments regarding these measure changes.

FINAL ACTION: We are finalizing the changes to measure Q364 as proposed for the 2019 Performance Period and future years.

D.9. Depression Remission at Twelve Months

Category	Description
NQF #:	0710
Quality #:	370
CMS eCQM ID:	CMS159v7
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18 years of age and or older with major depression or dysthymia who reached remission 12 months (+/- 30 days) after an index visit
Substantive Change:	**The new description is revised to read**: The percentage of adolescent patients 12 to 17 years of age and adult patients18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date. **The new denominator is revised to read:** Adolescent patients 12 to 17 years of age with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event. The new numerator is revised to read: Adolescent patients aged 12 to 17 years of age who achieved remission at 12 months as demonstrated by a 12-month (+/- 60 days) PHQ-9 or PHQ-9M score of less than five.
Steward:	Minnesota Community Measurement (MNCM)
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We added adolescents to the denominator via stratification and references to the PHQ-9M, which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of 18. The score to determine denominator eligibility was based on the PHQ-9 assessment, this was expanded to include the PHQ-9M to accommodate the expanded age with age appropriate assessment tools. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agreed with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciated the collaboration among the stakeholders to broaden the measure.

Comment: One commenter noted the benefits and challenges associated with reporting the Depression Remission at 12 Months measure. While its inclusion in MIPS provides a more comprehensive measure set from which clinicians can choose to report, the commenter noted it carries a significant data collection burden. A second commenter stated that measure Q370 has been a challenge for academic medical centers is the depression remission measure. The depression remission measure (MH-1) measures the number of patients with major depression as defined as an initial PHQ-9 score> 9 who demonstrate remission at 12 months as defined as a PHQ-9 score <5. The requirement for PHQ-9 use for evaluating patients combined with a follow-up evaluation is problematic for many large group practices. The measure must be recorded for 248 patients, a very difficult bar for large multi-specialty group practices which refer patients for treatment and follow-up to psychiatrists if they have a PHQ-9. The measure seems to be designed for group practices that do not have this type of referral pattern. This is just one example of practice pattern differences between large academic medical groups and small and or/ rural practices. The commenter requested that the measure be removed, and that CMS determine if there may be other measures related to depression that would be more appropriate to use in the MIPS program.

Response: We believe this measure aligns with our policy to maintain meaningful measures within the program. Mental health issues have become prevalent in the nation and we believe it is critical to maintain measures that support improvement in mental health especially since our proposal is to expand this measure to adolescents. For this reason, we believe the benefit of measuring outcomes, as well as providing a more comprehensive measure set for the eligible clinician to report outweighs the data collection burden. In response to the commenter concern regarding the workflow of a large academic medical centers, the PHQ-9 derived from the psychiatrist could be used to determine remission as long as it is documented within the medical record. This would require communication and care coordination between the referring clinician and psychiatrist.

FINAL ACTION: We are finalizing the changes to measure Q370 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS159v6" to "CMS159v7." These changes were also applied to specialty measure sets in Table Group B where this measure is included.

D.10. Depression Utilization of the PHQ-9 Tool

Category	Description
NQF #:	0712
Quality #:	371
CMS eCQM ID:	CMS160v7
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	The percentage of patients age 18 and older with the diagnosis of major depression or dysthymia who have a completed PHQ-9 during each applicable 4-month period in which there was a qualifying visit.
Substantive Change:	**The new description is revised to read**: The percentage of adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the measurement period. **The new denominator is revised to read**: Adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia. **The new numerator is revised to read**: Adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) included in the denominator who have at least one PHQ-9 or PHQ-9M tool administered and completed during a 4-month measurement period.
Steward:	Minnesota Community Measurement (MNCM)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We added adolescents to the denominator via stratification and references to the PHQ-9M for both denominator and numerator, which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of 18. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agreed with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciated the collaboration among the stakeholders to broaden the measure.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q371 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure: The CMS eCQM ID changed from "CMS160v6" to "CMS160v7." These changes were also applied to specialty measure sets in Table Group B where this measure is included.	

D.11. Melanoma Reporting

Category	Description
NQF #:	N/A
Quality #:	397
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.
Substantive Change:	**The new numerator is revised to read**: Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We updated the numerator to include mitotic rate for all pT categories. The current measure specification only requires a statement the mitotic rate for pT1. The American Joint Committee on Cancer's Melanoma Expert Panel strongly recommends that mitotic rate be assessed and recorded for all primary melanomas, although it is not used for T1 staging in the eighth edition. The mitotic rate will likely be an important parameter for inclusion in the future development of prognostic models applicable to individual patients. Although it is not included in the T1 subcategory criteria, mitotic activity in T1 melanomas also has been associated with an increased risk of sentinel lymph node metastasis. We agreed with the addition of mitotic rate assessment for all primary melanomas. This creates valuable clinical information to the eligible clinician in order to create an effective treatment plan specific to the melanoma.
We did not receive specific comments regarding these measure changes. **FINAL ACTI**ON: We are finalizing the changes to measure Q397 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to **"**Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate." These changes were also applied to specialty measure sets in Table Group B where this measure is included. .	

D.12. Psoriasis: Clinical Response to Systemic Medications

Category	Description
NQF #:	N/A
Quality #:	410
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of psoriasis vulgaris patients receiving oral systemic or biologic therapy who meet minimal physician-or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.
Substantive Change:	**The new description is revised to read**: Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment **The new denominator is revised to read**: All patients with a diagnosis of psoriasis vulgaris and treated with a systemic medication. **The new numerator is revised to read**: Patients who have a documented physician global assessment (PGA; 5-point OR 6-point scale), body surface area (BSA), psoriasis area and severity index (PASI) and/or dermatology life quality index (DLQI) that meet any one of the below specified benchmarks.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We updated the measure title, description and denominator to expand the measure to include systemic medications that are administered both orally and subcutaneously. The measure still includes biologics rather than only oral and biologic medications. The patient population includes those diagnosed with psoriasis vulgaris receiving systemic medications that are administered both orally and subcutaneously or biologic therapy who meet minimal physician-or patient- reported disease activity levels. In addition, the numerator is being expanded to include the 5-point PGA scale as an additional benchmark. The current numerator allow the use of PGA; 6-point scale), body surface area (BSA), psoriasis area and severity index (PASI) and/or dermatology life quality index (DLQI) to assess clinical response. The measure steward believes the update to allow all systemic medications is relevant as they have deemed them to all apply to the measure. Based on recent literature, there is a strong correlation in how the 5-point scale is used like the 6-point PGA scale, resulting in comparative results. This scale is requested to be added to allow clinicians a shorter scale to choose from which would be more user-friendly in a clinical setting. We agreed with the expansion of the denominator to include all systemic medications, not limited to oral systemic or biologic therapy. Including systemic medications administered subcutaneously provides an additional opportunity to assess effective outcomes this treatment option. We agreed with the 5-point PGA scale to allow an additional tools to assess psoriasis outcomes.

Comment: Several commenters supported the measure expansion for Q410: Psoriasis: Clinical Response to Systemic Medications to systemic drugs that are administered both orally and subcutaneously. Psoriasis had been an underrepresented clinical category within the MIPS measure set in recent years, and the expansion of this measure creates additional opportunities to demonstrate the effectiveness of new treatment options.

Response: We thank the commenters for their support of measure Q410: Psoriasis: Clinical Response to Systemic Medications.

FINAL ACTION: We are finalizing the changes to measure Q410 as proposed for the 2019 Performance Period and future years. We are finalizing this measure as a MIPS CQMs Specification only. This measure will not be available as a Medicare Part B Claims Measure Specification as it is not analytically feasible for this collection type. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Psoriasis: Clinical Response to Oral Systemic or Biologic Medications" to "Psoriasis: Clinical Response to Systemic Medications." These changes were applied to specialty measure sets in Table Group B where this measure is included.

D.13. Depression Remission at Six Months

Category	Description
NQF #:	0711
Quality #:	411
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18 years of age or older with major depression or dysthymia who reached remission 6 months (+/- 30 days) after an index visit.
Substantive Change:	**The new description is revised to read**: The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 6 months (+/- 60 days) after an index event date. **The new denominator is revised to read:** Submission Criteria 1: Adolescent patients 12 to 17 years of age with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event. Submission Criteria 2: Adult patients 18 years of age or older with a diagnosis of major depression or dysthymia and an initial PHQ-9 or PHQ-9M score greater than nine during the index event.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We added adolescents to denominator via stratification and references to the PHQ-9M which is specific for adolescents. The patient population has been revised to include patients 12 years of age and older, when previously only included patients over the age of 18. The score to determine denominator eligibility was based on the PHQ-9 assessment, this was expanded to include the PHQ-9M to accommodate the expanded age with age appropriate assessment tools. The measure steward worked in collaboration with NCQA, who requested a consideration of incorporating adolescents into the existing depression measures. We agreed with the expansion of the denominator to include the adolescent patient population. Depression assessment is a clinically relevant and important topic to address among adolescents. We appreciated the collaboration among the stakeholders to broaden the measure.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q411 as proposed for the 2019 Performance Period and future years.	

D.14. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF #:	N/A
Quality #:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT
Substantive Change:	Updated the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. **The new description is revised to read:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care clinician who have an indication for a head CT. **The new denominator is revised to read**: All emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider **Updated the numerator**: To indicate the GCS score less than 15 is an appropriate indication for a head CT. The new definition within the numerator is revised to include a GSC score less than 15.
Steward:	American College of Emergency Physicians (ACEP)
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We updated to the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. We updated the numerator to indicate the GCS score less than 15 is an appropriate indication for a head CT. The new description is revised to read: Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT. Based on feedback from the measure steward, this measure is appropriate for all minor blunt head traumas, regardless of when they occurred in relation to presentation to the ED. Additionally, in order to better align the measure with the evidence base and guidelines supporting the measure, the measure steward determined that the GCS of <15 data element would be more accurately included as an appropriate indication for ordering a head CT, so this has been relocated to the numerator definition. We agreed with the recommendation and accept the revision as this promotes utilization of the most current guidelines to determine imaging requirements based on the documented GCS.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q415 as proposed for the 2019 Performance Period and future years.	

D.15. Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years

Category	Description
NQF #:	N/A
Quality #:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury
Substantive Change:	**Updated denominator**: To remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. **The measure description is revised to read**: Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury. **Updated the numerator**: To indicate the GCS score less than 15 is an appropriate indication for a head CT.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We updated the measure description and denominator to remove the requirement of a patient presenting to the emergency department within 24 hours of a minor blunt head trauma, as well as remove the requirement to document a GCS of 15. We updated the numerator to indicate the GCS score less than 15 is an appropriate indication for a head CT. Based on feedback from the measure steward, this measure is appropriate for all minor blunt head traumas, regardless of when they occurred in relation to presentation to the ED. Additionally, in order to better align the measure with the evidence base and guidelines supporting the measure, ACEP physician leaders determined that the GCS of <15 data element would be more accurately included as an appropriate indication for ordering a head CT, so this has been relocated to the numerator definition. We agreed with the revision as this promotes utilization of the most current guidelines to determine imaging requirement based on the documented GCS.
We did not receive specific comments regarding these measure changes. **FINAL ACTION:** We are finalizing the changes to measure Q416 as proposed for the 2019 Performance Period and future years.	

D.16. Functional Status Change for Patients with Knee Impairments

Category	Description
NQF #:	0422
Quality #:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status for patients 14 year+ with knee impairments. The change in functional status (FS) assessed using FOTO's (knee) PROM (patient-reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q217: Functional Status Change for Patients with Knee Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted, not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing changes to measure Q217 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.17. Functional Status Change for Patients with Hip Impairments

Category	Description
NQF #:	0423
Quality #:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status (FS) for patients 14 years+ with hip impairments. The change in functional status (FS) assessed using FOTO's (hip) PROM (patient- reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q218: Functional Status Change for Patients with Hip Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q218 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.18. Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF #:	0424
Quality #:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report measure of change in functional status (FS) for patients 14 years+ with foot and ankle impairments. The change in functional status (FS) assessed using FOTO's (foot and ankle) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agree with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for the Q219: Functional Status Change for Patients with Foot or Ankle Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q219 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Functional Status Change for Patients with Foot or Ankle Impairments" to "Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments". The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.19. Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF #:	0425
Quality #:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of change in functional status for patients 14 years+ with lumbar impairments. The change in functional status (FS) assessed using FOTO (lumbar) PROM (patient reported outcome measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for the Q220: Functional Status Change for Patients with Lumbar Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q220 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Title was changed from "Functional Status Change for Patients with Lumbar Impairments" to "Functional Status Change for Patients with Low Back Impairments". The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was changed from "Outcome" to "Patient Reported Outcome." These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.20. Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF #:	0426
Quality #:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in functional status (FS) assessed using FOTO's (shoulder) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	**The new description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey). Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q221: Functional Status Change for Patients with Shoulder Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q221 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was updated from "Outcome" to "Patient Reported Outcome". These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.21. Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF #:	0427
Quality #:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS assessed using FOTO (elbow, wrist and hand) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q222 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was updated from "Outcome" to "Patient Reported Outcome". These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.22. Functional Status Change for Patients with General Orthopedic Impairments

Category	Description
NQF #:	0428
Quality #:	223
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A self-report outcome measure of functional status (FS) for patients 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS assessed using FOTO (general orthopedic) PROM (patient reported outcomes measure) is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level by to assess quality
Substantive Change:	Updated the denominator to allow coding for chiropractors and outpatient eligible clinicians. **The new denominator is revised to expand to**: Physician Denominator Criteria and Chiropractic Care Denominator Criteria.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We expanded the denominator to allow coding for chiropractors and outpatient eligible clinicians. The current measure only includes coding to support physical and occupational therapists. The measure steward has recommended expanding the denominator to include other types of eligible clinicians providing outpatient and chiropractic services. Physical functional status is relevant to a broad spectrum of specialties in order to assess the effectiveness of a treatment plan. We agreed with the recommendation and are proposing the expansion as it allows a broader spectrum of eligible clinicians the opportunity to submit outcome measures.

Comment: Two commenters supported the substantive change proposed for measure Q223: Functional Status Change for Patients with Other General Orthopedic Impairments measure by allowing coding for chiropractic clinicians but emphasized that unless chiropractors are reimbursed for CPT code 98943 which covers extraspinal, one or more regions (currently NOT covered by Medicare), the current three codes will not apply to this measure.

Response: This measure can only be submitted utilizing the MIPS CQMs Specifications, which allows all payer data to be submitted not just Medicare. Therefore, chiropractors utilizing CPT code 98943 can include those patients in the denominator for this measure. Specific Medicare reimbursement for this code would not preclude the eligible clinician from submitting this measure.

FINAL ACTION: We are finalizing the changes to measure Q223 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: The Measure Description was updated to "A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients aged 14 years+ with general orthopedic impairments (neck, cranium, mandible, thoracic spine, ribs or other general orthopedic impairment). The change in FS is assessed using the General Orthopedic FS PROM (patient reported outcome measure) (©Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static survey)." The Measure Type was updated from "Outcome" to "Patient Reported Outcome". These changes were also applied to specialty measure sets in Table Group B where this measure is included. (Please note that these technical changes were erroneously characterized as substantive changes in the proposed rule.)

D.23. Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
NQF #:	N/A
Quality #:	419
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a diagnosis of primary headache disorder whom advanced brain imaging was not ordered
Substantive Change:	Updated the measure analytics to be an inverse measure and remove the assessment of the appropriate use for Computed Tomography Angiography (CTA) and Magnetic Resonance Angiography (MRA). **The new description is revised to read**: Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present **The new numerator is revised to:** Patients for whom imaging of the head (Computed Tomography (CT) or Magnetic Resonance Imaging (MRI)) is obtained for the evaluation of primary headache when clinical indications are not present.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We adjusted the measure analytics to produce inverse performance data and update the numerator to reflect new clinical evidence regarding the diagnostic imaging modalities (removing CTA and MRA). Updating inverse measure analytics for this measure will appropriately represent the data produced by an overuse measure. The measure development workgroup, procured by AAN, reviewed available evidence and found that there are different indications for imaging with CTA and MRA compared to CT and MRI. The indications for clinical management of primary headache, (which are listed in the measure) are only appropriate for CT and MRI. The updated clinical guidelines included in the measure support this as well.

Comment: One commenter supported changes to measure Q419: Overuse Of Imaging For Patients With Primary Headache so that it would focus only on CT and MRI scans ordered (omitting CTA and MRA imaging to create consistency with the indication for clinical management of primary headache), and will also capture inverse performance data. However, the commenter underscored that unmet needs continue to exist related to quality measures for migraine and primary headache disorder, and that CMS is missing an opportunity to consider the costly impact of medication overuse that can result from inadequate response to existing treatments for migraine and primary headache disorder. The commenter requested that CMS, along with the MAP, NQF, and other stakeholders consider new and/existing measures that addresses the rate of acute medication overuse among patients suffering from migraine. The Institute for Clinical Systems Improvement (ICSI) has developed the measure, "Percentage of patients with migraine headache with a prescription for opiates or barbiturates for the treatment of migraine" to address overuse of opioids and narcotics for the treatment of migraine headache.

Response: We encourage the commenter to collaborate with measure developers to submit measures to the Call for Measures process that have been fully tested and address migraine and headache disorder.

FINAL ACTION: We are finalizing the changes to measure Q419 as proposed for the 2019 Performance Period and future years. Please note that the following technical changes were also made to this measure for further accuracy based on feedback from the measure steward: Measure Title was updated from "Overuse of Imaging For Patients With Primary Headache" to "Overuse of Imaging for the Evaluation of Primary Headache". Measure Type was updated from "Efficiency" to "Process". These changes were also applied to specialty measure sets in Table Group B where this measure is included.

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction

Specialty Sets: Cardiology, Family Medicine, Internal Medicine

Comment: One commenter supported measure Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction because there is good evidence that ACE inhibitors and ARBs improve the health of people with heart failure and LVEF < 40%, and the measure aligns with current guidelines and represents high-value care for patients with chronic heart failure.

Response: We thank the commenter for the support of measure Q005: Heart Failure: Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction.

Q006: **Coronary Artery Disease: Antiplatelet Therapy**

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q006: Coronary Artery Disease: Antiplatelet Therapy. The evidence base would benefit from re-evaluation as data surfaces on the benefits and risks of aspirin therapy in patients who are already prescribed warfarin therapy as supported by several societies. It may also be difficult for clinicians to capture over the counter aspirin use unless explicitly stated by the patient.

Response: We do not see the over the counter aspirin use to be a major impact to performance. In addition, medication lists should include all known prescriptions, over-the counters, herbals, and vitamin/mineral/dietary (nutritional) supplements with the medications' name, dosages, frequency and route of administration.

Q007: **Coronary Artery Disease: Beta-Blocker Therapy--Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF < 40%)**

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q007: Coronary Artery Disease: Beta-Blocker Therapy--Prior Myocardial Infarction or Left Ventricular Systolic Dysfunction (LVEF < 40%). However, the commenter cited that skepticism exists surrounding consistency across operating systems to include all billing codes for appropriate exclusion criteria. Furthermore, while the measure is based on clinical recommendations of a number of societies, there is some question surrounding the need for continued beta-blocker therapy for 3 years in low-risk patients in the contemporary era of revascularization. Lastly, it is unnecessarily burdensome for clinicians to look at all LVEF assessments in a complete patient history, and developers should consider revising the specifications to limit the look-back window and exclude patients with a normal LVEF without history of LVSD.

Response: The measure is based on the ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guidelines and we will continue to monitor and collaborate with the measure steward if updated guidelines are published. We disagree that inconsistent billing coding would not allow appropriate exclusion submission. As an eCQM, it has been fully tested to appropriately identify exclusions within an EHR. As a MIPS CQMs, data is not limited to billing coding to determine exclusions. Documentation of prior LVEF <40% is required to determine denominator eligibility is supported by clinical guidelines. Beta-blockers have been shown to reduce risk of death are recommended indefinitely for patients with CAD and LV systolic dysfunction.

Q008: **Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction**

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q008: Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction because the balance of evidence shows that long-term treatment with beta-blockers can lessen the symptoms of heart failure, improve the clinical status of patients, and enhance the patient's overall sense of well- being. The measure aligns with current guidelines and represents high-value care for patients with chronic heart failure.

Response: We thank the commenter for the support of measure Q008: Heart Failure: Beta-blocker therapy for Left Ventricular Systolic Dysfunction.

Q009: Antidepressant Medication Management

Specialty Sets: Family Medicine, Internal Medicine, Mental/Behavioral Health

Comment: One commenter did not support measure Q009: Antidepressant Medication Management. Reasons cited included: the time frame used in the measure contradicts recommendations from evidence-based guidelines; measure specifications do not consider alternative interventions for depression management such as psychotherapy, electroconvulsive therapy (ECT), or the combination of somatic and psychotherapy; the measure excludes patient choice to switch to another modality of effective therapy due to side effects (where measure specifications should include exclusion criteria for lack of patient adherence due to the side effects of medication with documentation of alternative therapy); the requirement for acute phase treatment should be deleted; and the measure intends to evaluate quality outcomes at the health plan level, but the measure as included in MIPS intends to assess performance at the individual clinician level where clinicians are unaware of information (for example, medication refill data) related to effective management of medication adherence.

Response: We consulted with the measure steward and they will take your suggestions regarding adjustment of timeframes, alternative interventions, inclusion of patient choice, and assessing outcome evaluation levels under consideration for future updates to this measure.

Q039: Screening for Osteoporosis for Women 65-85 Years of Age

Specialty Sets: Family Medicine, Internal Medicine, Preventive Medicine, Rheumatology, Geriatrics

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Comment: One commenter supported measure Q039: Screening for Osteoporosis for Women 65-85 Years of Age. The commenter noted that implementation could promote overuse of screening if patients receive care from multiple clinicians and/or have poor record continuity, and in women who are at lower risk for osteoporosis based on reasonably identifiable factors (for example, BMI, ethnicity). The commenter suggested that developers should consider updating the denominator specifications to include exclusion criteria for patients who have already been assessed with the FRAX tool and for patients receiving hospice and palliative care where the intervention

Response: We do not agree that it would promote overuse of screening as it requires documentation of one historical screening. Eligible clinicians are expected to coordinate their care with eligible clinicians. We will provide feedback to the measure steward to include the FRAX tool exclusion to be fully vetted through the annual revision process. In response to the commenter's request to include a hospice exclusion, this is included within the measure specification.

Q046: Medication Reconciliation Post-Discharge

Specialty Sets: Orthopedic Surgery, Nephrology, General Surgery, Geriatrics

Comment: One commenter did not support measure Q046: Medication Reconciliation Post-Discharge although it can help to eliminate medication errors that may occur during transitions of care and will not promote over- or underuse and timely reconciliation of discharge medication lists. The commenter expressed the following concerns: 2013 PQRS participation results do not necessarily represent performance on a national level; the measure has insufficient evidence to support this as an accountability measure and it is a "check the box measure;" a more standardized approach is needed for medication adherence, the numerator specifications exclude clinicians who are capable of reconciling medication lists which could limit the success of this measure from a health plan/integrated delivery system perspective; and clinicians may encounter interoperability barriers to data access.

Response: This measure promotes appropriate medication management, communication and care coordination between caregivers. Although the impact of medication reconciliation alone on patient outcomes is not well studied, there is expert agreement that potential benefits outweigh the harm. We applaud the clinicians that adhere to this practice, but believe this concept improves communication and patient safety. This is considered a process measure and we are looking to move towards outcome-based measures. In addition, we encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process. We disagree with the commenter citing barriers based on clinicians utilizing different EHRs. The measure stewards allow multiple methods of medication reconciliation as defined in the numerator. The measure steward has standardized the clinicians that are able to complete the quality action. A prescribing practitioner, clinical pharmacists or registered nurse should conduct medication reconciliation. We will provide your recommendation to the measure steward to include pharmacy technicians in future iterations of the measure specification.

Q047: Advance Care Plan

Specialty Sets: Cardiology, Gastroenterology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Nephrology, General Surgery, Vascular Surgery, Thoracic Surgery
Urology, Oncology, Rheumatology, Geriatrics, Skilled Nursing Facility

Comment: One commenter did not support measure Q047: Advance Care Plan, and cited it could prevent overuse of unnecessary end of life care interventions. The commenter noted the measure is burdensome for clinicians to annually document an advance care plan for all patients aged 65 years and older and also objects to the 12-month measurement period included in the denominator specifications. There is no evidence to guide optimal frequency and at what age to begin planning, and it may be inappropriate for clinicians to perform this intervention during an initial office visit. Lastly, the denominator population could be revised to established patient visits only.

Response: We disagree with concern this measure may be burdensome to document an advance care plan annually. The eligible clinician is not required to create a new advance care plan but confirms annually that the plan in the medical record is still appropriate or starts a new discussion. We will provide your suggestion to the measure steward regarding the narrowing of the patient population to established patient only. The measure steward does state the measure is appropriate for use in all healthcare settings (for example, inpatient, nursing home, and ambulatory) except the emergency department. For each of these settings, there should be documentation in the medical record(s) that advance care planning was at least discussed or documented. Eligible clinicians are still able to be numerator compliant if the advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. We maintain the notion that Q047 is a good measure that promotes initiation of communication. With the inclusion of new patient visit coding, this would likely affect all eligible clinicians submitting the measure, therefore data would be comparable.

Q050: Urinary Incontinence: Plan of care for Urinary Incontinence in Women Aged 65 Years and Older

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Urology, Geriatrics

Comment: One commenter supported measure Q050: Urinary Incontinence: Plan of care for Urinary Incontinence in Women Aged 65 Years and Older because a performance gap exists, treatments exist to create meaningful improvements in clinical outcomes/quality of life and the benefits of reducing the patient disease burden outweigh the clinician measurement burden. Although, they stated that developers cite weak evidence to support the benefit of care plan development on clinical outcomes in women with urinary incontinence. Additionally, developers should consider updating denominator specifications to include exclusion criteria for patients who refuse care plan services. Lastly, this measure is meant for the system level and individual clinicians may encounter interoperability barriers retrieving this data.

Response: There is some high quality evidence for use pelvic floor muscle training in the treatment of older women with UI and pharmacologic treatment if training is unsuccessful. In response to the request to add a denominator exception for patient refusal of a care plan, the measure steward does not allow patient refusals for this measure. We understand the commenter's concern; however, all eligible clinicians submitting measure Q050, regardless of data method, will not have the ability to submit a patient refusal and therefore are comparable when calculating the performance of the measure.

Q107: Adult Major Depressive Disorder: Suicide Risk Assessment

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Specialty Sets: Family Medicine, Emergency Medicine, Mental/Behavioral Health

Comment: One commenter supported measure Q107: Adult Major Depressive Disorder: Suicide Risk Assessment but noted several recommendations that could improve the measure quality. These included: the measure is close to being topped out and developers should include current, national performance data in the updated measure report; the numerator is not clearly specified, such as what constitutes a "recurrent" episode because as currently stated, the measure could apply to all follow-up visits with the mention of even well-controlled depression; this is a "check the box measure" with little potential to shift quality; and the measure poses significant burden.

Response: We will work with the measure developer to provide additional context in future years. We suggest the commenter to review the full measure specification for guidance on defining a recurrent episode. It clarifies an episode of major depressive disorder (MDD) would be considered to be recurrent if a patient has not had an MDD-related encounter in the past 105 days. If there is a gap of 105 or more days between visits for major depressive disorder (MDD) that would imply a recurrent episode. The 105-day look-back period is an operational provision and not a clinical recommendation, or definition of relapse, remission, or recurrence.

Q109: Osteoarthritis: Function and Pain Assessment

Specialty Sets: Family Medicine, Orthopedic Surgery, Physical Medicine

Comment: One commenter did not support measure Q109: Osteoarthritis: Function and Pain Assessment, citing insufficient evidence to support an appropriate assessment time interval and the denominator specifications are unclear. The measure should specify utilization of a validated, standardized assessment tool that demonstrates improvements in quality outcomes. It is burdensome for clinicians to perform this assessment at every visit where OA is not the primary patient complaint. The commenter stated this measure is not an appropriate accountability measure for general internists. Additionally, clinicians may encounter interoperability barriers to data access and embedding data into the information system.

Response: It is important to remember that absence of hard evidence supporting function and pain assessment is not evidence that it is not effective. It allows eligible clinicians to adjust their treatment plans at the patient level. In response to the request to specify the validated tools, we direct the commenters to review the measure specification as it provides an extensive list of assessment tools. The submission frequency has been updated for the 2019 performance period to once per performance period. This measure is not required and encourage eligible clinicians to select quality measures that are applicable to their specialty.

Q110: Preventive Care and Screening: Influenza Immunization

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Otolaryngology, Pediatrics, Preventive Medicine, Nephrology, Oncology, Infectious Disease, Rheumatology, Geriatrics, Skilled Nursing Facility

Comment: One commenter supported measure Q110: Preventive Care and Screening: Influenza Immunization because the measure aligns with current CDC Advisory Committee recommendations. However, the commenter noted that electronic health record (EHR) information blocking could prevent the transmission of immunization information between competing electronic systems.

Response: We continue to align with the Centers for Disease Control and Prevention recommendations for routine annual influenza vaccinations for all persons aged greater than or equal to 6 months. We continue to promote interoperability through Certified Electronic Health Record technology and the prevention of Information blocking. We encourage the reporting of immunizations to the appropriate Registries through Promoting Interoperability performance category and Registry reporting measures.

Comment: One commenter supported having measure Q110: Preventive Care and Screening: Influenza Immunization available in multiple specialty sets.

Response: We thank the commenter for their support of this measure.

Q111: Pneumococcal Vaccination Status for Older Adults

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Otolaryngology, Nephrology, Oncology, Infectious Disease, Rheumatology, Geriatrics

Comment: One commenter did not support measure Q111: Pneumococcal Vaccination Status for Older Adults. While this measure represents an important clinical concept, implementation could promote treatment overuse if patients seek medical care from multiple clinicians and/or have poor medical record continuity. In addition, the developer should update the numerator specifications to align with current clinical recommendations on pneumococcal vaccination.

Response: The Centers for Disease Control and Prevention continues to recommend the pneumococcal vaccine in adults 65 years and older due to the high incidence of pneumococcal-related deaths and costs associated with this condition. We recommend attempts to locate missing records in a reasonable timeframe so that the initial vaccine not be postponed. We will provide the numerator language feedback to the measure steward. There is a numerator note included within the specification to provide submission guidance. We are exploring options to replace this measure in future performance periods that more closely aligns with the guidelines. However, until this measure can be replaced with a measure promoting pneumococcal vaccination, we believe this measure still promotes pneumococcal vaccination and addresses an important population health matter. As stated within the measure specification: The measure allows administration or documentation of PCV13 or PPSV23 vaccine (or both) to be numerator compliant. According to ACIP recommendations, patients should receive both vaccines. The order and timing of the vaccinations depends on certain patient characteristics, and are described in more detail in the ACIP recommendations.

Comment: One commenter supported having measure Q111: Pneumococcal Vaccination Status for Older Adults available in multiple specialty sets.

Response: We thank the commenter for their support of this measure.

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Q112: Breast Cancer Screening

Specialty Sets: Family Medicine, Obstetrics/Gynecology, Preventive Medicine

Comment: One commenter supported measure Q112: Breast Cancer Screening due to current evidence and that most health systems that have networks in place to address this issue. However, the commenter expressed concern that this measure could promote screening overuse and that a stronger measure may include exclusion criteria for system and patient related issues (for example, availability of mammography screening tools, patient preference, and limited life expectancy). Also, this measure may be less impactful than other cancer screening measures (for example, MIPS 113: Colorectal Cancer Screening).

Response: The measure's intent is to promote preventive breast cancer screening, not to address the overuse of screening. If data supports an overuse of breast screening, we encourage the development of an appropriate use of breast cancer screening measure to be submitted to the annual Call for Measures. The measure steward does incorporate denominator exclusion to exclude patients with bilateral mastectomy, receiving hospice services or residing in an Institutional Special Needs Plans (SNP) or long-term care facility. The intent of the exclusion for individuals age 65 and older residing in long-term care facilities, including nursing homes, is to exclude individuals who may have limited life expectancy and increased frailty where the benefit of the process may not exceed the risks. The numerator allows for patient preference and more accessible screening methods by including screening, diagnostic, film, digital or digital breast tomosynthesis mammography to be considered numerator compliant.

Q113: Colorectal Cancer Screening

Specialty Sets: Family Medicine, Preventive Medicine

Comment: One commenter supported measure Q113: Colorectal Cancer Screening but expressed that the developer should update the measure specifications to align with current clinical recommendations on colorectal cancer screening. Specifically, numerator specifications should include the option for clinicians to document emerging cancer screening tests (for example, stool FIT-DNA, CT colonography). Additionally, measure specifications do not include appropriate exclusion criteria and could promote overuse of screening in patients where the benefits do not outweigh the risk of harms, and this risk adjustment could be addressed by measure developers. A better measure would include exclusion criteria for patients diagnosed with dementia, patients with limited life expectancy, patients with advanced comorbidities, and patient refusal.

Response: The specification defines the screening to include any of following: Fecal occult blood test (FOBT), Flexible sigmoidoscopy, Colonoscopy Computed tomography (CT) colonography, Fecal immunochemical DNA test (FIT-DNA). The measure's intent is to promote preventive colorectal cancer screening, not to address the overuse of screening. We suggest the commenter review measure Q439: Age Appropriate Screening Colonoscopy which addresses the appropriate use with consideration to the benefits and risks. The measure excludes patients with a diagnosis or past history of total colectomy or colorectal cancer, receiving hospice services, and patient aged 65 or older in Institutional Special Needs Plans or residing in long-term care. The intent of the exclusion for individuals age 65 and older residing in long-term care facilities, including nursing homes, is to exclude individuals who may have limited life expectancy and increased frailty where the benefit of the process may not exceed the risks. The measure steward does not include a patient refusal as it is the eligible clinician's responsibility to educate their patients to see the value of preventive colorectal screening. In addition, all eligible clinicians submitting measure Q113, regardless of data submission method, will not have the ability to submit a patient refusal and therefore are comparable when calculating the performance of the measure.

Q116: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis

Specialty Sets: Family Medicine, Internal Medicine, Preventive Medicine, Urgent Care

Comment: One commenter supported measure Q116: Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis because implementation could lead to measurable and meaningful improvements in clinical outcomes and prevent overuse of inappropriate antibiotic therapy in patients diagnosed with acute bronchitis. However, the commenter noted the potential for clinicians to manipulate the measure through inaccurate coding of disease classification (that is, ICD10).

Response: Eligible clinicians should not change their billing or documentation to manipulate eligibility or determination of appropriate treatment. Any claims submitted to the CMS are subject to an audit, inclusive of any performance data submitted to the quality program.

Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation

Specialty Sets: Family Medicine, Internal Medicine, Preventive Medicine, Podiatry

Comment: One commenter did not support measure Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy –Neurological Evaluation. Issues cited included: the measure developer cites a 44 percent performance gap based on data from the 2012 PQRS reporting year which may inaccurately represent nationwide performance levels; there is insufficient evidence to support a dedicated monofilament examination or the need to repeat the exam once the patient produces negative examination results. The numerator should specify the utilization of neurological assessment tools that are equally as effective as the mono filament in diagnosing neurological deficits in diabetic patients; and there is a lack of high-quality evidence to suggest that regular, comprehensive full lower extremity neurological examinations in the primary care setting improves outcomes for asymptomatic patients. While this measure represents good clinical care, quality improvement programs should not implement this measure to assess the performance quality of individual clinicians. The commenter cited that measure specifications had appropriate exclusion criteria.

Response: We disagree with the commenter's performance data as it was based on 2012 PQRS performance data. The 2018 MIPS Benchmark Results reflect an average 58.7 percent compliance rate. This measure is consistent with the recommendation from the Diabetics Foot Disorders: A Clinical Practice Guideline. The measure does not require the test to be repeated once the patient produces a negative result. Neurological examination is required at least once within the 12 months prior to eligible encounter. This aligns with the guidelines for a normal risk profile. We encourage eligible clinicians to perform neurological examination more frequently based on the risk. In response to the lack of evidence to support primary care to evaluate footwear, this is not a required measure

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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and encourage eligible clinicians to select measures that are clinically appropriate and align with their clinical workflow.

Q127: Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear

Specialty Sets: Podiatry

Comment: One commenter did not support measure Q127: Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear, citing a lack of high-quality evidence on improved patient outcomes. This measure is topped with a 93 percent compliance rate although the measure may appropriately evaluate quality performance of podiatrists.

Response: We disagree with the commenter's performance data. The 2018 MIPS Benchmark Results reflect an average 55 percent performance rate. The measure is applicable to all eligible clinicians, not just podiatry that was the basis of the commenter's performance data. In response to the lack of evidence to support primary care to evaluate footwear, this is not a required measure and encourage eligible clinicians to select measures that are clinically appropriate and align with their clinical workflow.

Q130: Documentation of Current Medications in the Medical Record

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/ Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, Nephrology, General Surgery, Vascular Surgery, Thoracic Surgery, Urology, Oncology, Infectious Disease, Neurosurgical, Rheumatology, Physical Therapy/Occupational Therapy, Geriatrics, Urgent Care

Comment: One commenter did not support measure Q130: Documentation of Current Medications in the Medical Record due to lack of high-quality evidence, it is burdensome for clinicians to document complete medication lists at every patient visit, and it is a "check the box" measure. A more appropriate measure may encourage documentation of medication lists according to clinical necessity and incentivize a standardized, methodological approach to reconciliation, according to clinician practice level (for example, physician, nurse, medical assistant) that leads to improvements in the medication management process. Furthermore, practice variables can impede the physician's ability to document complete accurate medication lists.

Response: This measure promotes patient safety to avoid adverse drug events (ADE). Documentation of current medications in the medical record facilitates the process of medication review and reconciliation by the eligible clinicians, which are necessary for reducing ADEs and promoting medication safety. This is considered a process measure and we are looking to move towards outcome-based measures. In addition, the commenter suggested substantive revisions that would require a new measure to be developed. We will continue to explore opportunities to revise this measure, but we encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process. The quality action requires eligible clinicians to attest to documenting, updating or reviewing a patient's current medications using all immediate resources available on the date of encounter. We would expect if eligible clinicians identify unnecessary medications, they would collaborate with their patient to make appropriate adjustments of their medications. While we move towards outcome-based measure, we maintain Q130 initiates a clinical process that would impact patient safety.

Q131: Pain Assessment and Follow-Up

Specialty Sets: Orthopedic Surgery, Physical Medicine, Urology, Rheumatology, Physical Therapy/Occupational Therapy, Geriatrics, Urgent Care

Comment: One commenter did not support measure Q131: Pain Assessment and Follow-Up due to specification flaws that included: (1) performance rates are close to 100 percent; (2) the measure distracts from measurement of change in functional status; (3) implementation of this measure could unintentionally promote overuse of opioid therapy; (4) outdated evidence is cited to form the basis of the measure; (5) specifications do not address the importance of including a functional assessment during the patient visit; 96) specifications do not exclude patients who have known diversions to opioid therapy (for example, substance abuse and alcohol abuse disorders) and this could fuel the opioid epidemic; (7) it is burdensome for clinicians to document pain assessment and follow-up plan at every visit regardless of the patient's primary complaint; (8) referral to a pain management specialist is not practical in every area of the country; and (9) the measure language around "eliminating" pain is unreasonable.

Response: We continue to move towards high priority measures which include outcome-based measures and opioid measures. The quality action does not require an opioid prescription. We disagree with the commenter's performance data, based on the 2018 MIPS Benchmark Results this measure has an average 68.2 percent (MIPS CQMs Specifications) and 87.2 percent (Medicare Part B Claims Measure Specifications) performance rate. The measure does not require a pain management specialist nor an opioid prescription. A follow-up plan may consist of planned follow-up appointment or a referral, a notification to other care clinicians as applicable OR indicate the initial treatment plan is still in effect. These plans may include pharmacologic, interventional therapies, behavioral, physical medicine and/or educational interventions. We do not agree this measure to be burdensome as the tools to assess pain may include the Numeric Rating Scale where documentation of a fraction would meet the screening requirement. We agree with the addition of functional assessment but may add burden which was a concern raised by the commenter. In response to the measure language surround "eliminating pain," we refer the commenter to the measure specification as this is not included within the measure language.

Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Pediatrics, Preventive Medicine, Neurology, Mental/Behavioral Health

Comment: One commenter did not support measure Q134: Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan although it aligns with USPSTF recommendations on screening for clinical depression. The commenter suggested the denominator specifications exclude patients who are currently under the care of a mental health specialist for comorbid illness or severe cognitive impairment. Developers should consider revising the denominator specifications to reflect patients seen in the calendar year instead of all patients. Measure specifications do not define an appropriate screening frequency. It is not clear whether this measure applies to all patients in a clinicians' panel or only those seen during the calendar year in a face-to-face visit.

Response: In response to the concerns surrounding the denominator, the measure does not include patients within an active diagnosis of depression or has a

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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diagnosed bipolar disorder within that patient population. In addition, the measure also allows denominator exceptions for situations where the patient's functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment tools. Patients are denominator eligible when they meet the denominator criteria within the performance period. For all MIPS quality measures at this time, eligibility is not based on the eligible clinicians' panel but requires an eligible encounter within the performance period as defined by the denominator criteria which allows both face-to-face and telehealth visits.

Comment: One commenter provided extensive information on how the PREV 12 Depression Screening (Q134) using the Web Interface methodology is being operationalized in its facility. The commenter provided specific related to the PHQ scores in its decision-making. The commenter's practice has decided on 4, but a score of 3 is also accepted in the literature and could be a reasonable cutoff for the PHQ-2. As a result, the commenter asked that CMS consider revisiting how this measure is operationalized to allow the use of evidence-based cutoffs for when further documentation is required. The commenter was also concerned that the measure numerator poses a discrepancy by still requiring depression screening and review to occur in a visit setting. The commenter has adopted a care coordination program where the primary health care provider oversees a multi-disciplinary team to address complex health conditions in a non-visit modality. A Registered Nurse care coordinator may perform the depression screening, review, and arrange for follow up during a non-visit interaction performed at regular intervals. If no active concerns are present, the patient may not be seen again before the end of the measurement period for the health care provider to review the screening at an eligible visit. This results in a measure failure, despite the patient receiving quality team-based care individualized to the patient's situation. Another situation where a patient may receive quality team-based care yet result in the patient not meeting numerator conditions is at the Annual Medicare Wellness visit. Depression Screening is a component of the Medicare Annual Wellness Visit, and one of the MIPS Web Interface required metrics in addition to being used for collection methods such as the EHR collection method. However, the PREV-12 Depression Screening specifications state: The depression screening must be reviewed and addressed in the office of the health care provider filing the code, on the date of the encounter. Our Annual Wellness Visits are typically scheduled within a month of the patient's annual visit with the health care provider; therefore, the only way to meet both requirements is to have the patient complete the depression screening questionnaire twice. The commenter noted this is redundant and takes time away from other components of patient care. The commenter requested that CMS either accept the depression screening performed at the Annual Wellness Visit as meeting the PREV-12 requirements, or eliminate depression screening from the Annual Wellness Visit, or preferably simplify the numerator to allow the latest depression screening and review to occur any time during the measurement period and not tie it to a particular visit.

Response: In regards to the determination of a positive screen, whether or not a PHQ-9 (or other standardized screening tool) screening score is considered positive would be determined by the eligible professional administering and reviewing the standardized tool results. The measure steward does not define "positive" so it is at the discretion of the eligible clinician based on their knowledge of the patient to determine if the result is considered positive or negative. For the purpose of submitting PREV-12 information, the measure requires medical record documentation of positive or negative for the depression screen result per the measure steward. There are only two instances when specific documentation of positive or negative is not required. One instance is when the PHQ result is 0 in which case the result can be assumed to be negative. The other instance is when there is documentation of a depression screen using a normalized and standardized screening tool and at the same encounter there is documentation of a recommended follow up, in which case it can be assumed the result of the screen was positive. The Web Interface allows for telehealth for PREV-12, so it is not necessary to tie the review of the screening results to a specific encounter. As long as the most recent screening during the measurement period is used, the screening occurred during the measurement period, there is documentation of positive or negative, the results have been reviewed by the clinician, and if positive a recommended follow up, the measure has been met.

Based on the commenter's scenario, this workflow would not cause the eligible clinician to fail the quality action. We encourage the commenter to work with the measure subject matter experts through the Quality Payment Program Service Center to address the concerns.

Q154, Q155, and Q318

Specialty Sets:
Q154: Family Medicine, Internal Medicine, Orthopedic Surgery, Otolaryngology, , Neurology, Podiatry, Physical Medicine, Preventive Medicine
Q155: Family Medicine, Internal Medicine, Neurology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Podiatry
Q318-Orthopedic Surgery, Nephrology

Comment: One commenter did not support measures Q154, 155, and 318 (NQF measure Q0101): Falls: Screening, Risk-Assessment, and Plan of care to Prevent Future Falls as it is unclear whether they will lead to meaningful improvements in clinical outcomes. The commenter suggested that developers consider revising the denominator specifications to include only those patients who are at high-risk of falling. Clinicians should individualize the plan of care and the care plan should be less prescriptive to account for individual patient requirements. Data collection burden associated with the multiple measure components is high and data elements seem unlikely to capture how well the service was performed. The measure relies heavily on CPT-II codes which are not widely used or captured in electronic health records (EHRs). Also, developers should consider updating the specifications to reflect the most current clinical recommendations of the USPSTF. Additionally, the evidence-base for what clearly defines best practice is complex. Lastly, while the numerator is clearly defined, it is complicated with variable validity and the components of the risk assessment model are not clearly defined.

Response: Please note these measures were being proposed for removal from the MIPS program in 2019 and we proposed a new combined Falls measure (Q477 based on specifications in NQF 0101) that will include strata components for Future Falls Risk, Falls Risk Assessment, and Falls Risk Plan of Care. As discussed already, the proposed new Q477 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls measure will not be finalized for inclusion as the measure steward believes it is not implementable at this time. Therefore, these three measures will remain in the program for the 2019 performance period as it is important to evaluate for high-risk of falling. We appreciate the feedback regarding these measures and encourage the commenter to discuss their suggestions with the measure steward for their consideration in updates for these measures. A comprehensive falls assessment is multifactorial and should be performed by a health care professional with appropriate skills and experience.

Q180: Rheumatoid Arthritis: Glucocorticoid Management

Specialty Sets: Orthopedic Surgery, Rheumatology

Comment: One commenter did not support measure Q180: Rheumatoid Arthritis: Glucocorticoid Management, citing that they did not receive adequate

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information from the developer to evaluate the validity of this measure. The commenter noted the numerator and the denominator are poorly specified. The measure specifications do not include appropriate exclusions for patients prescribed prednisone therapy for a symptomatic flare. A cleaner measure may specify "patients with rheumatoid arthritis who are on glucocorticoids" in the denominator statement. Additionally, clinical guidelines demonstrate the importance of assessing glucocorticoid use, but only in patients who have specifically been prescribed glucocorticoid therapy.

Response: We will work with the measure steward to consider the suggested denominator exception. Limiting the denominator to those patients with RA who are on a glucocorticoid would limit the clinician's ability to report on the measure and may not capture those RA patients who are started on a glucocorticoid during the performance period.

Q181: Elder Maltreatment Screen and Follow-Up

Specialty Sets: Family Medicine, Internal Medicine, Neurology, Mental/Behavioral Health, Geriatrics, Skilled Nursing Facility

Comment: One commenter did not support measure Q181: Elder Maltreatment Screen and Follow-Up, citing that implementation could promote overuse of unnecessary, elder services referrals and potentially fracture relationships between clinicians and their patients. The commenter stated the measure does not align with USPSTF recommendations on abuse of elderly and vulnerable adults. The commenter also stated that developers should consider revising the numerator specifications to clearly define "high risk" as some way other than age (for example, cognitive impairment, functional impairment). Moreover, the numerator details specify an overly prescriptive screening process. It may be clinically inappropriate to screen all patients over the age of 65 for elder abuse. Developers should consider revising the measure to specifically encourage screening in patients who are dependent on a caregiver or who are otherwise at risk for abuse. It is unnecessarily burdensome for physicians to document maltreatment screening for all patients aged 65 years and older at every visit. Finally, the measure requires clinicians to assess for maltreatment using a screening tool even when abuse may be readily apparent.

Response: Though the USPSTF does not support elder maltreatment screening, we respectfully disagree. It is important to remember that absence of hard evidence supporting screening is not evidence that it is not effective. There have been many qualitative reports that do support the benefits of screening. Expert consensus and public policy for mandatory reporting support the value of screening this vulnerable population. It is unclear how a definition of high risk would benefit the numerator. Limiting the denominator to patients who are dependent on a caregiver or who are otherwise at risk for abuse would be subjective and may not identify all instances of elder maltreatment. This measure advocates for a vulnerable patient population and do not agree that limiting the measure to a high-risk patient population would be appropriate. The measure does not limit to high risk patients but requires elder maltreatment screening for all patients over the age of 65 years.

Q205: HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis

Specialty Sets: Pediatrics, Infectious Disease

Comment: One commenter did not support measure Q205: HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis even though developers cite a significant performance gap based on data from the 2011 PQRS reporting year and that implementation will likely lead to meaningful improvements in clinical outcomes. The measure does align with the USPSTF and CDC recommendations on the prevention and treatment of opportunistic infections in HIV-infected adults, yet the commenter stated the implementation of the measure could promote overuse of screening in asymptomatic patients and in situations where clinicians encounter interoperability barriers to data retrieval. While specifications include an evidence-based time interval, they are flawed in a number of respects. The numerator and denominator envision one test since HIV diagnosis, although new infections and reinfections may occur repeatedly; gonorrhea screening may encompass several loci of infection, which should be listed; and the measure does not include an appropriate exclusion for patients who are not sexually active or otherwise unlikely to become infected. Also, the numerator specifies an indefinite look-back window. Developers should consider revising the specifications to include an evidence-based look-back window.

Response: We disagree this measure will lead to screening overuse. The denominator is limited to a high-risk patient population and we promote interoperability and is the responsibility of the care team to provide care coordination. We do agree that the subsequent screening may be appropriate to detect new or recurrent infections. We will provide this suggestion to the measure steward for possible inclusion during the annual revision cycle. In response to the request for appropriate exclusion for patients who are not sexually active or otherwise unlikely to become infected, the measure does allow for patient refusal as a denominator exception. While we agree with the suggestion to add subsequent screening for reinfection, it does not invalidate the measure. It may be more appropriate to include an annual risk assessment. The cost of screening and the variability of prevalence of these infections, decisions about routine screening for these infections should be based on epidemiologic factors (including prevalence of infection in the community or the population being served), availability of tests, and cost

Q217: Functional Status Change for Patients with Knee Impairments
Q218: Functional Status Change for Patients with Hip Impairments
Q219: Functional Status Change for Patients with Foot or Ankle Impairments
Q220: Functional Status Change for Patients with Lumbar Impairments
Q221: Functional Status Change for Patients with Shoulder Impairments
Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments
Q223: Functional Status Change for Patients with General Orthopedic Impairments

Specialty Sets: Physical Therapy/Occupational Therapy

Comment: One commenter stated that the issue with FOTO (Focus on Therapeutic Outcomes) measures is the measure may require payment to use the measure. Eligible clinicians may not have 100 patients in the specific joint being measured to meet the measure requirements. As a result, the clinician needs to get an exemption because he or she may not have 100 patients eligible, such as for the hip measure Q218. Also, the measure for functional outcome (general) becomes mutually exclusive to these individual FOTO measures.

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Response: As indicated within the measure specification's Copyright, the functional status measures are available in both short form (static/paper-pencil) and computer adaptive test formats, together with a scoring table and risk adjustment specifications, free of charge for the purposes of individual clinical practice, that is, patient-level measurement, including but not limited to for the purposes of participation in MIPS. We acknowledge that meeting this minimum threshold can be challenging for some eligible clinicians but for scoring purposes you would only need 20 eligible patients to meet the minimum reliability threshold for each of the measures which may be more feasible to achieve. The functional outcome (general) measure is ensuring that all visits regardless of impairment has functional outcomes assessed and although these would be covered in the functional status change measures it also measures other impairments.

Q226: Preventive Care and Screening: Tobacco use: Screening & Cessation Intervention

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, General Surgery, Vascular Surgery, Thoracic Surgery, Urology, Oncology, Neurosurgical, Podiatry, Rheumatology, Urgent Care

Comment: One commenter supported measure Q226: Preventive Care and Screening: Tobacco use: Screening & Cessation Intervention because reduction of tobacco use slows the progression of respiratory disease, tobacco use is a modifiable risk factor, and the measure aligns with clinical recommendations.

Response: We thank the commenter for the support of measure Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.

Q236: Controlling High Blood Pressure

Specialty Sets: Obstetrics/Gynecology, Vascular Surgery, Thoracic Surgery, Rheumatology

Comment: One commenter did not support measure Q236: Controlling High Blood Pressure although it may result in measurable and meaningful improvements in clinical outcomes and there is a known performance gap in the area of blood pressure control. The commenter stated that the specifications for the measure under consideration for NQF-endorsement align with several societies, the MIPS measure specifications do not stratify patients into well-defined risk groups (that is, comorbid disease diagnosis) and guidelines from its own society. Furthermore, the numerator specifications define office measurements as the preferred monitoring method, while home monitoring is the preferred method to assess for adequately controlled BP. The commenter suggested that developers update the numerator specifications to include an average of several measurement results to increase accuracy and reduce the potential for overtreatment. Finally, the measure was created to assess system-level performance and may not be an appropriate accountability measure for individual clinicians who do not have access to all BP measurement results. The commenter supported CMS adoption of this measure if approved by NQF.

Response: We agree with updating the numerator to reflect the updated blood pressure values and have been discussing the revision with the measure steward. We do not agree with taking an average blood pressure as the performance is determined by the most recent blood pressure value. It does allow for multiple blood pressure readings during an eligible visit, using the lowest systolic and the lowest diastolic reading as the most recent blood pressure reading. We agree with the measure steward to exclude home readings due to the variability and may not be an accurate representation of blood pressure measurements. In addition, performance can be determined by blood pressure taken by any clinician within the clinician office. This would include blood pressure readings from other eligible clinicians participating in the patient care (that is consultation notes). We maintain the opinion this is a good measure since the new guidelines have not been widely accepted and will allow time for eligible clinicians to adopt the updated blood pressure values. This measure also encourages management of a prevalent condition.

Comment: Several commenters indicated that for measure Q236: Controlling High Blood Pressure that it should be revised to reflect recent national consensus about appropriate blood pressure measurements. A national consensus has developed that blood pressure should vary by age and diagnosis. The MIPS measure requires a strict policy of controlling to less than 140/90 for hypertensive patients, regardless of age, and 120/80 for screening purposes. These levels are not consistent with current medical evidence or opinion such as those noted in the Eighth Joint National Committee. There should be a mechanism for removal of a measure that is no longer consistent with clinical guidelines or current practice and adding the measure back to the program when re-specified.

Response: We appreciate the recommendation to update the guidelines and agree the measure should be updated in future revision cycles. However, we maintain the opinion this is a good measure since the new guidelines have not been widely accepted and will allow time for eligible clinicians to adopt the updated blood pressure values. This measure also encourages management of a prevalent condition and is limited to patients with an existing hypertension diagnosis. Additionally, the intent of the measure is not to screen patients for hypertension.

Q238: Use of High-Risk Medications in the Elderly

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Rheumatology, Geriatrics

Comment: One commenter did not support measure Q238: Use of High-Risk Medications in the Elderly, citing that controversial criteria was used to form the basis of the measure, which is based on expert opinion as opposed to high-quality evidence. The commenter noted issues with the measure specifications as follows: the denominator may inaccurately define "elderly adults" as > 65 years of age and developers should consider increasing the denominator threshold to > 80 years of age; the denominator specifications do not stratify patients into well-defined risk groups; the measure specifies medications that are not presumed to be high risk in all elderly adults (for example, acetaminophen); and the specifications do not include exclusion criteria for patient preference. Lastly, individual clinicians may encounter interoperability barriers to patient information access.

Response: We disagree with interoperability barrier, but suggest all eligible clinician maintain a current medication list, especially for patient received high-risk medications. We will provide the commenter's recommendation to risk-stratify and increase the age criteria from 65 to 80 years of age to be vetted through a technical expert panel and possible inclusion in subsequent revision cycles. One study of the prevalence of potentially inappropriate medication use in older adults found that 40 percent of individuals 65 and older filled at least one prescription for a potentially inappropriate medication and 13 percent filled two or more (Fick et al. 2008). While some adverse drug events are not preventable, studies estimate that between 30 and 80 percent of adverse drug events in the elderly are preventable (MacKinnon and Hepler 2003). The measure is based on recommendations from the American Geriatrics Society Beers Criteria for

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Potentially Inappropriate Medication Use in Older Adults. The criteria were developed through key clinical expert consensus processes by Beers in 1997, Zahn in 2001 and an updated process by Fick in 2003, 2012 and 2015.

Q243: Cardiac Rehabilitation: Patient Referral from an Outpatient Setting

Specialty Sets: Cardiology, Family Medicine, Internal Medicine

Comment: One commenter supported measure Q243: Cardiac Rehabilitation: Patient Referral from an Outpatient Setting. However, the commenter advised developers to address the following concerns during the update process to improve the measure quality: the measure is nearly capped out; implementation of this measure could unfairly penalize clinicians who practice in rural areas and who care for medically complex patient populations, so risk or socioeconomic adjustment is advised; the measure is an inappropriate accountability measure for general internists who do not report data in the PINNACLE registry; the measure may not apply well to clinicians practicing in rural settings where patients have limited access to rehabilitative services; and patients who are faced with significant travel burdens are less likely to adhere to prescribed services.

Response: We encourage the commenters to work with measures' developers to submit new measures through the Call for Measures process that would address the appropriate diagnosis and testing of COPD as we currently do not have a benchmark established for this measure. In addition, the performance data supplied was derived from a single qualified registry. We disagree that this measure may unfairly penalize clinicians who practice in rural areas and who care for medically complex patient populations. The numerator includes denominator exceptions for both system and medical reasons for not referring to an outpatient cardiac rehabilitation program. The measure does not hold general internists inappropriately accountable for referrals, as this is not a required measure. Eligible clinicians are able to choose the measures that are clinically appropriate for their specialty.

Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Specialty Sets: Neurology

Comment: One commenter did not support measure Q268: Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy although it addresses a clinical condition that is high- impact and the measure developers cite a significant gap in care. The commenter stated that evidence cited to form the basis of the measure where the interventions could potentially result in harmful patient outcomes. Problems were cited with measure specifications. The denominator specifications should include exclusion criteria for surgically sterile women, women without a history of recent seizure, and women who are not currently prescribed pharmacotherapy; the numerator definition of counseling seems overly inclusive and not necessary in all cases. Requiring six dimensions for counseling could be overly prescriptive and developers should consider revising the specifications to allow for selection of appropriate therapy that is most relevant to individual patients (that is, change the definition to include "or" rather than "and"); Developers should consider revising the denominator specifications to include women aged 45 years and older who are of childbearing potential. The commenter stated that while the many of the specifications are flawed, the developers do include validity and reliability data in the measure.

Response: To address the comment regarding denominator exclusion, we encourage the commenter to review the 2019 measure specification as the measure steward has revised the measure to exclude menopausal or surgically sterile patients. We disagree on the exclusion for patients without a recent seizure, and women who are not currently prescribed pharmacotherapy. Impacts to fertility and pregnancy risks are not limited patients receiving pharmacologic therapy. The measure steward indicates counseling should include discussion about folic acid supplementation, contraception, and potential anti-seizure medications effect on pregnancy, safe pregnancies, and breastfeeding. While we agree this definition covers an inclusive list of counseling areas, it does allow eligible clinicians to exercise their clinical judgment if medical reasons exist for not completing counseling women of childbearing potential with epilepsy. We agree with the expansion of the denominator criteria to include women who are 45 years and older who are of childbearing potential. We have requested the measure steward to consider expanding the age criteria during the annual revision cycle of the quality measures. We still believe the measure addresses an important clinical topic; the narrow denominator does not invalidate the measure.

Q271: IBD: Preventive Care: Corticosteroid Related Iatrogenic Injury--Bone Loss Assessment

Specialty Sets: Gastroenterology

Comment: One commenter did not support measure Q271: IBD: Preventive Care: Corticosteroid Related Iatrogenic Injury--Bone Loss Assessment, citing that measure developers do not cite high-quality evidence to form the basis of the measure and using dexa-scans to assess for risk of bone loss does not necessarily prevent hip fractures in patients prescribed corticosteroid therapy for IBD. Furthermore, implementation could promote overuse of dexa scans and underuse of corticosteroid therapy. Numerator specifications encourage clinicians to screen patients who receive 10 mg/day of prednisone for 60 days, while evidence demonstrates that hip fractures are significantly higher in patients treated with medium steroid doses (2.5-7mg/day) over a duration of time. As written, the numerator could miss patients who are at risk for fracture. Also, it is unclear whether the measure encourages clinicians to screen patients who are currently prescribed prophylactic bisphosphonate therapy for risk of bone loss, which may not be clinically necessary. Lastly, developers should consider revising the numerator specifications to include an evidence-based look-back window for review of medication history as that is less burdensome. Another commenter also expressed concerns related to the numerator of this measure reflecting the risk of bone loss associated with oral corticosteroids, at any time over the patient's life, exceeding 5 mg/day for 3 or more consecutive months.

Response: The intent of the measure is to screen patients who are at risk of fracture. This knowledge can assist eligible clinicians in creation of their treatment plan. We disagree that the measure would lead to overuse of dexa-scans. Individuals who received an assessment for bone loss during the year prior and current year are considered adequately screened. Corticosteroid use is the variable most strongly associated with osteoporosis (level A evidence). However, it is difficult to distinguish corticosteroid use from disease activity in terms of causal impact on bone density, because the two are closely linked. However, there is strong evidence that those on long-term steroids of greater than 3 months have a significant increase risk of fracture (Papaioannou A. et al. All Patients with Inflammatory Bowel Disease Should Have Bone Density Assessment: Pro. Inflammatory Bowel Diseases. 2001.7(2):158-162). In response to lowering the threshold from 10 mg/day to 2.5-7 mg/day, this would expand the denominator requiring additional screening. We will provide both of the commenter's concerns regarding dexa overuse and the request to expand the denominator to the measure steward to identify the appropriate population, but based on the

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provided response, we maintain the notion this is an appropriate measure.

Q281: Dementia: Cognitive Assessment

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q281: Dementia: Cognitive Assessment, citing a lack of high-quality evidence on the assessment of cognitive status on clinical outcomes or assessment intervals, and it is unclear how clinicians should manage assessment results. The numerator specifications include cognition assessment tools that will not necessarily benefit clinical outcomes and adherence to a formal assessment protocol is burdensome on clinicians. A more meaningful measure may encourage assessments that are likely to lead to meaningful improvements in clinical outcomes. Furthermore, the numerator specifications include proprietary cognition assessment tools (for example, Mini-Mental State Examination) that are not readily accessible to clinicians who practice in primary care settings.

Response: The measure is supported by the Guidelines for the Management of Cognitive and Behavioral Problems in Dementia. Initial and ongoing assessments of cognition are fundamental to the proper management of patients with dementia. These assessments serve as the basis for identifying treatment goals, developing a treatment plan, monitoring the effects of treatment, and modifying treatment as appropriate. While there is not a set interval for assessment, the guidelines state that assessments and visits will be based on the severity or complexity of the patient's status. For this measure, the cognitive assessment should be completed at least once per performance period but does not penalized clinicians for additional cognitive assessments completed throughout the performance period. We thank the commenter for the suggestion create more meaningful improvements to clinical outcomes and encourage the commenter to work with measures' developers to submit new measures through the Call for Measures process. We do not agree with the concern that the numerator has proprietary cognition tools as the measure also includes non-proprietary options for eligible clinician use.

Q283: Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q283: Dementia: Associated Behavioral and Psychiatric Symptoms Screening and Management, citing a lack of high-quality evidence examining the impact of assessment on clinical outcomes or on appropriate assessment intervals, and implementation may result in overuse of pharmacologic therapy. Non-pharmacologic treatment modalities exist to manage neuropsychiatric symptoms, but implementation requires caregiver involvement. The commenter stated that numerator details do not clearly specify a structured process for documentation of neuropsychiatric symptom assessment and the measure developers do not describe any reliability or validity data in the measure report.

Response: The measure is supported by the Guidelines for the Management of Cognitive and Behavioral Problems in Dementia. Neuropsychiatric symptoms may go unrecognized and untreated by eligible clinician do not actively screen their patients with specific attention to discrete symptom domains. We disagree with the unintended consequences identified by the commenter. The measure does not promote the use of pharmacologic interventions. The Clinical Recommendation Statements within the specification state, "new trials and studies better define adverse effects, but they do not strengthen the evidence for efficacy of antipsychotic drugs in treating psychosis or agitation. Rather, they demonstrate minimal or no efficacy with strong placebo effects, as well as variations in response with trial duration. These findings strengthen the support for using nonpharmacological interventions and environmental measures to attempt to reduce psychosis and agitation prior to initiation of medications." In addition, the specification provides examples of reliable and valid instruments to document neuropsychiatric symptom assessment.

Q286: Dementia: Counseling Regarding Safety Concerns

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q286: Dementia: Counseling Regarding Safety Concerns although it can lead to improved safety outcomes and the measure specifications are appropriate. The commenter stated there is no evidence to support the impact of this intervention on clinical outcomes, the level or intensity of counseling required to change behavior, or the interval at which this intervention should be performed. This measure is also burdensome on clinicians and there is a lack of high quality evidence to support the intervention as an accountability measure.

Response: The measure is supported by the American Psychiatric Association practice guideline for the treatment of patients with Alzheimer's disease and other dementias. Screening for safety concerns has been identified as a major unmet need of persons with dementia. Though the guidelines do not identify the impact of the intervention, it is important to remember that absence of hard evidence supporting screening is not evidence that it is not effective.

Q288: Dementia: Caregiver Education and Support for Patients with Dementia

Specialty Sets: Neurology, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q288: Dementia: Caregiver Education and Support for Patients with Dementia because it may be inappropriate for clinicians to advise caregivers on medical concerns without performing appropriate clinical assessments and there is no evidence to support the impact of this intervention on clinical outcomes, the level or intensity of counseling required to change behavior, or the interval at which this intervention should be performed. Developers do not present any validity or reliability data within the measure report. Lastly, this measure is burdensome on clinicians and there is a lack of high- quality evidence to support the intervention as an accountability measure.

Response: The measure is supported by the Optimal management of Alzheimer's disease patients: Clinical guidelines and family advice. The American Medical Association (AMA) has developed a standard Caregiver Health Self-Assessment Questionnaire to help caregivers analyze their own behavior and health risks and, with the eligible clinician's assistance, make decisions that will benefit both the caregiver and the patient. This questionnaire is available on the AMA website. Based on the results of the assessment, the eligible clinician would be required to provide education and resources based on their clinical expertise. These components have been defined within the measure specification. Though the guidelines do not define the level of counseling or impact of the

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intervention, it is important to remember that absence of hard evidence supporting screening is not evidence that it is not effective.

Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Specialty Sets: Family Medicine, Internal Medicine, Pediatrics

Comment: One commenter did not support measure Q305: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment because the specifications are flawed and the measure is not appropriately specified to evaluate performance at the level of the individual clinician. Developers should consider dividing the numerator statement to form two discrete measures: (1) initiation of alcohol and other drug dependence treatment; and (2) engagement of alcohol and other drug dependence treatment. Also, it is unclear what constitutes a "new episode of drug or alcohol dependency." The commenter did not support including this measure in accountability programs designed to assess performance of individual clinicians. It is unclear whether individual clinicians will be able to control the outcomes of this measure, and individual clinicians will likely face interoperability challenges to data collection.

Response: We will forward the commenter's recommendation to divide the numerator into two separate measures, but we believe the measure is appropriately specified into one measure. We refer the commenter to the measure specification for the definition of episode: The new episode of alcohol and other drug dependence should be the first episode of the measurement period that is not preceded in the 60 days prior by another episode of alcohol or other drug dependence. This measure is attributed to eligible clinicians who provide care to patients diagnosed with alcohol, opioid, or other drug abuse or dependency. It is important to intensify the monitoring for substance use during periods when the patient is at a high risk of relapsing, including during the early stages of treatment, times of transition to less intensive levels of care, and the first year after active treatment has ceased.

Q309: Cervical Cancer Screening

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology

Comment: One commenter supported measure Q309: Cervical Cancer Screening because the current evidence supports screening in women 21-64 years of age, and this measure is based on the most recent USPSTF recommendations on cervical cancer screening.

Response: We thank the commenter for the support of measure Q309: Cervical Cancer Screening.

Q310: Chlamydia Screening in Women

Specialty Sets: Obstetrics/Gynecology, Pediatrics

Comment: One commenter supported measure Q310: Chlamydia Screening in Women because it aligns with USPSTF and CDC recommendations, is supported by evidence and denominator criteria is clearly specified.

Response: We will continue to align with USPSTF and CDC recommendations on Chlamydia screening.

Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Specialty Sets: Cardiology,
Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Emergency Medicine, Obstetrics/Gynecology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, Nephrology, General Surgery, Vascular Surgery, Thoracic Surgery, Urology, Oncology, Rheumatology, Urgent Care, Skilled Nursing Facility

Comment: Two commenters provided feedback for measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented, citing that the measure developers should update the measure specifications to align with current Joint National Committee-8 (JNC-8), USPSTF, and American College of Physicians (ACP) clinical recommendations on blood pressure screening and management. Additionally, the denominator specifications should include exclusion criteria for patients with medical contraindications to treatment (for example, frail, elderly adults, patients with life limiting diagnoses). Another commenter expressed concerns about the numerator criteria for measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented. Specifically, the commenter stated that most doctors believe it goes against their medical training to recommend evaluation/referral to a primary care physician and/or lifestyle changes to someone who has a blood pressure reading of 122/82.

Response: We agree with aligning with the most current blood pressure guidelines. We disagree with the recommendation to exclude elderly, frail, or patients with life limiting diagnosis citing contraindications for treatment. In response to the commenters concerns regarding the numbers, for the 2019 performance period, this blood pressure value falls into the "Pre-Hypertensive BP Reading" classification. The recommendation may consist of a blood pressure rescreen within 1 year and promoting of physical activity, alcohol reduction, weight reduction or changes in diet which have limited contraindications to recommend. We may update the level of blood pressure reading in the future based on new blood pressure guidelines. We maintain the opinion this is a good measure since the new guidelines have not been widely accepted and will allow time for eligible clinicians to adopt the updated blood pressure values. This measure also encourages management of a prevalent condition.

Q321: CAHPS Clinician & Group Surveys (CG-CAHPS)-Adult, Child

Specialty Sets: Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q321: CAHPS Clinician & Group Surveys (CG-CAHPS)-Adult, Child, citing that implementation could promote overuse of unnecessary treatments where the potential benefits do not outweigh the risk of harms (for example, opiate prescriptions, imaging studies). The commenter stated that developers do not present any evidence to form the basis of the measure and that validity of the survey process and the impact of survey results on improving patient outcomes is in question. Individual clinicians should not be held accountable to organizational factors beyond their control (for example, appointment wait times, and friendliness of staff).

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Response: We disagree that the CAHPS survey promotes the overuse of unnecessary treatments, but rather addresses the quality and appropriate access to healthcare services. While the survey does ask patients the level of friendliness of the staff, improving the patient experience throughout the course of treatment aligns with program goals.

Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients

Specialty Sets: Cardiology

Comment: One commenter did not support measure Q322: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients. While this measure promotes appropriate use of cardiac stress imaging in low-risk surgery patients and cites clinical recommendations on perioperative evaluation of patients undergoing non-cardiac surgery to form the basis of the measure, developers do not cite a performance gap. Additionally, the denominator population is not specified for individual clinician use and clinicians may misinterpret the measure as currently written. The commenter recommended that developers consider revising the numerator to include cardiac stress images performed within 30 days preceding low-risk, non-cardiac surgery and the denominator specifications to include asymptomatic patients undergoing low-risk surgery.

Response: We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. Performance data is evaluated annually to ensure the measure addresses a gap in care. The measure mimics the NQF #0670: Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients with minor updates regarding the timing of imaging assessment. The National Quality Forum indicated the level of analysis is based on the clinician, group/practice and facility data. We will provide the numerator language feedback to the measure steward. There is a numerator note included within the specification to provide submission guidance. We appreciate the revision suggestion to clarify the numerator, but the measure still addresses appropriate use of healthcare resources.

Q324: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients

Specialty Sets: Cardiology

Comment: One commenter did not support measure Q324: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients. The commenter stated that the numerator is not specified for individual clinician use, the measure does not specify a standardized approach to risk assessment, and it relies on the individual clinician's ability to appropriately document level of risk. Clinicians attest to the accuracy of their estimation by submission, but a stronger measure may specify a more systematic approach to risk assessment. Developers should consider revising the numerator specifications to include "healthy, low-risk patients."

Response: The measure directs clinicians should consider the maximum number of available patient factors used to estimate risk based on Framingham (ATP III criteria), typically age, gender, diabetes, smoking status, and use of blood pressure medication, and integrate age appropriate estimates for missing elements, such as LDL or standard blood pressure. The measure mimics the NQF #0672: Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients with language updates. The National Quality Forum indicated the level of analysis is based on the clinician, group/practice and facility data. We will provide the numerator language feedback to the measure steward. We appreciate the revision suggestion to clarify the numerator, but the measure still addresses appropriate use of healthcare resources.

Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions

Specialty Sets: Mental/Behavioral Health

Comment: One commenter did not support measure Q325: Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions, citing a lack of high quality evidence examining the impact of disease communication on meaningful clinical outcomes. Additionally, the measure specifications do not include appropriate exclusion criteria for patients with mild or stable depression. It is also burdensome for clinicians to retrieve specialists' reports for all patient visits, especially if the primary care clinician did not refer the patient to care.

Response: The cited guidelines recommend with substantial clinical confidence, patients with major depressive disorder will be evaluated by or receive treatment from other eligible clinicians in addition to the psychiatrist or behavioral health provider. If more than one eligible clinician is involved in providing the care, all treating clinicians should have sufficient ongoing contact with the patient and with each other to ensure that care is coordinated, relevant information is available to guide treatment decisions, and treatments are synchronized. In response to the concern of the diagnosis criteria, the diagnosis codes indicate major depressive disorder and need to be active at the date of the encounter. We disagree commenters concern that the measure is burdensome for eligible clinicians to retrieve specialists' reports. The intent of the measure is to promote care coordination by requiring the eligible clinician treating MDD to provide relevant information to the clinician treating the comorbid condition.

Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

Comment: One commenter supported measure Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy but stated that inclusion of broad exclusion criteria may discourage clinicians from prescribing therapy in patients where the benefits outweigh the risk of harms. The commenter suggested this issue be addressed by developers by explicitly defining denominator exclusion criteria to prevent underuse of anticoagulation therapy in clinically appropriate cases, and that denominator specifications should be updated to include the CHADs2VASc risk stratification tool.

Response: The denominator exclusion removes patients that have mitral stenosis, prosthetic heart valves, or transient or reversible cause of atrial fibrillation. Any documentation meeting the defined criteria would remove the patient from the measure and would not be evaluated for anticoagulation therapy. The 2018

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measure specification was updated in during the previous measure revision cycle to utilize the CHADs2VASc risk stratification tool.

Q331: Adult Sinusitis: Appropriate Choice of Antibiotic Prescribed for Acute Sinusitis (Overuse)

Specialty Sets: Family Medicine, Internal Medicine, Emergency Medicine, Otolaryngology, Urgent Care,

Comment: One commenter did not support measure Q331: Adult Sinusitis: Appropriate Choice of Antibiotic Prescribed for Acute Sinusitis (Overuse). They cited that numerator specifications do not define an appropriate performance rate and a 0 percent performance rate will promote underuse of antibiotic therapy in appropriate treatment cases. Furthermore, the numerator specifications define "acute sinusitis" according to typical bacterial infection symptoms and it is appropriate to prescribe antibiotics to treat a bacterial infection. The commenter suggested that developers should consider revising denominator specifications to define "acute sinusitis" according to viral symptoms to prevent overuse of antibiotic therapy in viral sinusitis infections, and to align the measure with current clinical recommendations. The commenter supported inclusion of appropriate exclusion criteria, but cites that inclusion of broad exclusion criteria may provide opportunity for measure manipulation by reporting clinicians.

Response: The Centers for Disease Control and Prevention identifies that 98 percent of rhino sinusitis cases are viral. Treatment of these cases with antibiotics may increase patient harm and lead to antibiotic resistance. The numerator note adds clarification for inverse measures, which indicates as the performance rate trends towards 0 percent, quality increases. In response to manipulation of data, any claims submitted to the CMS are subject to an audit, inclusive of any performance data submitted to the quality program. The measure is specific to viral sinusitis, we do not agree that it promotes underuse of antibiotic therapy in the appropriate cases. The clinical recommendation within the measure specification includes diagnosis of acute bacterial rhino sinusitis when symptoms persist for at least 10 days or worsening of symptoms after initial improvement. The measure includes a denominator exception for a documented reason for antibiotic regimen prescribed within 10 days of symptom onset, which is appropriate for this inverse measure.

Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin with or without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Specialty Sets: Family Medicine, Internal Medicine, Emergency Medicine, Otolaryngology, Urgent Care

Comment: One commenter did not support measure Q332: Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin with or without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use) as numerator specifications do not align with specialty society recommendations. The commenter suggested that developers update the measure specifications to encourage prescription of amoxicillin-clavulanate as first-line therapy in patients diagnosed with bacterial sinusitis. In addition, the measure specifications do not include exclusion criteria for patients who do not tolerate amoxicillin. About 30-40 percent of patients are bacterial resistant to amoxicillin therapy alone.

Response: The measure specification does include a denominator exception for a documented reason for not prescribing amoxicillin. The IDSA identifies their clinical recommendation of use of Amoxicillin-clavulanate rather than amoxicillin alone weighted as low strength and weak quality of evidence. The Centers for Disease Control and Prevention continue to recommend Amoxicillin or amoxicillin/clavulanate as the recommended first-line therapy in confirmed cases of bacteria sinusitis.

Q333: Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)

Specialty Sets: Family Medicine, Internal Medicine, Emergency Medicine, Otolaryngology, Urgent Care

Comment: One commenter supported measure Q333: Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse) because it is clinically important to promote appropriate use of CT scans in patients diagnosed with acute sinusitis. However, the commenter stated that developers do not clearly define denominator exclusion criteria and as such, implementation could promote underuse of CT scans in clinically appropriate cases. Developers should consider revising exclusion criteria based on current guidelines.

Response: The measure includes a denominator exception for documented reasons of a CT scan ordered at the time of diagnosis which is appropriate for this inverse measure and would allow for use of CT scan for appropriate cases. We refer the commenter to the clinical recommendation statements within the measure specification that indicate that clinicians should not obtain radiographic imaging for patients presenting with uncomplicated acute rhino sinusitis (ARS) to distinguish ABRS from VRS, unless a complication or alternative diagnosis is suspected. Radiographic imaging of the paranasal sinuses is unnecessary for diagnosis in patients who already meet clinical diagnostic criteria for ABRS. Sinus involvement is common in documented viral URIs, making it impossible to distinguish ABRS from VRS based solely on imaging studies. This measure is intended to avoid costly diagnostic tests that do not improve diagnostic accuracy yet expose the patient to unnecessary radiation.

Q342: Pain Brought under Control within 48 Hours

Specialty Sets: Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q342: Pain Brought under Control within 48 Hours as it is unclear whether implementation will produce reliable, meaningful results, and there is insufficient evidence to support the 48 hour time interval. Additionally, the specifications include an assessment tool is that is not well validated. Measure developers should consider modifying the specifications to include a more appropriate assessment tool (for example, Numeric Pain Rating Scale). The commenter stated this is an inappropriate internal medicine accountability measure.

Response: The measure is intended to evaluate the effectiveness and timeliness of initial pain management after the start of palliative care services vs. immediate pain control. It strives to incorporate the patient's pain goals relative to perception of comfort rather than aiming for a specific numeric pain intensity rating. This is not a required measure and encourage eligible clinicians to select clinically appropriate measures.

Q357: Surgical Site Infection (SSI)

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Specialty Sets: Otolaryngology, General Surgery, Vascular Surgery

Comment: One commenter noted the Q357: Surgical Site Infection (SSI) measure lacks rigor, and the chance for misclassification of surgeons is high. The commenter stated that standardized risk adjustment methodologies are critical when comparing clinical outcomes across different registries/cohorts, yet surgical MIPS measures do not account for risk factors. For example, the commenter tested the SSI measure collected through the ACS Surgeon Specific Registry (SSR). The commenter compared the unadjusted SSI measure rates to the risk-adjusted SSI rates and found that approximately 50 percent of cases were misclassified when risk adjustment was not performed. Yet, CMS does not require the risk adjustment of the SSI measure.

Response: This measure is constructed so that risk adjustment is performed by the parsimonious dataset and aims to allow efficient data collection resources and data submission. In the prior PQRS program, risk-adjustment methodology was provided to vendors if they wanted to provide their clients with this comparison to other eligible clinicians. We do understand the concern of disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with risk factors or degree of invasiveness. We do not want to mask potential disparities or minimize incentives to improve the outcomes for different patient populations and procedures. However, at this time, we do not require measures to be risk-adjusted. We believe this is still a valid measure to maintain within the program as the denominator is restricted. We will provide this feedback to the measure steward but encourage the commenter to collaborate with the measure steward as well.

Q370: Depression Remission at Twelve Months

Specialty Sets: Family Medicine, Internal Medicine, Mental/Behavioral Health, Geriatrics

Comment: One commenter did not support measure Q370: Depression Remission at Twelve Months, citing that the measure does not account for individual starting points for each patient and there is a lack of high-quality evidence to support the 12-month (+/- 30 days) time interval. The threshold of reaching a specific PHQ-9 score (<5) is arbitrary and does not take into account the individual starting points for each patient. The measure may unfairly penalize clinicians caring for severely depressed patients for their inability to satisfy the measure requirements and as such, this measure may encourage clinicians to overtreat patients for major depressive disorder. Many patients are unable to achieve a PHQ-9 score of <5 and the PHQ-9 is not necessarily the best tool to track patient remission. The commenter suggested that developers consider revising the denominator specifications to include additional depression remission tracking tools and that measure specifications exclude patients with dementia or severe cognitive impairments and patients permanently residing in nursing homes. Lastly, the commenter would be amenable to using this measure as a tracking mechanism but opposed any linkage to performance and payment.

Response: This measure is not intended to assess the depression response, but the remission. Full remission is defined as a 2-month period devoid of major depressive signs and symptoms (American Psychiatric Association, 2013). If using a PHQ-9 tool, remission translates to PHQ-9 score of less than 5 (Kroenke, 2001). We agree that depression response and remission take time. In the STAR*D study, longer times than expected were needed to reach response or remission. In fact, one-third of those who ultimately responded did so after 6 weeks. Of those who achieved remission by Quick Inventory of Depressive Symptomatology (QIDS), 50 percent did so only at or after 6 weeks of treatment (Trivedi, 2006). If the eligible clinician is seeing improvement, this measure encourages the continuation of treatment to reach remission. This can take up to 3 months. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse (American Psychiatric Association, 2010). For that reason, we agree with the remission outcome be assessed at multiple points in time.

Q371: Utilization of the PHQ-9 Tool

Specialty Sets: Family Medicine, Internal Medicine, Mental/Behavioral Health

Comment: One commenter did not support measure Q371: Utilization of the PHQ-9 Tool although it is clinically important and could lead to the development of an accurate outcome measure by determining well validated levels of depression severity. The commenter stated there is insufficient evidence to support the 4-month time interval specified in the denominator and the 4-month measurement period is unclear as to whether it's one measurement within a 4-month period, or every 4 months for patients with an on-going disease diagnosis. Evidence supports utilization of the PHQ-9 tool, but many clinicians utilize additional remission screening tools that are equally as effective as the PHQ-9. The measure intends to assess performance at the system level. While this measure may appropriately assess the performance of mental health practitioners (for example, psychiatrist), it may be an inappropriate accountability measure for primary care clinicians who may encounter interoperability barriers to satisfy the measure requirements (for example, subspecialist reports).

Response: We have proposed substantive changes to this measure that address the commenter's concerns. The measure has been revised to assess both adolescent patients (12 to 17 years of age) and adult patients (18 years of age or older) with a diagnosis of major depression or dysthymia who have a completed PHQ-9 or PHQ-9M tool during the performance period. Regarding the interoperability barriers for primary care clinicians, this is not a required measure and encourage eligible clinicians to select measures that are clinically appropriate and align with their clinical workflow.

Q374: Closing the Referral Loop: Receipt of the Specialist Report

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Ophthalmology, Orthopedic Surgery, Otolaryngology, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, Vascular Surgery, General Surgery, Thoracic Surgery, Urology, Oncology, Rheumatology

Comment: Two commenters provided feedback on measure Q374: Closing the Referral Loop: Receipt of the Specialist Report because it could lead to an unintended consequence of encouraging unnecessary care. One commenter provided a number of suggestions for measure developers: the specifications are not well defined and should include an evidence-based time interval and some element of risk-adjustment; there is not enough evidence cited to form the basis of the measure; the outcome is based on the level of integration of the participating information system rather than on how well the individual clinician tracks the referral; the data trail for submission may vary by submitter type; it is not necessary for clinicians to close all referral loops; and the patient may not see the specialist within the measurement period causing the referring clinician to fail the measure. Lastly, this measure may become less relevant due to the use of electronic health records (EHRs), and there is less evidence that this measure will improve care if it is implemented at the individual clinician level. One

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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commenter recommended that CMS work with measure developers to change Q374: Closing the Referral Loop: Receipt of Specialist Report from patient-based to episode-based because reports are associated with a specific encounter and it would reduce the timing complexity.

Response: We disagree that the measure encourages unnecessary care but promotes communication between eligible clinicians. We will evaluate the request to determine an appropriate timeframe but need to consider the variance between specialties and testing. As indicated within the comment, depending on the urgency to complete the referral within a given timeframe, the patient may not see the specialist. We agree the variance of timeframes may be mitigated by risk-adjustment but may overcomplicate the measure. We disagree that performance is based on the level of integration of information systems. Referral tracking methods should be developed within individual practices or networks. In response to the request to move towards episode-based reporting, the measure is specified at the patient-level and limited to the first referral of the measurement period to minimize reporting burden on clinicians. However, we received similar feedback from stakeholders during our periodic reassessment of the measure, and we are currently testing an episode-based revision to this measure. We will consider implementing the revised measure in future program years if it continues to meet our standards for feasibility, reliability, and validity. This measure promotes communication and care coordination no matter the method of referral tracking. We maintain the notion that Q374 is still a valid measure to promote care coordination based on the responses above.

Q377: Functional Status Assessment for Patients with CHF

Specialty Sets: Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q377: Functional Status Assessment for Patients with CHF as it is unclear whether implementation of this measure will lead to meaningful improvements in quality outcomes and the measure developers do not cite a performance gap. Also, incentivizing clinicians to perform routine assessments in asymptomatic patients may result in underuse of more meaningful clinical interventions. The commenter supported valid, reliable patient reported outcome measures (PROMs), there says this measure has insufficient evidence to support the benefit of this intervention on quality outcomes. Implementation of evidence-based PROMs using validated instruments to assess clinical performance is likely the first step towards collecting PROM data. As currently specified, congestive heart failure is not clearly defined, and developers should consider revising the specifications to clearly differentiate between preserved ejection fraction and systolic dysfunction because this intervention will more likely lead to quality improvements in the latter population .

Response: We consulted with the measure steward and they will give consideration to providing further clarity on the definition of congestive heart failure included in the measure in the future.

Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Specialty Sets: Family Medicine, Internal Medicine, Infectious Disease

Comment: One commenter supported measure Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users. The commenter agreed that the implementation will likely lead to measurable and meaningful improvements in clinical outcomes and it aligns with USPSTF recommendations and other society recommendations. The commenter advised developers to address the following concerns during the update process: the benefit of diagnosing active injection drug users on injection habits is unclear and implementation is unlikely to largely benefit population health outcomes because most clinicians treat a low patient denominator for the measure; denominator specifications may not capture patients who deny injection drug use status and denominator specifications could be revised to be more inclusive of all patients at risk for HCV (for example, baby-boomer populations); and clinicians may encounter barriers to data access as information systems may not automatically identify the denominator population unless end users create a specific code to capture injection drug use.

Response: We will continue to monitor the level of impact to this patient population and will collaborate with the measure steward to potentially expand the patient population. However, we refer the commenter to measure Q400 One-Time Screening for Hepatitis C Virus for Patients at Risk that would include the requested patient population. We do not agree that data access will create any type of barrier. The data abstraction is not limited to a specific code or discrete data. As long as the medical record can substantiate the quality action, it would meet the intent of the measure.

Q390: Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options

Specialty Sets: Gastroenterology

Comment: One commenter did not support measure Q390: Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options because it ceases to be relevant in an era of superior pharmacologic treatment advancements. Newer treatments have minimal side effects, and therefore, decisions about tolerability are no longer applicable. Furthermore, measure developers do not cite any evidence to form the basis of the measure and do not include measurement validity or reliability data in the measure report. Additionally, the numerator specifications are unclear. Developers should consider revising the specifications to define explicit "shared decision making" documentation requirements. Lastly, patients who receive government funded insurance may encounter accessibility barriers to treatment options. It may inappropriate to base treatment options on shared- decision making alone because payers play a significant role in the therapy selection process.

Response: To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment. This would include the superior pharmacologic treatment with consideration to financial burden. We do understand the concern of socioeconomic disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with social risk factors. We do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations.

Q398: Optimal Asthma Control

Specialty Sets: Family Medicine, Internal Medicine, Otolaryngology, Pediatrics

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Comment: One commenter did not support measure Q398: Optimal Asthma Control, citing that implementation of the measure will likely prevent overuse of emergency department services to treat acute disease exacerbations. The commenter noted that measure developers did not cite enough evidence to form the basis of the measure, that measure specifications are difficult to navigate, and that the measure is not currently risk-adjusted for disease severity and socioeconomic status. Lastly, the commenter stated that the Asthma Control Test (ACT) is a best practice but it is a proprietary assessment tool.

Response: We will work with the measure steward to incorporate the citation within the specification. We have been trying to reduce the burden of reporting but disagree with the commenter indicating 6 components are required. It is only requiring 3 components: well-controlled, risk of exacerbation, and emergency visits. The measure is stratified by age to accommodate the age-specific assessment tools. The measure is not risk-adjusted at this time to address socioeconomic status but do not believe this should deter eligible clinician from making every effort to accommodate patients' financial situations. Eligible clinicians could provide sample controller medication to improve asthma control. We do understand the concern of socioeconomic disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with social risk factors. We do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. The ACT may be proprietary, but the measure allows for additional asthma control tools to be utilized (Asthma Control Questionnaire or Asthma Therapy Assessment Questionnaire). We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. We have explored alternative asthma measures that promote controller medication therapy over quick reliever medication, but unable to implement at the clinician level at this time. We agree that the goal is to achieve 100 percent adherence and will continue to collaborate with the measure steward to raise the Percentage Days Covered (PDC) to drive quality improvement. The measure is not risk-adjusted at this time to address socioeconomic status but do not believe this should deter adherence and all efforts should be made to accommodate patients' financial situations. As indicated within the comment, eligible clinicians could provide sample medication to improve patient adherence and alleviate financial burden. Medications dispensed as samples would be included within the PDC assessment. While this may pose difficulty in abstracting by pharmacy data, the medical record should capture this provision. Within the 2018 measure specification, there is a table that defines appropriate asthma controller medications. Based on the provided response, we maintain the notion this is an appropriate measure.

Q400: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Specialty Sets: Family Medicine, Internal Medicine, Nephrology, Infectious Medicine

Comment: One commenter supported measure Q400: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk**.** They agreed that a performance gap does exist, it is important to screen for HCV in patients at risk because it is a treatable disease, the measure aligns with CDC and USPSTF recommendations on screening for HCV in patients at risk and the measure specifications include appropriate exclusion criteria. However, the commenter stated that while the measure is clearly specified, clinicians may encounter interoperability barriers to patient information retrieval. One recommendation for the measure developers is to re-assess the benefit of screening all patients included in the denominator population during the measure update, particularly patients born in the years 1945-1965.

Response: We will forward the commenters suggestion to restrict the screening for patients born in the years 1945-1965. One-time HCV testing is recommended for persons born between 1945 and 1965 without prior ascertainment of risk (Rating: Class I, Level B) (AASLD/IDSA, 2017). However, the same commenter requested this population be added to measure Q387: Annual Hepatitis C Virus Screening for Patients who are Active Injection Drug Users. We will collaborate with all stakeholders to vet the appropriate patient population. The measure is currently appropriate for each separate patient populations. One requires an annual screening for high-risk active injection drug use, while the broader denominator requires a one-time screening which is appropriate for historical risk factors (born from 1945-1965, history of blood transfusion prior to 1992, hemodialysis, or history of drug use).

Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis

Specialty Sets: Gastroenterology, Family Medicine, Internal Medicine

Comment: One commenter did not support measure Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis because the screening benefits do not outweigh the substantial risks of harms related to radiation exposure and treatment of incidental findings. Developers cite weak evidence to form the basis of the measure, and a recent evidence review demonstrates insufficient evidence for screening for hepatocellular carcinoma among patients with cirrhosis.

Response: We will continue to monitor the clinical guidelines that suggest the benefits do not outweigh the risks. In regards to the comment, to weighing the risk versus benefits, the measure allows for a denominator exception for patient and medical reasons for not completing the screening.

Q402: Tobacco Use and Help with Quitting among Adolescents

Specialty Sets: Cardiology, Gastroenterology, Dermatology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Orthopedic Surgery, Otolaryngology, Pediatrics, Physical Medicine, Preventive Medicine, Neurology, Mental/Behavioral Health, General Surgery, Vascular Surgery, Thoracic Surgery, Oncology, Rheumatology, Urgent Care

Comment: One commenter supported measure Q402: Tobacco Use and Help with Quitting among Adolescents because, tobacco use is a modifiable risk factor and clinical evidence supports patient counseling. The commenter stated the denominator population is unclear, and the developer should consider separating the measure into two distinct measures: (1) tobacco use screening measure; and (2) tobacco cessation measure for patients who screened positive on measure 1.

Response: We do not agree in separating the measure into two distinct measures. We will provide your recommendation to the measure steward to stratifying the measure so to provide separate performance rates to identify areas where a gap exists.

Q408: Opioid Therapy Follow-Up and Evaluation

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Physical Medicine, Neurology, Geriatrics

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Comment: One commenter did not support measure Q408: Opioid Therapy Follow-Up and Evaluation as it is a "check the box measure." A more appropriate measure may incentivize a standardized, methodological approach to evaluation that is likely to improve the opioid therapy management process and result in improved clinical outcomes. There is insufficient evidence to support the 6 weeks and 3 months durations included in the denominator and numerator specifications. The commenter suggested that developers revise the specifications to include an evidence based-definition of chronic opioid therapy. Furthermore, it is unclear whether clinicians who prescribe therapy for less than 3 months should require patient follow-up earlier than 3 months' time. The measure would benefit from reliability and validity testing prior to inclusion in quality payment programs**.**

Response: We agree with the commenter's suggestion to revise the quality action to require follow up or mitigation plan if patient is not responding or misusing the opioid. We have collaborated with the measure steward to provide a definition of follow-up evaluation included in the 2019 measure specification. We will provide the commenter's recommendation to the measure steward to align the denominator with the definition of chronic opioid therapy. However, we believe frequent patient education and follow-up regarding opioid use is necessary and aligns with our program goals to address the opioid epidemic.

Q411: Depression Remission at Six Months

Specialty Sets: Mental/Behavioral Health

Comment: One commenter did not support measure Q411: Depression Remission at Six Months, citing a lack of high-quality evidence to support the 6-month (+/- 30 days) time interval included in the numerator specifications and the threshold of reaching a specific PHQ-9 score (<5) is arbitrary, does not take into account the individual starting points for each patient, and is difficult for patients to achieve. The measure may also penalize clinicians caring for severely depressed patients for their inability to satisfy measure requirements and as such, this measure may encourage clinicians to over treat patients for major depressive disorder. The commenter recommended that developers: should consider revising the specifications to include risk adjustment to account for individual starting points for each patient; that PHQ-9 is not necessarily the best tool to track patient remission; that denominator specifications could be revised to include additional depression remission tracking tools; and that measure specifications exclude patients with dementia or severe cognitive impairments and patients permanently residing in nursing homes.

Response: This measure is not intended to assess the depression response, but the remission. Full remission is defined as a 2-month period devoid of major depressive signs and symptoms (American Psychiatric Association, 2013). If using a PHQ-9 tool, remission translates to PHQ-9 score of less than 5 (Kroenke, 2001). We agree that depression response and remission take time. In the STAR*D study, longer times than expected were needed to reach response or remission. In fact, one-third of those who ultimately responded did so after 6 weeks. Of those who achieved remission by Quick Inventory of Depressive Symptomatology (QIDS), 50 percent did so only at or after 6 weeks of treatment (Trivedi, 2006). If the eligible clinician is seeing improvement, this measure encourages the continuation of treatment to reach remission. This can take up to 3 months. Relapse is common within the first 6 months following remission from an acute depressive episode; as many as 20-85 percent of patients may relapse (American Psychiatric Association, 2010).

Q412: Documentation of Signed Opioid Treatment Agreement

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Physical Medicine, Neurology, Geriatrics

Comment: One commenter supported measure Q412: Documentation of Signed Opioid Treatment Agreement because it protects clinicians from the repercussions of patients who violate the opioid agreement. Also, considering the magnitude and urgency of the opioid epidemic, quality programs should adopt this measure unless data is otherwise available to describe the negative consequences of this measure. The commenter suggested that developers update the measure specifications to include appropriate exclusion criteria for patients receiving active cancer treatment, and patients receiving palliative and end-of-life care.

Response: We agree with the commenter's suggestion to exclude patients who are undergoing active cancer treatment and who are receiving palliative and end-of-life care. We have previously collaborated with the measure steward to add a hospice exclusion for the 2019 performance period. We encourage the commenter to review the measure specification when published.

Q414: Evaluation or Interview for Risk of Opioid Misuse

Specialty Sets: Family Medicine, Internal Medicine, Orthopedic Surgery, Physical Medicine, Neurology, Geriatrics

Comment: One commenter supported measure Q414: Evaluation or Interview for Risk of Opioid Misuse because implementation will likely lead to measurable and meaningful improvements in patient outcomes and prevent the misuse and abuse of opioid prescription therapy. However, the commenter stated that evidence exists to suggest that opioid addiction develops in less than 6 weeks duration of prescribed therapy, so the measure could unfairly penalize clinicians who do not initiate opioid therapy. Measure developers should consider updating the denominator specifications to include an evidence-based therapy duration. Also, the opioid measures would benefit from additional testing to determine which interventions are most impactful in preventing opioid misuse and abuse, exclusion criteria could include patients receiving active cancer treatment, palliative care, and end-of-life care.

Response: We agree with the commenter's suggestion to exclude patients undergoing active cancer treatment, receiving palliative and end-of-life care. We have collaborated with the measure steward to add a hospice exclusion for the 2019 performance period. We encourage the commenter to review the measure specification when published. In addition, we will provide the commenter's recommendation to the measure steward to align the denominator with the definition of chronic opioid therapy. The revision of chronic opioid therapy does not make this an invalid measure as it promotes risk assessment for a large opioid epidemic.

Q418: Osteoporosis Management in Women who had a Fracture

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology, Orthopedic Surgery

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

Comment: One commenter supported measure Q418: Osteoporosis Management in Women who had a Fracture because a performance gap exists, the specifications align with current recommendations to screen for osteoporosis in women aged 65 years and older, and specifications include appropriate exclusion criteria for women with fracture related to traumatic injury. The commenter stated that implementation may promote overuse of bone mineral density testing, and developers should consider tapering the fracture definition to only include women with vertebral and hip fractures.

Response: We do not agree that it would promote overuse of screening as it allows a 2-year timeframe for completing the bone mineral density test. In addition, an eligible clinician can meet the intent of the measure by pharmacotherapy. Eligible clinicians are expected to coordinate their care with eligible clinicians. We will provide feedback to the measure steward regarding the narrowing of eligible ICD10 codes and possibly incorporated in a future annual revision process. In response to the commenter's request to include a hospice exclusion, this is included within the measure specification.

Comment: For measure Q418: Osteoporosis Management in Women Who Had a Fracture, one commenter stated that there is a disconnect between this quality measure and the communication and care transition quality measure application to the clinician treating the fracture. The commenter urged CMS to align measure Q418 with clinical guidelines recommending that patients with a history of hip or vertebral fracture receive (or are offered) pharmacotherapy to treat osteoporosis.

Response: This measure promotes further evaluation or pharmacotherapy to treat osteoporosis for patients experiencing a fracture. U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis include, in alphabetical order: bisphosphonates (alendronate, alendronate-cholecalciferol, ibandronate, risedronate, zoledronic acid, calcitonin, teriparatide, denosumab, and raloxifine.

Q419: Overuse of Imaging for Patients with Primary Headache and a Normal Neurological Evaluation

Specialty Sets: Neurology

Comment: One commenter supported measure Q419: Overuse of Imaging for Patients with Primary Headache and a Normal Neurological Evaluation. However, the commenter stated that measure developers cite outdated evidence to form the basis of the measure. Additionally, quality reporting programs should be aware of the potential for clinicians to manipulate the measure to work in their favor by documenting an exception to the rule (for example, "change in the type of headache"). To avoid potential measure gaming, developers should consider revising the specifications to clearly define appropriate exceptions to eligibility.

Response: In response to the outdate guidelines concern, we encourage the commenter to review the substantively updated measure specification that reflect the most recent guidelines. Eligible clinicians should not change their billing or documentation to manipulate eligibility or performance. Any claims submitted to the CMS are subject to an audit, inclusive of any performance data submitted to the quality program.

Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Specialty Sets: Cardiology, Gastroenterology, Family Medicine, Internal Medicine, Obstetrics/Gynecology, Otolaryngology, Physical, Medicine, Preventive Medicine, Mental/Behavioral Health, Urology, Oncology, Urgent Care

Comment: One commenter supported measure Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling because it is clinically important to screen for unhealthy alcohol use. They agreed that the measure aligns with the United States Preventive Services Task Force (USPSTF) recommendations on screening and behavioral health counseling interventions in primary care, and the measure does not pose undue burden on clinicians. The commenter suggested the developers revise the numerator specifications to clearly define "brief counseling.

Response: We direct the commenter to the measure specification that defines brief counseling: Brief counseling for unhealthy alcohol use refers to one or more counseling sessions, a minimum of 5-15 minutes, which may include: feedback on alcohol use and harms; identification of high risk situations for drinking and coping strategies; increased motivation and the development of a personal plan to reduce drinking.

Q435: Quality of Life Assessment for Patients with Primary Headache Disorders

Specialty Sets: Neurology

Comment: One commenter did not support measure Q435: Quality of Life Assessment for Patients with Primary Headache Disorders because it cannot estimate the measure impact on improved clinical outcomes. The commenter stated that following on the measure specifications: denominator specifications include exclusion criteria for patients without insurance to cover assessment costs, reinforcing uncertainty surrounding the intervention's ability to improve quality outcomes; the numerator specifies an assessment tool that is specific to migraine headaches; and as currently specified, clinicians are required to perform quality of life assessments on all patients with primary headache disorders, regardless of clinical relevance to the patient's primary complaints. Developers should consider revising the specifications to include a principle diagnosis of primary headache and more meaningful, evidence-based interventions.

Response: We disagree with the commenter's assessment of the measure and refer the commenter to review the MIPS quality measure. It does not have an exclusion for patients without insurance to cover assessment costs. The measure does provide a list of quality of life tools applicable to this specific patient population: Migraine Disability Assessment (MIDAS) and PedMIDAS (proprietary); Headache Impact Test-6 (HIT-6)(proprietary); Migraine Specific Quality of Life Tool (MSQ); Neck Disability Index (NDI)-used for cervicogenic headaches; McGill Questionnaire. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. The eligible clinician would only submit the measure if there was a qualifying encounter(s).

Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Preventive Medicine

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

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Comment: One commenter supported measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease based on an increase in the performance gap due to new guidelines, available evidence and that measure specifications include appropriate exclusion criteria for patient intolerance. The commenter noted that implementation of statin therapy alone does not guarantee meaningful improvements in clinical outcomes. A more meaningful measure may examine patient adherence to prescribed statin therapy. Additionally, a high percentage of patients prescribed statin therapy for the management of cardiovascular disease exacerbations (for example, acute MI) discontinue therapy without consulting their clinician. However, the measure may unfairly penalize clinicians for lack of control over non-adherent patients.

Response: We will evaluate the commenter's request for adding an adherence component, but the commenter also cited concerns that this may not attribute to the eligible clinician due to lack of control of non-adherent patients. Based on the commenter's feedback to add adherence but caution adherence would out of the eligible clinician's control, we maintain the notion this is a good measure,

Q441: Ischemic Vascular Disease: All or None Outcome Measure

Specialty Sets: Cardiology, Family Medicine, Internal Medicine, Vascular Surgery

Comment: One commenter did not support measure Q441: Ischemic Vascular Disease: All or None Outcome Measure, citing that it did not receive adequate information from the developer for review and that it rated the measure based on the specifications provided on the MIPS website. The commenter stated the measure because it disregards patient preferences, specifications do not consider factors beyond the clinician's control, and it does not align committee recommendations for hypertension management.

Response: We agree with updating the numerator to reflect the updated blood pressure values and have been discussing the revision with the measure steward. We maintain the opinion this is a good measure since the new guidelines have been controversial and encourages comprehensive management of a prevalent condition.

Q442: Persistence of Beta-Blocker Treatment after a Heart Attack

Specialty Sets: Cardiology, Family Medicine, Internal Medicine

Comment: One commenter supported measure Q442: Persistence of Beta-Blocker Treatment after a Heart Attack, citing high-quality evidence from the most recent recommendations of various organizations. The commenter noted this measure is close to being topped out.

Response: We encourage the commenter to review the most current MIPS performance data when available.

Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females

Specialty Sets: Family Medicine, Internal Medicine, Obstetrics/Gynecology

Comment: One commenter supported measure Q443: Non-Recommended Cervical Cancer Screening in Adolescent Females because implementation will likely promote appropriate use of cervical cancer screening in adolescents, the measure is well specified, and specifications include appropriate exclusion criteria for women diagnosed with HIV. The measure also aligns with USPSTF recommendations on cervical cancer screening. However, the commenter noted that earlier screening is not as effective and that the evidence base would benefit from re-evaluation as data surfaces on the benefits and risks of screening in women < 20 years old. Because the performance gap is not cited in the measure report, it is difficult to estimate the potential impact of the measure on quality outcomes.

Response: We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. The measure aligns with United States Preventive Services Task Force recommendations on cervical cancer screening in addition to the ACOG and ASCCP guidelines. We will continue to monitor for updated cervical cancer screening guidelines and collaborate with the measure steward to align with any updated guidelines.

Q444: Medication Management for People with Asthma

Specialty Sets: Family Medicine, Internal Medicine, Pediatrics

Comment: One commenter supported measure Q444: Medication Management for People with Asthma because implementation may promote patient adherence to prescribed controller medication therapy. However, the commenter indicated the following concerns: the performance gap is not cited; there is no evidence cited to support the Percentage of Days Covered (PDC) threshold; the measure is not measure is not risk-adjusted for disease severity or socioeconomic status and implementation; the measure numerator should clearly specify an appropriate asthma controller medication list; the measure could unfairly penalize clinicians who encounter interoperability barriers to data retrieval; the measure uses pharmacy data to track medication adherence where lower socioeconomic patients may encounter cost barriers and adherence issues; and lastly, the measure assesses quality at the system level where individual clinicians may encounter interoperability barriers to data retrieval.

Response: We continue to evaluate methods to display performance data. We have previously published Experience Reports to provide a detailed summary and continue to create meaningful benchmarks based on the submitted data. We have explored alternative asthma measures that promote controller medication therapy over quick reliever medication, but unable to implement at the clinician level at this time. We agree that the goal is to achieve 100 percent adherence and will continue to collaborate with the measure steward to raise the Percentage Days Covered (PDC) to drive quality improvement. The measure is not risk-adjusted at this time to address socioeconomic status but do not believe this should deter adherence and all efforts should be made to accommodate patients' financial situations. We do understand the concern of socioeconomic disparities and discussing mitigation strategies to not hold eligible clinicians to different standards for the outcomes of their patients with social risk factors. We do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. As indicated within the comment, eligible clinicians could provide sample medication to improve patient adherence

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

and alleviate financial burden. Medications dispensed as samples would be included within the PDC assessment. While this may pose difficulty in abstracting by pharmacy data, the medical record should capture this provision. Within the 2018 measure specification there is a table that defines appropriate asthma controller medications. Based on the provided response, we maintain the notion this is an appropriate measure.

Specialty Measure Sets: Cardiology, General Surgery, Skilled Nursing Facility

Comment: One commenter encouraged CMS to add the following immunization quality measures into a new Endocrinology specialty measure sets:

- ***Cardiology*** - Q474: Zoster (Shingles) Vaccination; Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumonia Vaccination Status for Older Adults
- ***General Surgery*** - Q110: Preventive Care and Screening: Influenza Immunization and Q111: Pneumonia Vaccination Status for Older Adults
- ***Skilled Nursing Facility*** -. Q111: Pneumonia Vaccination Status for Older Adults
- ***Endocrinology*** - Q474: Zoster (Shingles) Vaccination; Preventive Care and Screening: Influenza Immunization and Q111: Pneumonia Vaccination Status for Older Adults

Response: We thank the commenter for the recommendation to create an Endocrinology specialty measure set and to add these measures to existing specialty measure sets for Cardiology, General Surgery, and Skilled Nursing Facility. Prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. Specific measure to create an Endocrinology specialty measure set were not suggested as part of the feedback received from specialty stakeholders for the 2019 performance period. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking. This allows stakeholder to provide feedback to the specialty set proposed prior to the finalization of the specialty set. We do not agree with the recommendation to include Q110, Q111, and Q474 to the Cardiology and General Surgery specialty sets as the patient would likely be referred to the PCP to receive immunizations. While we agree that Q111 may apply to Skilled Nursing Facilities, the denominator coding does not support this request.

Specialty Measure Set: Allergy/Immunology (A/I)

Comment: One commenter expressed concerns with the Allergy/Immunology (A/I) Specialty Measure Set, which they noted includes measures that are not pertinent to our Allergy/Immunology Specialty. Given A/I specialists do not diagnose, treat or manage HIV/AIDS, measures related to this disease do not belong in the A/I Specialty Measure Set. Therefore, the commenter requested that CMS remove the following measures: Measure 160: HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis; Measure 338: HIV Viral Load Suppression; Measure 340: HIV Medical Visit Frequency.

In addition, the commenter noted that A/I specialists do diagnose, treat and frequently manage sinusitis and asthma, therefore, they requested that CMS return the following measures to the A/I Specialty Measure Set: Measure 331: Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis, Measure 332: Adult Sinusitis: Appropriate Choice of Antibiotic.

Response: Prior to rulemaking we solicit feedback from stakeholders with regards to measures that should be added or removed to existing specialty sets or the development of new specialty sets. The suggestion to remove the measures from the Allergy/Immunology specialty measure set was not provided as part of the feedback received from specialty stakeholders for the 2019 performance period. We ask the commenter to submit their feedback during this solicitation process for future consideration in rulemaking.

Specialty Measure Set: Dentistry

Comment: One commenter supported the inclusion of measure Q379: Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists, but stated the measure specifications do not reflect the best clinical evidence. Existing clinical recommendations recommend that topical fluoride be applied more frequently than once per year and as often as every 3 months for children at elevated risk for dental caries. The commenter recommended that this measure be amended to reflect increased risk for tooth decay in line with the existing pediatric measure set developed by the Dental Quality Alliance (DQA). The commenter also supported the inclusion of measure Q378: Children Who Have Dental Decay or Cavities, as it represents the type of outcome measures that oral health care has long been lacking. However, there has been no visible progress in developing or testing this measure for use by Medicaid programs. The commenter requested that CMS transfer the measure stewardship for measures Q378 and Q379 to the DQA, which was as established at the request of CMS to serve as a multi-stakeholder organization focused on oral health quality measurement and improvement Furthermore, the commenter noted that two additional measures have been developed by the DQA through support from the Office of National Coordinator for Health Information Technology (ONC) and tested for validity, reliability, feasibility and usability for use at the clinicians level and rely on standard data elements in electronic health records and are specified precisely using the Measure Authoring Tool based on the Quality Data Model and value sets.

Response: We thank the commenter for feedback that this outcome measure is not risk adjusted for clinical or sociodemographic factors. We support the goal of identifying and reducing disparities in health and healthcare. We will explore risk adjustment for this measure and the potential impact on clinician burden in the next update period. Thank you for bringing up the current evidence-based clinical recommendations and the need to incorporate within this measure. We will review these recommendations in the next update period. With regard to the DQA and measure stewardship, we seek collaborative partnerships and engagement with stakeholders in the development and continued maintenance of important, feasible, reliable, valid, and useful measures and appreciates the opportunity to engage the current measure steward and other stakeholders. Thank you for your comments on the need for additional measures for dental professionals and your recommendations to improve the current program dental measures. We will take your suggestions under consideration as we continue to review and update program measures. We provide opportunities for introducing new measures into programs through an annual call for measures and encourage the commenter to submit measures and measure concepts at the next Call for Measures solicitation.

General Comments

Comment: One commenter supported the inclusion of a number of dementia and cognitive impairment measures in MIPS. The commenter urged CMS to develop quality measures related to mild cognitive impairment and its detection for future years. The commenter further urged CMS to include the cognitive impairment quality measures currently under development by the measure steward when they are finalized. The commenter also stated that cognitive impairment detection is the only aspect of the Annual Wellness Visit that is not fully reinforced with clinicians through MIPS quality measures. The existing

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES

Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes.

dementia-related quality measures apply solely to patients who have already been diagnosed with dementia, and do not reflect overall incorporation of the required cognitive impairment component in the AWV. The Quality Payment Program, therefore, perpetuates ADRD under diagnosis and impedes appropriate interventions for patients and their families.

Response: We encourage the comment to collaborate with measure developers to submit measures to the Call for Measures process for future implementation.

Comment: One commenter urged CMS to adopt the following malnutrition eCQMs adopted by the National Quality Forum 14: NQF #3087/MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission; NQF #3088/MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At Risk for Malnutrition within 24 hours of a Malnutrition Screening; NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment; NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis. A second commenter indicated that given the demonstrated gap, it is critical that CMS act quickly to use its statutory authority through direction of the national quality strategy and focus on malnutrition care in the hospital. Malnutrition should be a priority area for CMS, as malnutrition care aligns with the main principles of the Meaningful Measures Initiative.

Response: We encourage the commenter to collaborate with the measure steward of the mentioned measures and submit to the Call for Measures process under the MIPS program. The referenced measures were submitted to the Hospital Inpatient Quality Reporting program, but not for MIPS consideration.

Comment: One commenter was disappointed that adult immunization quality measures were not included in a few key specialty areas who care for chronically ill patients at-risk of serious complications from vaccine preventable illness. The Advisory Committee on Immunization Practices (ACIP) includes age-based, as well as condition-specific recommendations for adult vaccination. For pregnant women, ACIP recommends a Tdap vaccination. We are pleased that efforts to develop a composite Tdap/influenza measure for pregnant women has completed testing and is now under review by the National Committee for Quality Assurance (NCQA). The commenter noted they look forward to further dialogue with CMS on this topic as it moves forward. In addition, patients living with chronic conditions such as heart disease and diabetes are at a significantly higher risk of complications and death from influenza and pneumonia. The CDC has reported that in 2013 only 21.2 percent of adults in this group had received a pneumococcal vaccination, and this number has remained unchanged for at least a decade. Individuals with diabetes are at increased risk for hepatitis B infection. As such, the ACIP recommends hepatitis B vaccination for all patients with diabetes age 6011 and under, as well as other at-risk patients, such as those living with HIV/AIDS and chronic kidney disease.

Response: We appreciate the support for the pneumococcal quality measures. We agree this is an important public health issue. We continue to explore opportunities to implement a composite adult vaccination measure for future implementation. We encourage the commenter to work with measure developers to submit the immunization measures to the Call for Measures process. We did add adult immunization measures to the existing Oncology and Internal Medicine specialty measure set, as well as new specialty measure set.

Comment: A few commenters supported the proposal to remove six measures from CMS Web Interface reporting criteria.

Response: We thank the commenters for their support. Note: Because measure Q318 is not finalized for removal from the MIPS program in this final rule, there are now five measures that will be finalized in this final rule with the change to remove the CMS Web Interface data collection type.

Comment: Concerning the quality category proposed to be weighted at 45 percent in Year 3 continuing to represent the performance category with the greatest contribution to a clinician's final score in MIPS, commenters noted that this performance category still represents the greatest challenge for chiropractic clinicians due to the limited CPT codes the provider is reimbursed by CMS. These codes are currently limited to two clinical quality measures, specifically #131 & #182. These measures have a high risk of being removed based on the proposed rule for topped out measures in Year 3, leaving the chiropractic clinician forced to bill his/her Medicare patients out of pocket expenses to report other quality measures.

Response: We encourage stakeholders to submit feedback on specific MIPS quality measures where they believe codes should be added to reflect a specialty practice not currently reflected in a given measure. We would take that feedback into consideration, and if we agree with the recommendation, could communicate such recommendations to the measure stewards for their consideration. MIPS eligible clinicians should report on quality measures that are meaningful to their practice and within the scope of the care they provide. We note that chiropractor clinician codes have been added to the following measures for the 2019 performance period: Quality ID# 217: Functional Status Change for Patients with Knee Impairments; Quality ID# 218: Functional Status Change for Patients with Hip Impairments; Quality ID# 219: Functional Status Change for Patients with Foot or Ankle Impairments; Quality ID#220: Functional Status Change for Patients with Lumbar Impairments; Quality ID#221: Functional Status Change for Patients with Shoulder Impairments; Quality ID#222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments; and Quality ID#223: Functional Status Change for Patients with Other General Orthopaedic Impairments. We remind all clinicians that they should bill Medicare only for services that are reasonable and necessary. We encourage MIPS eligible clinicians to review the list of MIPS quality measures and QCDR measures available for quality reporting in order to report on measures that are meaningful to their scope of practice. We believe it is important to gradually remove topped out measures from the program as they demonstrate high, unvarying performance with no gaps for quality improvement.

APPENDIX 2: Improvement Activities

NOTE: For previously finalized improvement activities, we refer readers to the finalized Improvement Activities Inventory in Table F in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175) and in Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77818). Unless modified or removed in the CY 2019 Physician Fee Schedule final rule, previously finalized improvement activities continue to apply for the MIPS CY 2019 performance period and future years.

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53569) for previously adopted criteria for nominating new improvement activities. We refer readers to section III.I.3.h.(4)(d)(i) of this final rule, where we are finalizing our proposals to add one new criterion and remove a previously adopted criterion. In addition, we refer readers to section III.I.3.h.(4)(d)(i) of this final rule where we clarify: (1) considerations for selecting improvement activities for the CY 2019 performance period and future years; and (2) the weighting of improvement activities. In the CY 2019 PFS proposed rule (83 FR 36359), for CY 2019 performance period and future years we proposed: six (6) new improvement activities; the modification of five (5) existing activities; and the removal of one (1) existing activity. These are discussed in greater detail below.

TABLE A: New Improvement Activities for the MIPS CY 2019 Performance Period and Future Years

Proposed Improvement Activity	
Proposed Activity ID:	**IA_AHE_7**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Comprehensive Eye Exams
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign[84] and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America[85] and the American Optometric Association's VISION USA.[86] This activity is intended for: (1) non-ophthalmologists/optometrist who refer patients to an ophthalmologist/optometrist; (2) ophthalmologists/optometrists caring for underserved patients at no cost; or (3) any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high- risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Proposed Weighting:	Medium
Rationale:	This activity fills a gap as the Inventory does not currently contain an activity related to ophthalmology. Furthermore, we believe promoting and educating patients about the importance of a comprehensive eye exam can improve access to this service and, in turn, improve health status particularly for traditionally underserved populations or to those who are otherwise unable to access these important services. For these reasons, we believe this activity meets the inclusion criteria of an activity that could lead to improvement in practice to reduce health care disparities. We proposed the weighting of this activity as medium because this activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. This task may be incorporated into a patient's regular visit with a relatively low investment of time or resources
Comments:	Several commenters supported the inclusion of this improvement activity. Commenters stated that the activity will have positive clinical impacts on patients. In addition, routine eye exams can identify both ocular conditions as well as other health problems, including serious conditions like brain tumors, thyroid disease, and pituitary tumors. Another commenter supported improvement activities that specifically promote health equity, the goal of this improvement activity. One commenter recommended this improvement activity not be finalized due to concern that comprehensive eye exams are not appropriate for most healthy populations and should only be targeted to those at risk. The commenter stated the improvement activity may lead to increases in unnecessary expenditures for public programs and low income patients.
Response:	We believe this improvement activity will have a positive impact on patient care and promote health equity. Regarding the commenter's concern that this improvement activity may lead to the provision of comprehensive eye exams for those who are not at risk, as stated in the description, "this activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams." Therefore, we believe that the improvement activity is appropriately targeted at populations with the highest risk for conditions that

[84]The Think About Your Eyes resource at http://thinkaboutyoureyes.com.
[85] The American Academy of Ophthalmology's EyeCare America resource at https://www.aao.org/eyecare-america.
[86] The American Optometric Association's VISION USA resource at http://www.aoafoundation.org/vision-usa/.

	can be detected through a comprehensive eye exam. Additionally, since comprehensive eye exams are relatively low cost interventions and early detection of conditions that can be identified through an eye exam may reduce more costly treatment later, we believe this improvement activity will not unnecessarily increase expenditures for public programs and the target population.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_7**
Subcategory:	Achieving Health Equity
Activity Title:	Comprehensive Eye Exams
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign[87] and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America[88] and the American Optometric Association's VISION USA.[89] This activity is intended for: (1) non-ophthalmologists/optometrist who refer patients to an ophthalmologist/optometrist; (2) ophthalmologists/optometrists caring for underserved patients at no cost; or (3) any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high- risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_BE_24**
Proposed Subcategory:	Beneficiary Engagement
Proposed Activity Title:	Financial Navigation Program
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must attest that their practice provides financial counseling to patients or their caregiver about costs of care and an exploration of different payment options. The MIPS eligible clinician may accomplish this by working with other members of their practice (for example, financial counselor or patient navigator) as part of a team-based care approach in which members of the patient care team collaborate to support patient- centered goals. For example, a financial counselor could provide patients with resources with further information or support options, or facilitate a conversation with a patient or caregiver that could address concerns. This activity may occur during diagnosis stage, before treatment, during treatment, and/or during survivorship planning, as appropriate.
Proposed Weighting:	Medium
Rationale:	We believe there is the possibility for improved outcomes when financial navigation programs are in place, such as reducing patient anxiety about costs and improved access to care for underserved populations. For these reasons, we believe this activity meets the inclusion criteria of an activity that could lead to improvement in practice to reduce health care disparities. We proposed the weighting of this activity as medium because the activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. This task may be incorporated into a patient's regular visit with a relatively low investment of time or resources.

[87] The Think About Your Eyes resource at http://thinkaboutyoureyes.com.
[88] The American Academy of Ophthalmology's EyeCare America resource at https://www.aao.org/eyecare-america.
[89] The American Optometric Association's VISION USA resource at http://www.aoafoundation.org/vision-usa/.

Comments:	Several commenters supported the inclusion of this improvement activity. One commenter noted that this improvement activity may be challenging for clinicians, especially those in smaller practices who have difficulty accessing cost of care data and should therefore be weighted as high. Another commenter provided support for the inclusion of this improvement activity as proposed because this improvement activity is likely to have a large impact on patients with serious illnesses who are at high risk for medical debt and its related problems, and recommended we remain flexible in the members of the patient care team that can provide financial navigation services.
Response:	As explained in section III.I.3.h.(4)(d)(i)(C) of this final rule, the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. We do not believe accessing cost of care data requires a significant investment of time and resources, even for smaller practices, and therefore, we do not believe a high weighting is warranted. We appreciate the supportive comment that this improvement activity will have an impact on patients with serious illnesses who are at risk for medical debt. Regarding the comment that we remain flexible in the members of the patient care team that can provide financial navigation services, the activity description states that the MIPS eligible clinician may meet this improvement activity by working with other members of the patient care team, including financial counselors or patient navigators and we intend to continue this flexibility.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_24**
Subcategory:	Beneficiary Engagement
Activity Title:	Financial Navigation Program
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must attest that their practice provides financial counseling to patients or their caregiver about costs of care and an exploration of different payment options. The MIPS eligible clinician may accomplish this by working with other members of their practice (for example, financial counselor or patient navigator) as part of a team-based care approach in which members of the patient care team collaborate to support patient-centered goals. For example, a financial counselor could provide patients with resources with further information or support options, or facilitate a conversation with a patient or caregiver that could address concerns. This activity may occur during diagnosis stage, before treatment, during treatment, and/or during survivorship planning, as appropriate.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_BMH_10**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Completion of Collaborative Care Management Training Program
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychological Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI),[90] available to the

[90] Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) information at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.

	public,[91] in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Proposed Weighting:	Medium
Rationale:	Collaborative care management approaches to integrating behavioral health into primary care practice have been associated with significant improvements in mental health symptom acuity and adherence to treatment in the short- to mid-term.[77] [78] [79] In addition, this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes. We proposed the weighting of this activity as medium because participation in a training program consists of online reading, attending webinars, or other one-time or short-term activities, which, though beneficial, do not require substantial time or effort by clinicians.
Comments:	Several commenters provided general support for the new improvement activities. A few commenters supported the inclusion of this improvement activity.
Response:	We appreciate the comments of support for this improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BMH_10**
Subcategory:	Behavioral and Mental Health
Activity Title:	Completion of Collaborative Care Management Training Program
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must complete a collaborative care management training program, such as the American Psychological Association (APA) Collaborative Care Model training program available as part of the Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI),[92] available to the public,[93] in order to implement a collaborative care management approach that provides comprehensive training in the integration of behavioral health into the primary care practice.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_CC_18**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Relationship-Centered Communication
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must participate in a minimum of eight hours of training on relationship-centered care[94] tenets such as making effective open-ended inquiries; eliciting patient stories and perspectives; listening and responding with empathy; using the ART (ask, respond, tell) communication technique to engage patients, and developing a shared care plan. The training may be conducted in formats such as, but not limited to: interactive simulations practicing the skills above, or didactic instructions on how to implement improvement action plans, monitor progress, and promote stability around improved clinician communication.

[91] American Psychological Association (APA) Collaborative Care Model training program information at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/get-trained.
[92] Centers for Medicare & Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) information at https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/.
[93] American Psychological Association (APA) Collaborative Care Model training program information at https://www.psychiatry.org/psychiatrists/practice/professional-interests/integrated-care/get-trained.
[94] Nundy, S. and J. Oswald (2014). "Relationship-centered care: A new paradigm for population health management." Healthcare 2(4): 216-219.

Proposed Weighting:	Medium
Rationale:	There is currently not an activity in the Inventory that addresses communication between patients and clinicians; this proposed activity would help fill a gap. We believe that this proposed activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes based on research citing the importance of relationship-centered care to patient safety. [81] We proposed the weighting of this activity as medium because participation in an eight hour training on relationship-centered care, though beneficial, does not require substantial time or effort by clinicians.
Comments:	A few commenters supported the inclusion of this improvement activity. One commenter recommended this activity be weighted high due to the potential for the training to be burdensome to clinicians.
Response:	As stated in section III.I.3.h.(4)(d)(i)(C) of this final rule, the weighting of "medium" is in accordance with our policy, as high weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. We do not believe relationship-centered trainings that can be completed in a minimum of eight hours is a significant investment of time and resources and therefore does not warrant a high weighting.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_18**
Subcategory:	Care Coordination
Activity Title:	Relationship-Centered Communication
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must participate in a minimum of eight hours of training on relationship-centered care[95] tenets such as making effective open-ended inquiries; eliciting patient stories and perspectives; listening and responding with empathy; using the ART (ask, respond, tell) communication technique to engage patients, and developing a shared care plan. The training may be conducted in formats such as, but not limited to: interactive simulations practicing the skills above, or didactic instructions on how to implement improvement action plans; monitor progress; and promote stability around improved clinician communication.
Weighting:	Medium
Proposed Improvement Activity	
Proposed Activity ID:	**IA_PSPA_31**
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Patient Medication Risk Education
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must provide both written and verbal education regarding the risks of concurrent opioid and benzodiazepine use for patients who are prescribed both benzodiazepines and opioids. Education must be completed for at least 75 percent of qualifying patients and occur: (1) at the time of initial co-prescribing and again following greater than 6 months of co-prescribing of benzodiazepines and opioids, or (2) at least once per MIPS performance period for patients taking concurrent opioid and benzodiazepine therapy.
Proposed Weighting:	High

[95] Nundy, S. and J. Oswald (2014). "Relationship-centered care: A new paradigm for population health management." Healthcare 2(4): 216-219.

Rationale:	This activity addresses the Meaningful Measures priority area of Prevention and Treatment of Opioid and Substance Use Disorders[96] and addresses the role of clinicians in management of concurrent prescriptions, a topic that is not currently represented in the Inventory. We believe this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes due to the prevalence of opioid and substance abuse disorders and the medical consequences of mismanagement of concurrent benzodiazepine and opioid prescription.[97] We proposed the weighting of this activity as high because it addresses a public health emergency[98] and may reduce preventable health conditions related to opioid abuse. High weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being, as explained in the CY 2017 Quality Payment Program final rule (81 FR 77194). We also refer readers to our clarifications regarding weighting at section III.I.3.h.(4) of this final rule. According to the CDC, about 63,000 people died in 2016 of a drug overdose, and well over half of them are attributed to opioids.[99] Additionally, according to the 2016 National Survey on Drug Use and Health (NSDUH), 11.8 million individuals ages 12 and older misused any opioid (that is, prescription and/or illicit opioids) and 11.5 million individuals misused prescription opioids. Of those who misused opioids, 2.1 million individuals meet the criteria for an opioid use disorder.[100] Since providing education regarding the risks of concurrent opioid and benzodiazepine use directly addresses the opioid epidemic, we believe this improvement activity meets our considerations for high-weighting.
Comments:	Several commenters supported the inclusion of this improvement activity. A couple commenters supported the improvement activity's high weighting due to it being part of addressing the increase in opioid drug use, abuse, and overdose deaths. Other commenters provided general support for new improvement activities that address the opioid crisis. Two commenters stated that there is a lack of evidence on when the risks of concurrent opioid and benzodiazepine prescribing outweigh the benefits and likewise when the benefits outweigh the risks.
Response:	We appreciate the comments of support for this improvement activity. We also appreciate the commenters who stated there is a lack of evidence on when the risks of concurrent opioid and benzodiazepine prescribing outweigh the benefits. However, this improvement activity does not require MIPS eligible clinicians to alter their prescribing protocol, except to provide written and verbal education regarding the known risks.
Rationale:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.

[96] Meaningful Measures Framework information available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

[97] McClure, F. L., Niles, J. K., Kaufman, H. W., & Gudin, J. (2017). Concurrent Use of Opioids and Benzodiazepines: Evaluation of Prescription Drug Monitoring by a United States Laboratory. Journal of Addiction Medicine, 11(6), 420–426. http://doi.org/10.1097/ADM.0000000000000354.

[98] Department of Health and Human Services. (2018) "HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis" Available at https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

[99] Hedegaard, H., Warner, M., & Miniño, A. M. (2017). NCHS Data Brief No. 294. Center for Disease Control and Prevention National Center for Health Statistics. Available at https://www.cdc.gov/nchs/products/databriefs/db294.htm.

[100] Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017). Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration NSDUH Data Review. Available at https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm.

Finalized Improvement Activity	
Activity ID:	**IA_PSPA_31**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Patient Medication Risk Education
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must provide both written and verbal education regarding the risks of concurrent opioid and benzodiazepine use for patients who are prescribed both benzodiazepines and opioids. Education must be completed for at least 75 percent of qualifying patients and occur: (1) at the time of initial co-prescribing and again following greater than 6 months of co-prescribing of benzodiazepines and opioids, or (2) at least once per MIPS performance period for patients taking concurrent opioid and benzodiazepine therapy.
Weighting:	High
Proposed Improvement Activity	
Proposed Activity ID:	**IA_PSPA_32**
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support
Proposed Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must utilize the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain[101] via clinical decision support (CDS). For CDS to be most effective, it needs to be built directly into the clinician workflow and support decision making on a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include, but are not limited to: electronic health record (EHR)-based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Proposed Weighting:	High
Rationale:	This activity addresses the Meaningful Measures priority areas of Prevention and Treatment of Opioid and Substance Use Disorders and Transfer of Health Information and Interoperability[102]. Electronic tools like CDS can assist clinicians in preventing adverse patient outcomes. We believe this activity meets the inclusion criteria of an activity that is likely to lead to improved beneficiary health outcomes due to the prevalence of opioid and substance abuse disorders and evidence of CDS supporting improved outcomes and patient safety.[103] We proposed the weighting of this activity as high because it promotes interoperability and addresses a public health emergency and may reduce preventable health conditions related to opioid abuse. High weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being, as explained in the CY 2017 Quality Payment Program final rule (81 FR 77194). We also refer readers to our clarifications regarding weighting at section III.I.3.h.(4) of this

[101] CDC Prescribing Guidelines resource at https://www.cdc.gov/drugoverdose/prescribing/guideline.html.
[102] Centers for Medicare & Medicaid "Meaningful Measures Framework" resource available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.
[103] Hummel, J. Office of the National Coordinator for Health Information Technology (2013) "Integrating Clinical Decision Support Tools into Ambulatory Care Workflows for Improved Outcomes and Patient Safety" at https://www.healthit.gov/sites/default/files/clinical-decision-support-0913.pdf.

	final rule. According to the CDC, about 63,000 people died in 2016 of a drug overdose, and well over half of them are attributed to opioids.[104] Additionally, according to the 2016 National Survey on Drug Use and Health (NSDUH), 11.8 million individuals ages 12 and older misused any opioid (that is, prescription and/or illicit opioid) and 11.5 million individuals misused prescription opioids. Of those who misused opioids, 2.1 million individuals meet the criteria for an opioid use disorder.[105] Since providing education regarding the risks of concurrent opioid and benzodiazepine use directly helps to addresses the opioid epidemic, and use of CDS addresses CMS's policy focus on Promoting Interoperability,[106] we believe this improvement activity meets our considerations for high-weighting.
Comments:	Several commenters supported the inclusion of this improvement activity. A couple commenters provided general support for new improvement activities that address the opioid crisis. Two commenters noted that the CDC Guideline for Prescribing Opioids for Chronic Pain are "for primary care physicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care," and that including this improvement activity may exacerbate a tendency for specialists to use the Guideline for patient populations for which it is not intended.
Response:	Clinicians may meet this improvement activity by appropriately adhering to the CDC Guideline for Prescribing Opioids for Chronic Care and should pick activities applicable to their clinical practice and patient population.
Final Action:	After consideration of the public comments received, we are finalizing this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_32**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support
Activity Description:	In order to receive credit for this activity, MIPS eligible clinicians must utilize the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain[107] via clinical decision support (CDS). For CDS to be most effective, it needs to be built directly into the clinician workflow and support decision making on a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include, but are not limited to: electronic health record (EHR)-based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Weighting:	High

[104] Hedegaard, H., Warner, M., & Miniño, A. M. (2017). NCHS Data Brief No. 294. Center for Disease Control and Prevention National Center for Health Statistics. Available at https://www.cdc.gov/nchs/products/databriefs/db294.htm.

[105] Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017). Receipt of Services for Substance Use and Mental Health Issues among Adults: Results from the 2016 National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration NSDUH Data Review. Available at https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR2-2016/NSDUH-DR-FFR2-2016.htm.

[106] Centers for Medicare & Medicaid Services "Promoting Interoperability (PI)" resource available at https://www.cms.gov/Regulations-andGuidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/.

[107] CDC Prescribing Guidelines resource at https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

TABLE B: Changes to Previously Adopted Improvement Activities for the MIPS CY 2019 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_CC_10**
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition documentation practice improvements
Current Activity Description:	Implementation of practices/processes for care transition that include documentation of how a MIPS eligible clinician or group carried out a patient-centered action plan for first 30 days following a discharge (for example, staff involved, phone calls conducted in support of transition, accompaniments, navigation actions, home visits, patient information access).
Current Weighting:	Medium
Proposed Changes and Rationale:	Addition of "…real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications" as additional examples of how a patient-centered action plan could be documented. Primary care physicians are considered the gatekeeper of patient care. Including them in communications from specialists to patients about their follow-up of transition-of-care promotes continuity between clinicians. Adding this example to this improvement activity underscores the important role specialists play in care transition documentation practice improvement. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Comments:	One commenter supported the proposed modification to this improvement activity. One commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. One commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement activities. Another commenter requested we modify the activity description to explicitly state that this improvement activity applies to care transitions from acute care and rehabilitation facilities following a fracture, and includes follow-up care related to promoting mobility, reducing falls, and other related activities.
Response:	The proposed modifications to this activity provide examples for further clarification of the role specialists play in care transition documentation practice improvement. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. Additionally, we disagree that we should modify the activity description to explicitly state that this improvement activity applies to certain care transitions, for example those from acute care and rehabilitation facilities, because, we would like to keep the activity description broad. We believe specifying certain care settings without including all others may lead some clinicians to believe they are not eligible to attest to this improvement activity. We will add fracture-related care to subregulatory guidance available on the Quality Payment Program website[108] so clinicians attesting to this activity are aware this is an allowable service to meet this improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to

[108] Improvement Activities Data Validation Criteria at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html.

	this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_CC_10**
Subcategory:	Care Coordination
Activity Title:	Care transition documentation practice improvements
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PM_9**
Current Subcategory:	Population Management
Current Activity Title:	Participation in Population Health Research
Current Activity Description:	Participation in research that identifies interventions, tools or processes that can improve a targeted patient population.
Current Weighting:	Medium
Proposed Change and Rationale:	We proposed to remove PM_9, because we believe IA_PM_9 and IA_PM_17 are duplicative and provide improvement activity credit for the same activity. In the CY 2017 Quality Payment Program final rule (81 FR 77820), we finalized IA_PM_9: Participation in Population Health Research (activity title); Participation in research that identifies interventions, tools or processes that can improve a targeted patient population (activity description). In the CY 2018 Quality Payment Program final rule (82 FR 54481), we finalized IA_PM_17: Participation in Population Health Research (activity title); participation in federally and/or privately funded research that identifies interventions tools, or processes that can improve a targeted patient population (activity description). We believe IA_PM_9 and IA_PM_17 are duplicative because they include the same subcategory and activity title, and nearly an identical description of the activity; participation in "research that identifies interventions, tools, or processes that can improve a targeted patient population." The two activities are only distinguished by the inclusion in the description for IA_PM_17 specifying that clinicians can meet this activity through participation in federally and/or privately funded research that IA_PM_9 does not. Therefore, we proposed to remove IA_PM_9 and preserve IA_PM_17 so that we will have a consolidated activity that encompasses both improvement activities.
Comments:	Several commenters supported the removal of this improvement activity, due to it being duplicative to IA_PM_17 with the only difference being IA_PM_17 stating that this activity can be met through participation in federally and/or privately funded research. One commenter expressed concern that removing an improvement activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities. An additional commenter recommended that if an improvement activity is removed from the Inventory it should be replaced by another improvement activity applicable to clinicians who could attest to the removed one.
Response:	We believe that while consistency in available improvement activities is important, it is confusing to have nearly identical activities that clinicians can attest to. Since these improvement activities are duplicative, a clinician may report IA_PM_17 in the place of IA_PM_9. We do not believe this change will make it more difficult for clinicians to become familiar with or implement improvement activities. Additionally, we do not believe it is necessary to add a new improvement activity to replace one that is being

	removed. We refer readers to section III.I.3.h.(d)(i) of this final rule where we discuss our criteria for nominating new improvement activities. We also clarified that we use the criteria for nominating new improvement activities in selecting improvement activities for inclusion in the program. Stakeholders can propose new activities through our Annual Call for Activities.
Final Action:	After consideration of the public comments received, we are finalizing the removal of this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	N/A – Removed
Current Improvement Activity	
Current Activity ID:	**IA_PM_13**
Current Subcategory:	Population Management
Current Activity Title:	Chronic Care and Preventative Care Management for Empaneled Patients
Current Activity Description:	Proactively manage chronic and preventive care for empaneled patients that could include one or more of the following: ● Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; ● Use condition-specific pathways for care of chronic conditions (for example, hypertension, diabetes, depression, asthma and heart failure) with evidence-based protocols to guide treatment to target; such as a CDC-recognized diabetes prevention program; ● Use pre-visit planning to optimize preventive care and team management of patients with chronic conditions; ● Use panel support tools (registry functionality) to identify services due; ● Use predictive analytical models to predict risk, onset and progression of chronic diseases; or ● Use reminders and outreach (for example, phone calls, emails, postcards, patient portals and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Current Weighting:	Medium
Proposed Change and Rationale:	Addition of examples of evidence based, condition-specific pathways for care of chronic conditions: "These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP) and the NCQA Heart/Stroke Recognition Program (HSRP)." These examples relating to diabetes, heart, and stroke pathways are examples of evidence based, condition-specific pathways for care of chronic conditions. These additions to this activity provide specialist-specific examples of actions that can be taken to meet the intent of this activity. We have received stakeholder feedback that additional specialty-specific activities would be welcome in the improvement activities inventory. Other language was revised for clarity.
Proposed Revised	Chronic Care and Preventative Care Management for Empaneled Patients In order to receive credit for this activity, a MIPS eligible clinician must manage chronic and preventive care for empaneled patients (that is, patients assigned to care teams for the purpose of population health management), which could include one or more of the following actions: ● Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; ● Use evidence based, condition-specific pathways for care of chronic conditions (for

	example, hypertension, diabetes, depression, asthma, and heart failure). These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP) [109] and the NCQA Heart/Stroke Recognition Program (HSRP). [110] ● Use pre-visit planning, that is, preparations for conversations or actions to propose with patient before an in-office visit to optimize preventive care and team management of patients with chronic conditions; ● Use panel support tools, (that is, registry functionality) or other technology that can use clinical data to identify trends or data points in patient records to identify services due; ● Use predictive analytical models to predict risk, onset and progression of chronic diseases; and/or ● Use reminders and outreach (for example, phone calls, emails, postcards, patient portals, and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Comments:	Several commenters supported the proposed modifications to this improvement activity. One commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. Another commenter recommended additional diabetes-related services, Diabetes Self Management Education and Support (DSME/S) services and Medical Nutrition Therapy (MNT), be included in the description as examples of appropriate services to be included in an individualized plan of care for patients with diabetes. One commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities.
Response:	The proposed modifications to this activity provide additional examples specialists may take to meet this activity. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. Additional diabetes-related services may be eligible for this improvement activity if they are part of a clinician's management of chronic and preventive care for empaneled patients. It is important to note that the examples provided in the description of the improvement activity are not all inclusive and do not preclude clinicians from providing other services to meet this improvement activity. We want this activity to be applicable to all MIPS eligible clinicians providing chronic care and preventative care management to empaneled patients, and since we cannot include all possible activities that could meet this improvement activity and one diabetes-related example is already included, we do not believe adding additional diabetes-related examples to the activity description assists in making the improvement activity applicable to a wide array of clinicians. Upon review of the evidence for DSME/S services and MNT, those examples will be added to the subregulatory guidance available on the Quality Payment Program website [111] for the improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PM_13**
Subcategory:	Population Management
Activity Title:	Chronic Care and Preventative Care Management for Empaneled Patients
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must manage chronic and preventive care for empaneled patients (that is, patients assigned to care teams for the purpose of population health management), which could include one or

[109] Diabetes Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/diabetes-recognition-program-drp.
[110] NCQA Heart/Stroke Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/heart-stroke-recognition-program-hsrp.
[111] Improvement Activity Data Validation Criteria at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html.

	more of the following actions: ● Provide patients annually with an opportunity for development and/or adjustment of an individualized plan of care as appropriate to age and health status, including health risk appraisal; gender, age and condition-specific preventive care services; and plan of care for chronic conditions; ● Use evidence based, condition-specific pathways for care of chronic conditions (for example, hypertension, diabetes, depression, asthma, and heart failure). These might include, but are not limited to, the NCQA Diabetes Recognition Program (DRP)[112] and the NCQA Heart/Stroke Recognition Program (HSRP).[113] ● Use pre-visit planning, that is, preparations for conversations or actions to propose with patient before an in-office visit to optimize preventive care and team management of patients with chronic conditions; ● Use panel support tools, (that is, registry functionality) or other technology that can use clinical data to identify trends or data points in patient records to identify services due; ● Use predictive analytical models to predict risk, onset and progression of chronic diseases; and/or ● Use reminders and outreach (for example, phone calls, emails, postcards, patient portals, and community health workers where available) to alert and educate patients about services due; and/or routine medication reconciliation.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_2**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in MOC Part IV
Current Activity Description:	Participation in Maintenance of Certification (MOC) Part IV, such as the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or American Society of Anesthesiologists (ASA) Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program. Performance of monthly activities across practice to regularly assess performance in practice, by reviewing outcomes addressing identified areas for improvement and evaluating the results.
Current Weighting:	Medium
Proposed Change and Rationale:	Added two examples of ways in which a MIPS eligible clinician can participate in Maintenance of Certification (MOC) Part IV: participation in "specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE);"[114] and "American Psychiatric Association (APA) Performance in Practice modules."[115] These additions to the activity provide specialist-specific examples of actions that can be taken to meet this activity. We have received stakeholder feedback through listening sessions and meetings with various stakeholder entities that additional specialty-specific activities would be welcome in the Inventory. Specifically, adding these examples of activities in psychiatry and obstetrics and gynecology, respectively, fill a gap in the

[112] Diabetes Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/diabetes-recognition-program-drp.
[113] NCQA Heart/Stroke Recognition Program information at http://www.ncqa.org/programs/recognition/clinicians/heart-stroke-recognition-program-hsrp.
[114] Safety Certification in Outpatient Practice Excellence for Women's Health resource at https://psnet.ahrq.gov/resources/resource/24964/acog-scope-safety-certification-in-outpatient-practice-excellence-for-womens-health.
[115] Certification and Licensure in Psychiatry, for ABMS Maintenance of Certification Part IV resource at https://www.psychiatry.org/psychiatrists/education/certification-and-licensure/moc-part-4.

	Inventory. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV.[116] MOC Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results. Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program,[117] National Cardiovascular Data Registry (NCDR) Clinical Quality Coach,[118] Quality Practice Initiative Certification Program,[119] American Board of Medical Specialties Practice Performance Improvement Module[120] or American Society of Anesthesiologists (ASA) Simulation Education Network,[121] for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE);[122] American Psychiatric Association (APA) Performance in Practice modules.[123]
Comments:	One commenter supported the proposed modifications to this improvement activity. Another commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. A few commenters supported the addition of the specialist examples for this improvement activity, and one commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities. An additional commenter requested the inclusion of a reference to specific practice activities related to comprehensive pediatric eye and vision examination clinical practice guidelines to meet this improvement activity.
Response:	The proposed modifications to this improvement activity provide additional examples of activities that can be completed to receive MOC Part IV credit. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. We appreciate the recommendation to include an additional example related to eye examinations, but we have included several examples and do not believe an additional example is needed in the activity description to describe the various ways clinicians can meet this improvement activity. We will add the American Board of Optometry's Performance in Practice activities, within which the comprehensive pediatric eye and vision examination clinical practice guidelines falls, to the subregulatory guidance available on the Quality Payment Program website [124] so

[116] American Board of Medical Specialties Maintenance of Certification Part IV resource at http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/.
[117] American Board of Internal Medicine Approved Quality Improvement Program resource at http://www.abim.org/reference-pages/approved-activities.aspx.
[118] American College of Cardiology National Cardiovascular Data Registry Clinical Quality Coach Practice Dashboard resource at https://cvquality.acc.org/NCDR-Home/clinical-quality-coach/marketing.
[119] American Society of Clinical Oncology Quality Oncology Practice Initiative Certification Program resource at https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program.
[120] American Board of Medical Specialties Multi-Specialty Portfolio Program resource at https://mocportfolioprogram.org/about-us/.
[121] American Society of Anesthesiologists Simulation Education Network resource at https://www.asahq.org/education/simulation-education.
[122] American College of Obstetricians and Gynecologists Safety Certification in Outpatient Practice Excellence for Women's Health resource at https://www.acog.org/About-ACOG/ACOG-Departments/VRQC-and-SCOPE/SCOPE-Program-Overview.
[123] American Psychiatric Association Learning Center resource at https://education.psychiatry.org/Users/ProductList.aspx?TypeID=8.
[124] Improvement Activities Data Validation Criteria at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Resources.html.

	clinicians attesting to this activity are aware these are allowable services to meet this improvement activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_2**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Participation in MOC Part IV
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV.[125] MOC Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results. Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program,[126] National Cardiovascular Data Registry (NCDR) Clinical Quality Coach,[127] Quality Practice Initiative Certification Program,[128] American Board of Medical Specialties Practice Performance Improvement Module[129] or American Society of Anesthesiologists (ASA) Simulation Education Network,[130] for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty-specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE);[131] American Psychiatric Association (APA) Performance in Practice modules.[132]
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_8**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use of Patient Safety Tools
Current Activity Description:	Use of tools that assist specialty practices in tracking specific measures that are meaningful to their practice, such as use of a surgical risk calculator, evidence based protocols such as Enhanced Recovery After Surgery (ERAS) protocols, the CDC Guide for Infection Prevention for Outpatient Settings, (https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html), predictive algorithms, or similar tools.
Current Weighting:	Medium
Proposed Change and	Addition of "opiate risk tool (ORT), or other similar tools" as an additional

[125] American Board of Medical Specialties Maintenance of Certification Part IV resource at http://www.abms.org/board-certification/steps-toward-initial-certification-and-moc/.
[126] American Board of Internal Medicine Approved Quality Improvement Program resource at http://www.abim.org/reference-pages/approved-activities.aspx.
[127] American College of Cardiology National Cardiovascular Data Registry Clinical Quality Coach Practice Dashboard resource at https://cvquality.acc.org/NCDR-Home/clinical-quality-coach/marketing.
[128] American Society of Clinical Oncology Quality Oncology Practice Initiative Certification Program resource at https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program.
[129] American Board of Medical Specialties Multi-Specialty Portfolio Program resource at https://mocportfolioprogram.org/about-us/.
[130] American Society of Anesthesiologists Simulation Education Network resource at https://www.asahq.org/education/simulation-education.
[131] American College of Obstetricians and Gynecologists Safety Certification in Outpatient Practice Excellence for Women's Health resource at https://www.acog.org/About-ACOG/ACOG-Departments/VRQC-and-SCOPE/SCOPE-Program-Overview.
[132] American Psychiatric Association Learning Center resource at https://education.psychiatry.org/Users/ProductList.aspx?TypeID=8.

Rationale:	example/category of an action that can be undertaken to meet the requirements of this activity. This addition highlights an evidence-based tool that can be deployed to assess opiate risk and addresses the CMS Meaningful Measures area of Prevention and Treatment of Opioid and Substance Use Disorders.[133] Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must use tools that assist specialty practices in tracking specific measures that are meaningful to their practice. Some examples of tools that could satisfy this activity are: a surgical risk calculator; evidence based protocols, such as Enhanced Recovery After Surgery (ERAS) protocols;[134] the Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings predictive algorithms;[135] and the opiate risk tool (ORT)[136] or similar tool.
Comments:	One commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. A couple of commenters provided support for the addition of the opiate risk tool or other similar tools as a way of addressing the opioid crisis. One commenter provided general concern that modifying an activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities.
Response:	The proposed modification to this improvement activity provides an additional tool as an example that can be undertaken to meet the requirements of this improvement activity. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_8**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Use of Patient Safety Tools
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must use tools that assist specialty practices in tracking specific measures that are meaningful to their practice. Some examples of tools that could satisfy this activity are: a surgical risk calculator; evidence based protocols, such as Enhanced Recovery After Surgery (ERAS) protocols;[137] the Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings predictive algorithms;[138] and the opiate risk tool (ORT)[139] or similar tool.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_17**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Implementation of analytic capabilities to manage total cost of care for practice population

[133] Centers for Medicare & Medicaid Services "Meaningful Measures Hub" resource at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html #MeasureAreasDefined.
[134] Enhanced Recovery After Surgery (ERAS) protocols at http://aserhq.org/protocols/.
[135] The Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings at https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html.
[136] The Opiate Risk Tool at https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf.
[137] Enhanced Recovery After Surgery (ERAS) protocols at http://aserhq.org/protocols/.
[138] The Centers for Disease Control (CDC) Guide for Infection Prevention for Outpatient Settings at https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html.
[139] The Opiate Risk Tool at https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf.

Current Activity Description:	Build the analytic capability required to manage total cost of care for the practice population that could include one or more of the following: ● Train appropriate staff on interpretation of cost and utilization information; and/or ● Use available data regularly to analyze opportunities to reduce cost through improved care.
Current Weighting:	Medium
Proposed Change and Rationale:	We added an example platform that uses available data to analyze opportunities to reduce cost through improved care: "An example of a platform with the necessary analytic capability is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform."[140] Based on stakeholder feedback, we proposed to add this example to clarify what type of a platform has the analytic capability to improve and manage total cost of care for the practice population described. Other language was revised for clarity.
Proposed Revised Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must conduct or build the capacity to conduct analytic activities to manage total cost of care for the practice population. Examples of these activities could include: ● Train appropriate staff on interpretation of cost and utilization information; ● Use available data regularly to analyze opportunities to reduce cost through improved care. An example of a platform with the necessary analytic capability to do this is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform.
Comments:	One commenter supported the modification of this improvement activity. Another commenter stated that the addition of specialty-specific examples in the modified improvement activities will provide clarity for specialty clinicians. One commenter provided general concern that modifying an improvement activity while it is still new makes it difficult for clinicians to become familiar with and implement improvement activities. One commenter suggested including Fracture Liaison Service (FLS) programs as an example of a model to manage fracture recovery and risk.
Response:	We appreciate the commenters' support and the additional suggested example to provide greater clarification for this improvement activity. The modifications to this activity provide an example to clarify the type of platform that has the analytic capability to improve and manage total cost of care for the practice population described. Therefore, we do not believe this modification makes it more difficult for clinicians to become familiar with and implement the activity. We do not believe the FLS program meets the requirements of this improvement activity, as we do not agree that it provides analytic capability to manage population cost of care.
Final Action:	After consideration of the public comments received, we are finalizing our changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_PSPA_17**
Subcategory:	Patient Safety and Practice Assessment
Activity Title:	Implementation of analytic capabilities to manage total cost of care for practice population
Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must conduct or build the capacity to conduct analytic activities to manage total cost of care for the practice population. Examples of these activities could include: ● Train appropriate staff on interpretation of cost and utilization information; ● Use available data regularly to analyze opportunities to reduce cost through improved care. An example of a platform with the necessary analytic capability to do this is the American Society for Gastrointestinal (GI) Endoscopy's GI Operations Benchmarking Platform.
Weighting:	Medium

[140] American Society for Gastrointestinal Endoscopy GI Operations Benchmarking at https://www.asge.org/home/practice-support/gi-operations-benchmarking.

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