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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; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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[CMS–1644–F]

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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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: Under the Medicare Shared Savings Program (Shared Savings Program), providers of services and suppliers that participate in an Accountable Care Organization (ACO) continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. This final rule addresses changes to the Shared Savings Program, including: Modifications to the program's benchmarking methodology, when resetting (rebasing) the ACO's benchmark for a second or subsequent agreement period, to encourage ACOs' continued investment in care coordination and quality improvement; an alternative participation option to encourage ACOs to enter performance-based risk arrangements earlier in their participation under the program; and policies for reopening of payment determinations to make corrections after financial calculations have been performed and ACO shared savings and shared losses for a performance year have been determined.

DATES: *Effective date:* The provisions of this final rule are effective on August 9, 2016.

Applicability dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) that lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

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SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of 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.

TABLE 1—APPLICABILITY DATES OF SELECT PROVISIONS OF THE FINAL RULE

Preamble section	Section title/description	Applicability date
II.A.2	Integrating regional factors in resetting ACO benchmarks	Second or subsequent agreement periods beginning in 2017 and subsequent years.
II.A.2.e.3	For factors based on National FFS expenditures used in establishing the ACO's historical benchmark: Use expenditures for assignable beneficiaries to determine trend factors and truncation thresholds.	Agreement periods beginning in 2017 and subsequent years. For 2014 starters electing the participation option to defer by 1 year entrance into a second agreement period under a two-sided model, 2015 starters, and 2016 starters/renewals, historical benchmarks will be adjusted for the 2017 performance year and any subsequent years in the current agreement period.
II.A.2.e.3	For factors based on National FFS expenditures used in benchmark calculations and performance year expenditure calculations during the agreement period: Use expenditures for assignable beneficiaries to determine the annual benchmark update, and the truncation thresholds for determining performance year expenditures.	Performance year 2017 and subsequent performance years.
II.C	An additional participation option that would allow eligible Track 1 ACOs to defer by 1 year their entrance into a performance-based risk model (Track 2 or 3) for their second agreement period.	Second agreement period beginning in 2017 and subsequent years.

Acronyms

ACO Accountable Care Organization
APM Alternative Payment Model
AWI Area Wage Index
BY Benchmark Year
CAHPS Consumer Assessment of Healthcare Providers and Systems
CBSA Core Based Statistical Area
CMS Centers for Medicare & Medicaid Services
CSA Combined Statistical Area
CY Calendar Year
DSH Disproportionate Share Hospital
ESRD End Stage Renal Disease
FFS Fee for service
GAO Government Accountability Office
GPCI Geographic Practice Cost Index
HCC Hierarchical Condition Category
IME Indirect Medical Education
MA Medicare Advantage
MACRA Medicare Access and CHIP Reauthorization Act of 2015
MedPAC Medicare Payment Advisory Commission
MIPS Merit-Based Incentive Payment System
MLR Minimum Loss Rate
MSA Metropolitan Statistical Area
MSR Minimum Savings Rate
NPI National Provider Identifier
OACT Office of the Actuary
PGP Physician Group Practice
PUF Public Use File
PY Performance Year
RHC Rural Health Clinic
RIA Regulatory Impact Analysis
TIN Taxpayer Identification Number

I. Executive Summary and Background

A. Executive Summary

1. Purpose

Section 1899 of the Social Security Act (the Act) established the Shared Savings Program, which promotes accountability for a patient population, fosters coordination of items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery. We published the proposed rule entitled ''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'' (2016 proposed rule), which appeared in the February 3, 2016 **Federal Register** (81 FR 5824). In the 2016 proposed rule, we proposed changes to the regulations for the Shared Savings Program that were promulgated in November 2011 and June 2015, and codified at 42 CFR part 425. Our intent in this rulemaking is to make refinements to the Shared Savings Program to address concerns raised by stakeholders regarding the benchmarking methodology, and to establish additional options for ACOs to enter performance-based risk arrangements, as well as to address policies for reopening of payment determinations to make corrections after financial calculations have been performed and ACO shared savings and shared losses for a performance year have been determined.

2. Summary of the Major Provisions

The policies adopted in this final rule are designed to improve program function and transparency in the following areas:

- Modifying the methodology for rebasing and updating ACO historical benchmarks when an ACO renews its participation agreement for a second or subsequent agreement period to incorporate regional expenditures, thereby making the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region.
- Applying a methodology for risk adjustment to account for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area in determining the regional adjustment that is applied to the ACO's rebased historical benchmark.
- Adding a participation agreement renewal option to encourage ACOs to enter performance-based risk arrangements earlier in their participation in the Shared Savings Program.
- Defining circumstances under which we would reopen payment determinations to make corrections after the financial calculations have been performed and ACO shared savings and shared losses for a performance year have been determined.

Although we proposed revisions to the methodology for adjusting ACO benchmarks to account for changes in ACO participant (TIN) composition, we will not finalize that proposal and are deferring any revisions to the methodology until future rulemaking. However, we are finalizing conforming changes to the current methodology for adjusting ACO benchmarks for ACO Participant List changes, to specify that the regional adjustment to the ACO's rebased historical benchmark will be redetermined annually using the most recent certified ACO Participant List for the relevant performance year.

3. Summary of Costs and Benefits

As a result of this final rule, the median estimate of the financial impact of the Shared Savings Program for CYs 2017 through 2019 is net federal savings of $110 million greater than what would have been saved if no changes were made. Although this is the best estimate of the financial impact of the Shared Savings Program during CYs 2017 through 2019, a relatively wide range of possible outcomes exists. While approximately two-thirds of the stochastic trials resulted in an increase in net program savings, the 10th and 90th percentiles of the estimated distribution show a net increase in costs of $240 million to net savings of $480 million, respectively.

Overall, our analysis projects that improvements in the accuracy of benchmark calculations, including through the introduction of a regional adjustment to the ACO's rebased historical benchmark, are expected to result in increased overall participation in the program. These changes are also expected to improve the incentive for ACOs to invest in effective care management efforts, increase the attractiveness of participation under performance-based risk in Track 2 or 3 for certain ACOs with lower beneficiary expenditures, and result in overall greater gains in savings on FFS benefit claims costs than the associated increase in expected shared savings payments to ACOs. We intend to monitor emerging results for effects on claims costs, changing participation (including risk for cost due to selective changes in participation), and unforeseen bias in benchmark adjustments due to diagnosis coding intensity shifts. Such monitoring will be used to inform future rulemaking, such as if the Secretary determines that a lower weight should be used in calculating the regional adjustment amount.

B. 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 Public Law 111–148. Collectively known as the Affordable Care Act, these public laws include a number of provisions designed to improve the quality of Medicare services, support innovation and the establishment of new payment models, better align Medicare payments with provider costs, strengthen Medicare program integrity, and put Medicare on a firmer financial footing.

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 a Shared Savings Program. This program is a key component of the Medicare delivery system reform initiatives included in the Affordable Care Act and is a new approach to the delivery of health care. The purpose of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and promote higher value care. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Consistent with the purpose of the Shared Savings Program, in establishing the program, we focused on developing policies aimed at achieving the three-part aim consisting of: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.

We published the final rule entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'' (November 2011 final rule), which appeared in the November 2, 2011 **Federal Register** (76 FR 67802) to establish the program. 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. We anticipated that subsequent rulemaking for the Shared Savings Program would be informed by lessons learned from our experience with the program as well as from testing through the Pioneer ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act.

Thereafter, we published a subsequent final rule entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'' (June 2015 final rule), which appeared in the June 9, 2015 **Federal Register** (80 FR 32692). In that rule, we adopted policies designed to codify existing guidance, reduce

administrative burden, and improve program function and transparency in a number of areas, such as eligibility for program participation and data sharing. Additionally, we modified policies related to the financial model, in response to stakeholder feedback, to encourage greater and continued ACO participation, for example, by offering ACOs the opportunity to continue participating under the one-sided model for a second agreement period, modifying the existing two-sided performance-based risk track (Track 2), and offering an alternative two-sided performance-based risk track (Track 3). Track 3 includes prospective beneficiary assignment and a higher sharing rate for shared savings as well as the potential for greater liability for shared losses, among other features, informed by CMS' experience with the Pioneer ACO Model. We finalized new policies for resetting an ACO's financial benchmark in a second or subsequent agreement period, by adding back a portion of the ACO's savings generated during the previous agreement period and equally weighting the historical benchmark years, to encourage ACOs to seek to continue their participation in the program and to address stakeholder concerns about the benchmark rebasing methodology. We also stated our intention to address other modifications to program rules in future rulemaking in the near term including modifying the methodology for resetting benchmarks by incorporating regional trends and costs.

We are encouraged by the high degree of interest in participation in the Shared Savings Program. As of January 1, 2016, over 400 ACOs were participating in the Shared Savings Program. This includes 147 ACOs with 2012 and 2013 agreement start dates that entered into a new 3-year agreement effective January 1, 2016, to continue their participation in the program, and 100 ACOs that entered the program for a first agreement period beginning January 1, 2016. See Fact Sheet: CMS Welcomes New Medicare Shared Savings Program (Shared Savings Program) Participants, (January 11, 2016) available online at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-01-11-2.html*.

We continue to look to experience gained by the Innovation Center in testing ACO models. In January 2016, we announced that 21 ACOs would be participating in the first performance year of the Next Generation ACO Model, a new ACO initiative being tested by the Innovation Center. The Next Generation ACO Model allows ACOs that are experienced in coordinating care for populations of patients to assume higher levels of financial risk and reward than are available under the Pioneer ACO Model and Shared Savings Program. See HHS press release: New hospitals and health care providers join successful, cutting-edge federal initiative that cuts costs and puts patients at the center of their care (January 11, 2016) available online at *http://www.hhs.gov/about/news/2016/01/11/new-hospitals-and-health-care-providers-join-successful-cutting-edge-federal-initiative.html*.

In the 2016 proposed rule (81 FR 5824), we proposed further modifications to the program's regulations, addressing several policy areas that we believed should be revisited in light of the additional experience we have gained during program implementation, including the methodology for resetting benchmarks, participation options to encourage ACOs to enter performance-based risk tracks, and reopening of payment determinations to make corrections.

II. Provisions of the Final Regulations and Responses to Public Comments

We received a total of 74 timely comments on the 2016 proposed rule (81 FR 5824). Stakeholders offered comments that addressed both high level issues related to the Shared Savings Program as well as our specific proposals and requests for comments. We extend our deep appreciation to the public for their interest in the program and the many thoughtful comments that were made in response to our proposed policies. In some instances, the public comments offered were outside the scope of the proposed rule, for example: Suggested revisions to the Shared Savings Program quality performance standard; suggestions for implementing the Skilled Nursing Facility (SNF) 3-day rule waiver for eligible Shared Savings Program ACOs; requests to modify the approach used to account for the costs of Critical Access Hospitals participating in Shared Savings Program ACOs; suggestions for limiting the liability of individual providers for shared losses incurred by ACOs; suggestions for modifying the financial incentives within the Shared Savings Program to encourage ACOs to use innovative treatments, technologies and diagnostics; suggestions for CMS to provide greater support for beneficiary engagement in their health care; and suggestions for the development of regulations pursuant to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). These comments will not be addressed in this final rule, but we have shared them with the appropriate subject matter experts in CMS. Summaries of the public comments that are within the scope of this rule and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In this introduction to section II of this final rule, we address several global comments related to the Shared Savings Program. The remainder of this section of the final rule is organized to give an overview of each issue and the relevant proposals, to summarize and respond to public comments on the proposals, and to describe our final policy decisions based upon our review of the public comments received.

Comment: Some commenters are encouraged by the momentum of the program in attracting organizations and advancing our goal of transitioning providers away from traditional FFS to arrangements focused on value-based payments. However, some pointed to the statistics on the number of ACOs eligible for shared savings payments in the initial performance years of the Shared Savings Program and the attrition rate from the program as evidence of the need for changes to the program including: (1) Policy changes to provide greater rewards to ACOs for their cost reductions and quality improvements for Medicare beneficiaries; (2) policy options to reward organizations of differing provider compositions, sophistication and cost history; and (3) additional resources from CMS, such as more timely and actionable data, to support their success. Commenters addressing the sustainability of the program over the longer term often pointed to the intersections of various policy factors as being influential, most commonly the need for a benchmarking methodology that allows ACOs to continue to generate sufficient returns over time to support their care coordination and quality improvement activities to meet the program's goals, and the need for policies to reduce beneficiary churn in an ACO's assigned beneficiary population (for example, through prospective beneficiary assignment in all program Tracks and implementation of an attestation process for beneficiaries to voluntarily align to an ACO). Some commenters underscored the challenges for ACOs in moving FFS providers towards payment models based on value instead of volume and for already efficient organizations to realize further reward within the Shared Savings Program.

In general, some commenters pointed to the need for sufficient stability and predictability in the program to

effectively drive ACOs to enter performance-based risk models. Some commenters, including commenters representing rural providers, suggested CMS consider allowing ACOs to remain under a one-sided model for a long period, and perhaps even indefinitely, particularly ACOs that continue to generate savings.

Response: We thank all commenters for helping us continue to develop the Shared Savings Program. We appreciate commenters' support for the program generally, as well as their thoughtful remarks on overarching considerations for the future of the Shared Savings Program.

The ACOs participating in the Shared Savings Program are recognized as being a critical part of the Administration's goal to help drive Medicare and the health care system at large towards rewarding the quality of care as opposed to the quantity of care provided to beneficiaries. In January 2015, the Administration announced an ambitious goal of tying 30 percent of Medicare FFS payments to quality and value by 2016 and by 2018 making 50 percent of payments through alternative payment models, such as the Shared Savings Program (*https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html*). In March 2016, the Administration announced that it estimated having achieved this first goal, 11 months ahead of schedule, in part a result of entry by new ACOs in CMS ACO initiatives including the Shared Savings Program (*https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-03-2.html*).

With these goals in mind, we believe this final rule will further strengthen the Shared Savings Program. In particular we believe it is critical to ensuring the sustainability of the program to make an ACO's benchmark incrementally less dependent on the ACO's historical spending and more reflective of spending in the ACO's region as the ACO continues in the program for multiple agreement periods. We also believe that the benchmarking methodology is only one of several factors that are important to ACOs' success in the Shared Savings Program. For example, we believe refinements to the Shared Savings Program's data sharing policies, finalized in the June 2015 final rule, including a streamlined process for ACOs to access Medicare beneficiary claims data and expanding the data that is made available through informational program reports, will facilitate ACOs' health care operations. Further, we believe that ACOs are more likely to become successful in achieving the goals of the accountable care model over time, as indicated by performance results showing that ACOs with more experience in the program are more likely to generate shared savings (CMS Fact Sheet: Medicare ACOs Provide Improved Care While Slowing Cost Growth in 2014, available online at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-25.html*).

We also recognize the needs of the Shared Savings Program are dynamic and will continue to change as CMS and ACOs gain more experience with the accountable care model being implemented on a national scale. We welcome and encourage stakeholders' engagement with CMS on future program improvements and policy considerations, including through the rulemaking process.

Comment: Some commenters requested that CMS address broader market dynamics, particularly in relation to aligning financial and quality targets between the Shared Savings Program and Medicare Advantage (MA). Several commenters pointed to this alignment as allowing for more equitable comparison between traditional FFS Medicare, MA and ACOs. Some pointed to the need for this alignment when indicating that Shared Savings Program ACOs and MA plans compete. A commenter explained that competition between traditional FFS Medicare, ACOs and MA plans would maximize value for Medicare beneficiaries and the Medicare program.

Response: We appreciate commenters' continued interest in developing the design of the Shared Savings Program to foster greater comparability between Medicare payment models. As explained in the June 2015 final rule, we continue to believe there are important distinctions between MA plans and the accountable care model in the Shared Savings Program. The Shared Savings Program is not a managed care program like MA. Under the Shared Savings Program, providers and suppliers receive traditional FFS Medicare payments, and Medicare FFS beneficiaries retain all rights and benefits under traditional Medicare, including the right to see any physician of their choosing. In addition, Medicare FFS beneficiaries do not enroll in the Shared Savings Program (see 80 FR 32696). However, in the 2016 proposed rule we acknowledged that one consideration in developing the proposed methodology for use of county-FFS data in calculating expenditures for an ACO's regional service area was to align more closely with the MA ratesetting methodology (see 81 FR 5829). Although we have relied on our experience in other Medicare programs, including MA, to help develop program requirements and design elements for the Shared Savings Program, many Shared Savings Program requirements deviate from those in the other programs precisely because the intent of this program is not to recreate or replace MA or other Medicare programs (see 80 FR 32697).

As discussed elsewhere in this final rule, we are finalizing, with certain modifications, our proposal to determine an ACO's regional FFS expenditures based on the county FFS expenditures for the ACO's regional service area for populations of beneficiaries according to Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). Although this approach differs from the MA rate-setting methodology (with respect to calculation of values for the ESRD population, and the number of years of data used in the calculating county FFS expenditures), we believe it continues to be a substantial step towards aligning the Shared Savings Program benchmarking methodology with the MA rate-setting methodology.

A. Modifications to the Benchmarking Methodology

1. Background on Establishing, Updating, and Resetting the Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Such benchmark shall be reset at the start of each agreement period. In addition to the statutory benchmarking methodology established in section 1899(d) of the Act, section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking methodologies, if the Secretary

determines that doing so would improve the quality and efficiency of items and services furnished under this title and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

In the November 2011 final rule establishing the Shared Savings Program, we adopted policies for establishing, updating and resetting the benchmark at § 425.602. Under this methodology, we use national FFS spending and trends as part of establishing, updating and resetting ACO-specific benchmarks. Specifically, we calculate a benchmark for each ACO using a risk-adjusted average of per capita Parts A and B expenditures for original Medicare FFS beneficiaries who would have been assigned to the ACO in each of the 3 calendar years prior to the start of the agreement period. In calculating an ACO's benchmark expenditures, we include individually beneficiary identifiable payments made under a demonstration, pilot or time limited program, and we make an adjustment to exclude IME payments and DSH and uncompensated care payments. We trend forward each of the first 2 benchmark years' per capita risk adjusted expenditures to third benchmark year (BY3) dollars based on the national average growth rate in Parts A and B per capita FFS expenditures verified by the CMS Office of the Actuary (OACT). In establishing the benchmark for an ACO's first agreement period, the first benchmark year is weighted 10 percent, the second benchmark year is weighted 30 percent, and the third benchmark year is weighted 60 percent. This weighting creates a benchmark that more accurately reflects the latest expenditures and health status of the ACO's assigned beneficiary population.

For each performance year, we adjust the ACO's historical benchmark for changes in the health status and demographic factors of the ACO's assigned beneficiaries (§ 425.604(a), § 425.606(a), § 425.610(a)). Consistent with section 1899(d)(1)(B)(ii) of the Act, we update the ACO's benchmark annually, based on our estimate of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program. Additionally, as described further in section II.B of this final rule, we also adjust ACO historical benchmarks annually based on changes to the ACO's certified ACO Participant List. In making this adjustment, the historical benchmark period remains constant, but beneficiary assignment is revised to reflect the influence of the ACO Participant List changes.

In trending forward the historical benchmark, adjusting for changes in beneficiary characteristics, and annually updating the benchmark by growth in national per capita Medicare FFS expenditures, we make calculations for populations of beneficiaries in each of the following Medicare enrollment types: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. Furthermore, to minimize variation from catastrophically large claims, we truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at a threshold of the 99th percentile of national Medicare FFS expenditures for the applicable Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

Under section 1899(d)(1)(B)(ii) of the Act and § 425.602(c) of the Shared Savings Program regulations, an ACO's benchmark must be reset at the start of each new agreement period. In the June 2015 final rule, we revised § 425.602(c) to specify that in resetting the historical benchmark for ACOs in their second or subsequent agreement period we: (1) Weight each benchmark year equally; and (2) make an adjustment to reflect the average per capita amount of savings earned by the ACO in its prior agreement period, reflecting the ACO's financial and quality performance, during that prior agreement period. The additional per capita amount is applied as an adjustment to the ACO's rebased historical benchmark for a number of assigned beneficiaries (expressed as person years) not to exceed the average number of assigned beneficiaries (expressed as person years) under the ACO's prior agreement period. If an ACO was not determined to have generated net savings in its prior agreement period, we do not make any adjustment to the ACO's rebased historical benchmark. We use performance data from each of the ACO's performance years under its prior agreement period in resetting the ACO's benchmark for its second or subsequent agreement period. In the June 2015 final rule, in which this adjustment was finalized, we stated that we believed it would be critical to revisit the policy of accounting for an ACO's savings generated in a prior agreement period when resetting its benchmark in conjunction with any future changes to the benchmarking methodology to incorporate regional FFS expenditures (see 80 FR 32791; see also 80 FR 32795 through 32796).

The June 2015 final rule also included a discussion of several options and methods for incorporating regional factors when establishing, updating, and resetting the benchmark, and CMS committed to engaging in additional rulemaking around modifications to the Shared Savings Program's methodology for resetting benchmarks (see 80 FR 32791 through 32796; see also 79 FR 72839 through 72843 (discussing options for revising the methodology for resetting an ACO's historical benchmark)). The 2016 proposed rule expanded upon the issues discussed in the June 2015 final rule. The proposed changes (reviewed in greater detail within this final rule) focused on incorporating regional FFS expenditures into the methodology for establishing, adjusting, and updating an ACO's historical benchmark for its second or subsequent agreement period.

2. Integrating Regional Factors When Resetting ACOs' Benchmarks

a. Overview

In the June 2015 final rule, we summarized comments received on three approaches to account for regional FFS expenditures in ACO benchmarks and technical issues related to these alternatives (80 FR 32791 through 32796). We committed to engaging in additional rulemaking to propose modifications to the Shared Savings Program's methodology for resetting ACO benchmarks. We signaled our anticipated policy direction by outlining an approach to rebasing that would account for regional expenditures and identified additional methodological issues we would need to address in implementing this approach (80 FR 32795 through 32796).

In the 2016 proposed rule, we acknowledged that any proposed changes to the benchmark rebasing policies would require consideration of tradeoffs among several criteria that were initially described in the June 2015 final rule (81 FR 5828):

- Strong incentives for ACOs to improve efficiency and to continue participation in the program over the long term.
- Benchmarks which are sufficiently high to encourage ACOs to continue to meet the three-part aim, while also safeguarding the Medicare Trust Funds against the possibility that ACOs' reset benchmarks become overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings.
- Generating benchmarks that reflect ACOs' actual costs in order to avoid potential selective participation by (and excessive shared payments to) ACOs with high benchmarks.

Further, we explained the addition of the following guiding principles to our considerations for modifying the benchmarking methodology (81 FR 5828):

- Transparency: Developed based on identifiable sources of data, and where possible publicly available data and data sets, in order to allow stakeholders to understand and model impacts.
- Predictability: Enable ACOs to anticipate their updated benchmark targets and their likely performance under the program.
- Simplicity: Methodology can be explained in relatively simple terms and in sufficient detail to be readily understood by ACOs and stakeholders.
- Accuracy: Methodology generates benchmarks that are an accurate reflection of the ACOs' expenditures and relevant regional expenditures, and can be accurately implemented and calculated, validated and disseminated in a timely manner.
- Maintain program momentum and market stability by providing sufficient notice of methodological changes and phase-in of these changes.

Applying these principles, we proposed the following changes, to the methodology for resetting an ACO's benchmark for a second or subsequent agreement period beginning on or after January 1, 2017:

- Replace the national trend factors with regional trend factors for establishing the ACO's rebased historical benchmark, and remove the adjustment to explicitly account for savings generated under the ACO's prior agreement period.
- Make an adjustment when establishing the ACO's rebased historical benchmark, to reflect a percentage of the difference between regional FFS expenditures in the ACO's regional service area and the ACO's historical expenditures. A higher percentage would be used in calculating this adjustment to the ACO's rebased historical benchmark for the ACO's third agreement period and all subsequent agreement periods. We further proposed to apply this phased approach to transitioning to the use of a higher weight in the calculation of the regional adjustment for ACOs with 2012 and 2013 agreement start dates that elected to continue their participation in the program for a second 3-year agreement period effective January 1, 2016, beginning in their third agreement period (starting in 2019).
- Annually, update the rebased benchmark to account for changes in regional FFS spending, replacing the current update, which is based solely on the absolute amount of projected growth in national FFS spending.

We proposed to define an ACO's regional service area to include any county where one or more assigned beneficiaries reside and to weight county-level FFS costs by the proportion of the ACO's assigned beneficiaries in the county. We proposed to calculate risk adjusted county FFS expenditures for the ACO's regional service area using the assignable beneficiary population, as a subset of the broader FFS population, residing in counties included in the ACO's regional service area. We proposed to align the calculation of regional FFS expenditures with the approach to calculating an ACO's benchmark and performance year expenditures. We also proposed a program-wide policy, to use beneficiaries eligible for ACO assignment instead of all FFS beneficiaries as the basis for program calculations using regional and national FFS expenditures. As part of the process of incorporating the revised rebasing methodology, we also proposed a number of technical changes to the program regulations to clarify the regulations text on the benchmarking methodology.

In the 2016 proposed rule we explained that the proposed approach to incorporating regional expenditures would make the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region (81 FR 5825). We also explained that adding the regional adjustment and replacing the current benchmark trend factor and annual update (calculated based on National FFS expenditures) with regional growth rates, would have mixed effects on ACOs overall by increasing or decreasing benchmarks for ACOs in various circumstances. For example, we explained that the proposed regional adjustment would likely benefit existing low spending ACOs operating in regions with relatively higher spending and/or higher growth in expenditures (81 FR 5834). We further explained that a phased-approach to transitioning to use of a higher weight in the calculation of the regional adjustment balanced our preference for quickly transitioning ACOs to a rebasing methodology that is more reflective of expenditures in the ACO's region than the ACO's historical expenditures with our concerns about the opportunity for arbitrage, and the potential for ACOs to alter their healthcare provider and beneficiary compositions or take other such actions in order to achieve more favorable performance relative to their region without actually changing their efficiency (81 FR 5834 through 5836). We also explained that the use of regional trend factors in resetting ACO benchmarks and regional growth rates to update benchmarks annually would likely result in relatively higher benchmarks for ACOs that are low growth in their region compared to benchmarks for ACOs that are high growth relative to their region (81 FR 5838 through 5840).

We anticipated these changes would strengthen the incentives for ACOs to invest in infrastructure and care redesign necessary to improve quality and efficiency and meet the goals of the Shared Savings Program (81 FR 5859). However, we expressed uncertainty about the effect on the level of ACO participation, provider and supplier response to the financial incentives under the program, interactions with other value-based payment models and programs, and the ultimate effectiveness of the changes in care delivery (81 FR 5860).

In section II.A.2 of this final rule, we discuss our final actions on the proposals for modifying the Shared Savings Program benchmarking methodology. Table 2 summarizes the final actions discussed in this section of the final rule. We begin this discussion by addressing comments on broader considerations for revising the benchmarking methodology.

Comment: Most commenters addressed the proposed changes to the benchmarking methodology, with the majority expressing support, in general, for incorporating regional FFS expenditures into ACOs' benchmarks. Many commenters offered specific suggestions on the proposed policies.

Some commenters detailed concerns, more generally, about the sustainability of the current rebasing methodology. A principal concern raised by commenters is that the current rebasing methodology forces ACOs to continually beat their own performance, by using historical expenditures from the performance years under an ACO's prior agreement period to reset the benchmark. Commenters raised a variety of concerns about the effects of this approach, including: ACOs that have performed well in the past are penalized under this methodology, while those who have performed poorly are rewarded; ACOs with lower spending have relatively lower benchmarks (and less opportunity for reward) compared to those with higher historical spending, including ACOs operating in different markets (with differing spending trends) as well as ACOs operating within the same market; over time there will be

diminishing opportunities to produce savings, that are used in part to support ACO operations (including investments that result in the provision of high value care), and ACOs will ultimately be forced to leave the program or participation in the program will be discouraged more generally. Many commenters explained that making an ACO's benchmark more independent of its historical expenditures and performance and more reflective of FFS spending and the healthcare environment in the ACO's region would be an improvement over the current approach.

Several commenters recognized that incorporating regional factors when resetting ACO benchmarks accounts for geographic variation in healthcare utilization. While some commenters considered this a necessary methodological development to ensure the sustainability of the Shared Savings Program, a commenter specified that this would be antithetical to CMS' larger goal of decreasing variability in per beneficiary spending on a nationwide scale. A commenter suggested CMS delay finalizing the proposed changes in light of CMS' concerns (including the potential for arbitrage or behavioral changes by ACOs) and the uncertainties about the impact of the alternative rebasing methodology, and further suggested CMS revisit the proposed changes in future rulemaking, after further analysis and once the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) requirements are proposed. However, even among those commenters that raised concerns about the details of the proposed policies, very few suggested that CMS abandon altogether an approach for incorporating regional FFS expenditures into ACO benchmarks.

The discussion in the comments also reflects commenters' consideration of the tradeoffs CMS identified in the proposed rule related to providing sufficiently strong incentives for ACOs to improve efficiency and continue participation in the program, while guarding the Trust Funds against the possibility that over inflating certain ACOs' reset benchmarks would result in selective participation by and excessive payments to ACOs with high benchmarks. Commenters illuminated that the balance of these concerns is complicated due to the diversity of the program's participants and regional variations/market circumstances.

Many commenters recognized that the benchmarking methodology, including any changes adopted in this final rule, will be crucial for determining the profile/characteristics of organizations that will have an incentive to enter and remain in the program over time. Comments discussed the effects of the proposed changes to the benchmarking methodology, including the following:

- Many commenters generally agreed that the proposed changes would encourage participation by ACOs that are historically efficient (low spending) in relation to their region, especially in high spending regions. Many commenters expressed support for the proposed policies to encourage participation by efficient ACOs. However, some commenters believe the resulting incentives would still be inadequate to encourage these ACOs to enter or remain in the program over the long term, citing concerns about diminishing returns when a component of the ACO's rebased historical benchmark continues to be based on expenditures under the ACO's prior agreement period and thereby reflects the ACO's past success.
- Some commenters expressed concern there may be little incentive for ACOs with spending equal to or higher than their region to enter the Shared Savings Program or continue participating under the proposals.
- Several commenters expressed concerns that the proposed changes could disadvantage certain ACOs, especially those in ACO-heavy markets and ACOs in existing low cost regions, as well as smaller ACOs comprised of geographically distant small- and mid-sized providers.
- Others expressed concern about the potential that the proposed changes would have unanticipated effects on particular organizations, pointing to the discussion in the proposed rule that ''a wide range of potential outcomes'' exist regarding financial performance under the proposed changes. Some commenters expressed uncertainty about the potential effects of the proposed changes and indicated that they lacked sufficient information to determine what outcomes they may have.

Some commenters addressed these concerns by suggesting CMS offer various benchmarking options to allow ACOs greater flexibility in determining the methodology that would be applied to determine their benchmark. Some commenters also suggested CMS stratify the regional benchmarking methodologies for historically low and high cost ACOs (in relation to their regions).

Response: We appreciate commenters' thoughtful remarks on the proposed changes to the benchmarking methodology, including the tradeoffs that we identified as relevant to the consideration of any revisions to the methodology for resetting an ACO's historical benchmark for a second or subsequent agreement period. The discussion in the latter sections of this final rule reflect our continued consideration of these important issues during the development of the policies in this final rule, and we believe the policies we are finalizing represent a balance of these considerations. We also believe the policies we are finalizing are responsive to a principal concern among stakeholders, as reflected in the comments, about the way in which ACOs' past performance is reflected in their benchmarks over time.

As explained in the 2016 proposed rule, the policy modifications are designed to reduce the impact of past performance and better reflect regional expenditures. We continue to believe an approach that incorporates regional FFS expenditures into an ACO's rebased historical benchmark will have mixed effects, increasing or decreasing benchmarks for ACOs in various circumstances. However, we believe that taking an incremental approach to incorporating regional elements when resetting the ACO's benchmark offers a balance between requests for faster or slower phase-in of these changes, and is responsive to the circumstances of differently situated organizations as we transition to this revised approach. When taking these issues into consideration, on the whole, we believe that this approach is consistent with a sustainable vision for the future of the Shared Savings Program, under which a variety of organizations will have sufficient incentive to enter and continue in the program, working to achieve the program's goals of better care for individuals, better health for populations, and lower growth in expenditures.

While we acknowledge the variation across ACOs participating in the program, in terms of their patient populations, location, and organizational structure, among other factors, we do not believe it is desirable or operationally feasible to implement an approach that would allow each ACO to select from a menu of options for customizing the benchmark methodology that would apply in any given performance year or agreement period. Doing so would introduce considerable operational complexity into the program's benchmarking methodology. Further an approach that allows an ACO to choose the more favorable of several methodologies for establishing its cost target would exacerbate our concerns about the potential for benchmarks to become

overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings. We are concerned that this flexibility could lead to opportunities for arbitrage and may dull incentives for ACOs to improve their performance under the Shared Savings Program.

Comment: Several commenters also, generally, agreed with the importance of transparency, predictability, simplicity, accuracy, and stability as guiding principles in developing a revised rebasing methodology, and provided feedback on how to accomplish these aims.

Response: We appreciate commenters' acknowledgement and support of the principles that guided our consideration of potential revisions to the methodology for resetting an ACO's historical benchmark for a second or subsequent agreement period. These principles also guided the development of our final policies, as reflected in the discussion throughout this section of this final rule.

Comment: A few commenters suggested alternative rebasing methodologies exceeding the scope of the modifications described in the proposed rule (for instance, allowing ACOs, particularly small and rural ACOs, to choose whether to move to the revised rebasing methodology; transitioning to pure regional benchmarks, or pure national benchmarks, or using a combination of ACO historical costs and blended regional/national costs in benchmarks; adopting the Next Generation ACO model methodology into the Shared Savings Program; and eliminating rebasing or reducing the frequency of rebasing). A commenter questioned whether CMS could establish a benchmark floor, an actuarial number beyond which CMS would not lower an ACO's benchmark. Another commenter suggested CMS adopt an option to allow Shared Savings Program ACOs to transition to a different payment model altogether such as a capitated payment model or population-based payments.

Response: Although we appreciate commenters' thoughtful recommendations for alternative methodologies for resetting the ACO's historical benchmark, and other approaches for improving the rewards under the Shared Savings Program, we consider these suggestions to be beyond the scope of this final rule, and decline at this time to adopt commenters' recommendations.

Comment: A commenter expressed concern about CMS' use of inconsistent terminology when describing the benchmarking methodology. In particular, the commenter noted that CMS used the words ''reset'' or ''rebase'' interchangeably. The commenter also noted a lack of clarity regarding the use of ''trend'' or ''trending.'' This commenter, pointing to the length of the program's rulemaking documents and the complexity of the policies discussed therein, encouraged CMS to be precise in its language.

Response: We thank the commenter for raising this concern about the language used in technical discussions within rulemaking for the Shared Savings Program. To clarify, we consider the references to reset/resetting and rebase/rebasing an ACO's historical benchmark to be synonymous (see for example, 76 FR 67912 (specifying ''. . . the benchmark would be reset (or rebased) [at] the start of each agreement period.'')) However, the use of the words trend and trending could have a meaning specific to the context in which the term is used. For example, we refer to the use of trend factors (or trending) when discussing the existing policy for restating BY1 and BY2 expenditures in terms of BY3 expenditures when establishing an ACO's historical benchmark. However, ''trends'' may refer more generally to historical Medicare spending and cost experience.

b. Regional Definition

As explained in the 2016 proposed rule (see 81 FR 5829 through 5830), we consider an ACO's region to be synonymous with the service area from which it derives its assigned beneficiaries. Furthermore, as discussed in this section of this final rule, issues related to the definition of an ACO's regional service area include: (1) The selection of the geographic unit of measure to define this area; and (2) identification of the population of beneficiaries to include in this area. Calculation of the FFS expenditures for this area is discussed in detail in sections II.A.2.b.2 and II.A.2.e.2 of this final rule.

A fundamental concept underlying our consideration of the definition of an ACO's regional service area is that this geographic definition bear a relationship to the area of residence of the ACO's assigned beneficiaries, as a means of accounting for the geographic spread of the ACO's assigned population. In some cases, an ACO's assigned beneficiary population may span multiple geographic boundaries, for example in cases where an ACO provides services to beneficiaries residing in multiple counties within a single state or multiple states. The approach of defining an ACO's regional service area based on the area of residence of its assigned beneficiaries would therefore reflect regionally-related factors unique to the region the ACO serves, including the health status of the region's population, the geographic composition of the region (such as rural versus urban areas), and socio-economic differences within the regional population.

(1) Defining the ACO's Regional Service Area

In the 2016 proposed rule, we considered the geographic unit of measure to use in defining an ACO's regional service area for the purpose of determining the corresponding regional FFS expenditures to be used in calculations based on regional spending in the modified approach to establishing, adjusting and updating the ACO's rebased historical benchmark (see 81 FR 5829). We explained that these regional FFS expenditures would be used in determining the regional adjustment to an ACO's rebased historical benchmark and in calculating the growth rates in regional spending used in establishing and updating the ACO's rebased historical benchmark.

We proposed to determine an ACO's regional service area by the counties of residence of the ACO's assigned beneficiary population. We explained our belief that county-level data offers a number of advantages over the other options, including Core Based Statistical Areas (CBSAs), Metropolitan Statistical Area (MSAs), Combined Statistical Area (CSAs), States/territories, and Hospital Referral Regions (HRR). Our considerations included the following:

- Counties tend to be stable regional units compared to some alternatives, as the definition of county borders tends not to change.
- The agency has experience with identifying populations of beneficiaries by county of residence and calculating county-level rates based on their costs, including using county-level data to set cost targets for value based purchasing initiatives. CMS used counties to define the service areas of Physician Group Practice (PGP) demonstration sites (a predecessor of CMS' ACO initiatives) and used Parts A and B spending by county as part of setting benchmarks for these organizations. We also use county-level FFS expenditure data, in combination with other adjustments, to establish the benchmarks used for setting local MA rates.
- In terms of determining regional costs, smaller areas (such as counties) better capture regional variation in Medicare expenditures, and allow for more customized regional definitions for each ACO, but risk being dominated

by expenditures from a single ACO or group of ACOs, which could potentially reduce ACO benchmarks in clustered markets. We explained that we can guard against the potential bias from this effect by using a sufficiently large county-based population.

- Currently, we produce quarterly and annual reports for Shared Savings Program ACOs that include aggregate data on distribution of assigned beneficiary residence by county.

Consistent with this proposed definition of regional service area, we proposed to define regional costs as county FFS expenditures for the counties in which the ACO's assigned beneficiaries reside calculated using the methodology discussed in section II.A.2.e.2 of this final rule. We explained that use of county-level FFS data in calculating expenditures for an ACO's regional service area would permit ACOs to be viewed as being on the spectrum between traditional FFS Medicare and MA, a concept some commenters in response to the December 2014 proposed rule and stakeholders have urged CMS to articulate. Additionally, we noted that use of county FFS expenditure data, which are publicly available, would allow for increased transparency in ACO benchmark calculations and would ease ACOs' and stakeholders' access to data for use in modeling and predictive analyses.

These proposals were reflected in our proposed addition of a new definition of ''ACO's regional service area'' to § 425.20 and in a proposed new § 425.603 describing the calculations that would be used in resetting an ACO's historical benchmark for a second or subsequent agreement period. We sought comment on these proposals and on the alternatives for defining an ACO's regional service area, specifically use of CBSA, MSA, CSA or State/territory designations.

Comment: Many of the commenters addressing the regional definition favored the proposed use of counties of residence of an ACO's assigned beneficiaries as the geographic unit of measure in defining an ACO's regional service area. Commenters explaining their support for the proposal cited a variety of reasons, including: Counties provide a stable, clearly defined geographic unit; counties will be effective in capturing regional variation, and allow for greater customization of the ACO's regional definition; and use of county-level data will further align ACOs with MA and other CMS initiatives. Of the few comments on alternatives discussed in the proposed rule (CBSAs, MSAs, CSAs, HRRs, states/territories), opinions tended to split for and against these approaches. A commenter pointed to the need for CMS to more consistently use the same geographic unit of measure for defining a region across its initiatives, preferring use of MSAs, which are also used by CMS in other payment systems and models. Several commenters raised alternatives not considered in the proposed rule. For instance, a commenter suggested CMS consider using a more sophisticated and granular methodology such as Primary Care Service Areas (PCSAs), pointing to consideration for use of this geographic unit in the Part B Drug Payment Model. Another commenter advised against using census regions.

Response: We are finalizing our proposal to define an ACO's regional service area by the counties of residence of the ACO's assigned beneficiary population. We continue to believe that using counties as the geographic unit of measure offers advantages over other approaches, as supported by some commenters. Counties tend to be stable geographic units. Use of counties in setting the ACO's regional service area more easily allows for the use of county FFS expenditures in calculating regional factors, an approach that will more closely align the Shared Savings Program methodology for incorporating regional FFS expenditures into ACO benchmarks with the MA rate-setting methodology. We have experience with use of county level data not only through MA but also previously with the PGP demonstration. In addition, we currently provide informational reports to Shared Savings Program ACOs that include aggregate data on distribution of assigned beneficiary residence by county. Given the short timeframe for implementing the changes in the benchmarking methodology described in this final rule, we believe this operational experience with use of county-level data within the Shared Savings Program will facilitate implementation of the revised methodology. We also believe that by using counties, rather than larger geographic units, we can more accurately reflect the geographic areas that the ACO serves. We decline at this time to use a different methodology to establish an ACO's regional service area, particularly alternatives that were not contemplated in the 2016 proposed rule, which may prove challenging to implement within a short period of time for the Shared Savings Program and without notice to ACOs and other stakeholders. We also recognize that CMS uses different geographic units of measure across payment models, but continue to believe that use of counties, similar to the approach used in Medicare Advantage, is an appropriate methodology for the Shared Savings Program.

FINAL ACTION: We are finalizing our proposal to determine an ACO's regional service area by the counties of residence of the ACO's assigned beneficiary population. Furthermore, we are finalizing our proposal to define regional costs as county FFS expenditures for the counties in which the ACO's assigned beneficiaries reside calculated using the methodology discussed in greater detail in section II.A.2.e of this final rule. These final policies are reflected in the addition of a new definition of ''ACO's regional service area'' to § 425.20 and new § 425.603 describing the calculations that will be used in resetting an ACO's historical benchmark for a second or subsequent agreement period.

(2) Establishing the Beneficiary Population Used To Determine Expenditures for an ACO's Regional Service Area

In the 2016 proposed rule we explained that the population that is the basis for calculating regional FFS costs must be sufficiently large to produce statistically stable mean expenditure estimates (avoiding biases that result from small numbers), and must be representative of the demographic mix, health status and cost trends of the beneficiary population within the ACO's regional service area. Therefore, as discussed in section II.A.2.b.1 of this final rule, we proposed to define the ACO's regional service area to include any county where one or more of the ACO's assigned beneficiaries reside.

We also proposed to calculate county FFS expenditures using the expenditures for all assignable FFS beneficiaries (a subset of the broader FFS population) residing within the county, including ACO assigned beneficiaries. We stated that we believed that this approach would result in the most accurate and predictable regional expenditure factor for each ACO (81 FR 5831).

We detailed in a different section of the 2016 proposed rule proposals related to the definition of assignable FFS beneficiaries (81 FR 5843). (See also the discussion in section II.A.2.e of this final rule.) In discussing which expenditures should be included in these calculations, we explained that the overall FFS population includes beneficiaries who are not eligible for assignment to an ACO. Including expenditures for all FFS beneficiaries

would introduce bias into the calculation of the ACO's regional service area expenditures.

We also considered whether to include the ACO's assigned beneficiaries within the population used to determine expenditures for the ACO's regional service area. We concluded that attempting to identify regional FFS expenditures for only non-ACO beneficiaries (or customizing the calculation of regional FFS expenditures for each ACO by excluding its own beneficiaries) would add significant complexity and create potential bias. Furthermore, excluding the ACO's assigned beneficiaries from the population used to determine regional FFS expenditures may also produce biased results where an ACO tends to serve beneficiaries of a particular Medicare enrollment type, demographic or socio-economic status (for example, ACOs serving largely dual-eligible populations) and when an ACO tends to dominate (serve a large proportion of FFS beneficiaries) in a region.

We considered addressing the circumstance of ACOs that are dominant in their region, by expanding the scope of the ACO's region (for example, by including adjoining counties) to allow the ACO's regional service area to include a greater mix of beneficiaries who are not assigned to the ACO. However, we explained our belief that this approach may be challenging to apply consistently and accurately given the potential for variation of populations across and within regional areas, and would be a potentially cumbersome policy to maintain as ACOs continue to develop across the country. Therefore, we indicated we would monitor for cases where an ACO tends to serve a large proportion of FFS beneficiaries in its region, and consider the effect of these circumstances on ACO benchmarks. If warranted, we would explore developing adjustments to the definition of an ACO's regional service area to account for this circumstance in future rulemaking.

Further, we proposed to weight an ACO's regional expenditures relative to the proportion of its assigned beneficiaries in each county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries. We explained that absent this weighting, we could overstate or understate the influence of the expenditures for a county where relatively few or many of an ACO's assigned beneficiaries reside.

These proposals on the calculation of county FFS expenditures and regional FFS expenditures were reflected in the proposed new § 425.603. We sought comment on alternatives to the proposal to use assignable beneficiaries, including beneficiaries assigned to the ACO, in establishing the expenditures for an ACO's regional service area, such as using all Medicare FFS beneficiaries in determining these expenditures.

Comment: While some commenters expressed support for the proposal to include any county in which at least one assigned beneficiary resides in an ACO's regional service area, many other commenters opposed this proposal. Some commenters questioned whether including data from counties with small numbers of assigned beneficiaries sufficiently improves the accuracy of the benchmark to justify the added complexity and administrative burden. The most commonly suggested alternative was to specify a higher threshold for the minimum number of assigned beneficiaries residing in a county included in the ACO's regional service area. For instance, commenters suggested we include in the definition of the ACO's regional service area counties where at least 1 percent of an ACO's assigned beneficiaries reside. Commenters also pointed out that publicly available ACO assignment data files (made available to support modeling of the proposed policies) as well as the PGP Demonstration methodology, omitted counties with less than 1 percent of ACO assigned beneficiaries.

Response: We are finalizing our proposal to include in the definition of an ACO's regional service area any county where one or more beneficiaries assigned to the ACO reside. We continue to believe this approach is necessary to accurately reflect the diversity of the ACO's assigned beneficiary population and to provide a complete picture of the ACO's regional service area. Based on our initial modeling of this policy using preliminary assignment data for 433 ACOs participating in the program for performance year 2016, we observed that ACOs have on average about 7 percent of their assigned beneficiaries residing in counties in which less than 1 percent of the ACO's total assigned beneficiary population resides. In this analysis, we observed a median of approximately 6 percent of assigned beneficiaries residing in counties where less than 1 percent of the ACO's total assigned beneficiary population resides, a minimum of approximately 2 percent, and a maximum of approximately 44 percent. We also observed that for nearly 20 percent of these ACOs (78 of the 433) more than 10 percent of the ACO's assigned beneficiaries were dispersed across counties in which less than 1 percent of the ACO's total assigned beneficiary population resides. Applying a threshold for including counties within the ACO's regional service area would likely affect ACOs differently depending on the size of the ACO's assigned beneficiary population residing in counties below the threshold because the remaining counties would need to be weighted proportionately higher, which could have a significant impact on the calculation of regional expenditures for an ACO. Further, we believe our approach to weighting county FFS expenditures, described later in this section of this final rule, will result in counties with very few assigned beneficiaries having a proportionately small effect on the expenditures for the ACO's regional service area.

Comment: The vast majority of commenters discussing the proposal to base regional FFS expenditures on assignable beneficiaries (instead of all FFS beneficiaries), favored an approach that would exclude from these calculations beneficiaries who would not meet the requirements for being assigned (such as non-utilizers of primary care services). A commenter expressed support for use of all Medicare beneficiaries from a particular region, instead of only assignable beneficiaries, in calculating regional expenditures. This commenter indicated that including expenditures for all Medicare FFS beneficiaries in these calculations accounts for beneficiaries seeking care within and outside the ACO, addresses concerns about smaller populations biasing the calculation, and is in line with other CMS initiatives that use calculations based on the entire Medicare population.

While some commenters favored the proposed inclusion of ACO assigned beneficiaries in the regional expenditure calculations, many opposed this proposal. Those opposed usually suggested that CMS exclude from these calculations either the ACO's assigned beneficiaries or all beneficiaries assigned to participants in any CMS ACO initiative (Shared Savings Program, Pioneer ACO Model, Next Generation ACO Model) or more broadly to participants in any alternative payment model. Commenters expressed concerns that including ACO beneficiaries' expenditures would skew regional expenditure calculations by reflecting ACOs' efforts to coordinate care and reduce expenditures for their assigned populations. Commenters indicated these concerns were more pronounced for ACOs that have significant market saturation, for

example, in cases where an ACO is dominant in its market, or where many ACOs have formed within the same market (referred to as ''ACO-heavy'' regions). A commenter expressed a concern which was also reflected in other comments, that this would create another dynamic where an ACO must compete against its own historical performance. Another commenter noted that inclusion of an ACO's assigned population in a comparison group would be unusual in a commercial ACO contract.

Among the commenters expressing support for the inclusion of the ACO's assigned beneficiaries in expenditure calculations for the ACO's regional service area, some indicated that the approach would protect both ACOs and the Trust Funds. A commenter explained this approach would reduce the impact of the regional adjustment impact, particularly in less densely populated areas, but did not detail the reason for this belief. Another commenter specified that if ACOs are successful in limiting growth of expenditures, then including their beneficiaries in calculations of county FFS spending would serve to control the growth in calculated regional FFS spending, and ultimately allow the Medicare program to capture further savings as ACOs' benchmarks move toward the regional average. Several commenters explained that removing the ACO's assigned beneficiaries from the population used to determine regional FFS expenditures could bias results, but did not explain the nature of this potential bias. A commenter expressed concern that excluding the ACO's assigned beneficiaries from the population used to determine regional FFS expenditures could effectively penalize ACOs for caring for the sickest patients, particularly if these ACOs are dominant in their markets. Some commenters also urged CMS to consider whether the proposed use of assignable beneficiaries in regional benchmark calculations could disadvantage rural ACOs, by showing artificially lower utilization rates in rural communities.

Response: We are finalizing as proposed the policy to include the expenditures for all assignable FFS beneficiaries (including ACO assigned beneficiaries) residing in the counties that make up the ACO's regional service area in calculating county FFS expenditures.

We discuss in detail, in section II.A.2.e.3 of this final rule, the definition of assignable beneficiaries. Some commenters seemed to misunderstand the scope of beneficiaries included within the assignable population (perceiving it as a broader population than the population currently used to calculate factors based on national FFS expenditures). To clarify, assignable FFS beneficiaries are a subset of the broader FFS population (see 81 FR 5843). The assignable beneficiary population, as defined in this final rule, would include any beneficiary receiving a primary care service from a primary care physician or from a physician with one of the primary specialty designations included in § 425.402(c). This primary care service must be one that is billed for under traditional FFS Medicare with a date of service during the 12-month assignment window as defined under § 425.20.

For the reasons discussed in the proposed rule, and as summarized previously in this section of the final rule, we continue to believe that including the ACO's assigned beneficiaries within the assignable population used to calculate county FFS expenditures for the ACO's regional service area will reduce the chance of bias in the calculations, particularly in the case of ACOs serving higher cost beneficiaries within the region. We believe that including the ACO's assigned beneficiaries among the population used to calculate risk adjusted county level expenditures (applying full CMS–HCC risk adjustment, as discussed in section II.A.2.e.2 of this final rule) is critical to ensuring regional expenditures accurately reflect the cost and acuity of beneficiaries in the ACO's region. Additionally, we have significant operational concerns with commenters' suggestions that CMS remove each ACO's assigned beneficiaries from the ACO's regional service area. This approach would entail calculating county rates tailored for each ACO for each benchmark and performance year, as opposed to the proposed approach of calculating county rates program-wide and determining on an ACO-specific basis which county expenditures to use and how to weight these expenditures. We are deeply concerned that this alternative approach would not be transparent because of the highly individualized nature of the exclusions that would be required for each ACO's county FFS expenditure calculations. In addition, we believe determining ACO-specific county-level FFS expenditures would be time intensive given the complexity of these calculations, and prevent timely provision of program reports based on these data to ACOs.

Furthermore, we continue to believe that the approach to determining county FFS expenditures based on assignable Medicare beneficiaries (as opposed to all Medicare beneficiaries) may avoid bias in these calculations, including biases that may be more pronounced in certain geographic regions as a result of healthcare patterns and population demographics. In the 2016 proposed rule, we explained our belief that including expenditures for all FFS beneficiaries would introduce bias into the calculations of the ACO's regional service area expenditures. We explained that regional FFS expenditures, which are calculated based on relatively smaller populations than the national FFS population currently used in benchmark calculations based on national FFS expenditures, may be more susceptible to the influence of this bias. For example, in counties where the health status of the overall beneficiary population leads more beneficiaries to be non-utilizers of services, a bias in the direction of relatively lower regional expenditures may be more pronounced. On the other hand, a bias in the direction of relatively higher regional expenditures may be more pronounced in counties where there are established patterns of accessing primary care services through specialists who are not the basis for assignment. We also noted that ultimately, such differences could factor more prominently in certain counties that are used to compute an ACO's regional service area expenditures (see 81 FR 5830 and 5831). Thus, using only assignable beneficiaries in expenditure calculations avoids biases that could result from including non-utilizers, among other factors, and that would be present in calculations based on the larger Medicare FFS population.

Comment: Commenters concerned about the situation of ACOs that have a regional service area population that is too small (particularly as a result of excluding ACO assigned beneficiaries) suggested alternatives for expanding the ACO's regional service area and encouraged CMS to adopt such an approach in the final rule (as opposed to monitoring the issue). Most commonly, commenters suggested including adjacent counties in the ACO's regional definition (for example, citing the approach used in the Pioneer ACO model, or describing details of an alternative approach), as well as increasing the number of years of data included in the calculations (for example, using a 5-year rolling average for county-level spending estimates, along the lines of the approach used by MA). Some commenters suggested increasing the weight given to the counties that have a lower proportion of ACO assigned beneficiaries in relation

to the population of Medicare FFS beneficiaries. However, a commenter acknowledged that any methodology for expanding the scope of an ACO's region would be both cumbersome and challenging to apply consistently.

Response: We appreciate commenters' suggestions for alternative approaches to defining the ACO's regional service area. In section II.A.2.e.2 of this final rule, we address commenters' suggestions to use additional years of data to calculate county FFS expenditures. We decline at this time to adopt alternatives suggested by commenters for expanding the ACO's regional service area population, particularly in relation to requests to exclude ACO assigned beneficiaries from the assignable population. We do not believe these adjustments are necessary under the methodology we are finalizing for determining the ACO's regional service area using the assignable FFS beneficiary population, including ACO assigned beneficiaries. As we implement the revised rebasing methodology established with this final rule, we will consider the impact of including ACO assigned beneficiaries within the population used to calculate the regional FFS expenditures, including the potential for bias in regional FFS expenditure calculations for ACOs that are dominant in their regions and ACO-heavy regions. In the event we determine that any changes to are necessary to address these issues, we will address them in future rulemaking.

Comment: Although not discussed in the proposed rule, a few commenters made suggestions to include or exclude MA beneficiaries in the population used to determine expenditures for the ACO's regional service area.

Response: As an initial matter, we wish to clarify the following: (1) The assignable population under this final rule could include beneficiaries who are enrolled in MA during part of the 12-month assignment-window; and (2) the assignable population excludes beneficiaries who have no primary care services billed under traditional FFS Medicare and thus do not meet the definition of an ''assignable beneficiary'' under this final rule, such as beneficiaries who received services only through a MA plan for the entirety of the 12-month assignment window. Underlying our proposal to use assignable beneficiaries in calculating regional and national FFS expenditures was our intent to ensure these calculations were based on beneficiaries that have some chance of being assigned to the ACO. Accordingly, we decline at this time to include in regional FFS expenditure calculations beneficiaries who have only received services through a MA plan during the 12-month assignment window used to determine assignable beneficiaries and who could not be eligible to be assigned to an ACO. However, we wish to clarify that some beneficiaries who meet the definition of ''assignable beneficiary'' adopted in this final rule will ultimately be excluded from assignment to an ACO for purposes of determining the ACO's benchmark or performance year expenditures because they fail to meet the assignment criteria specified under § 425.401(a).

Comment: Almost all commenters discussing the proposal to weight expenditures by the proportion of the ACO's assigned beneficiaries in each county supported the proposed approach. Commenters underscored the importance of this weighting for accurately reflecting expenditure levels in the ACO's market in regional calculations. Absent this weighting, CMS could over or understate the influence of expenditures for a county. A commenter indicated that the need to perform this weighting illustrated the inaccuracies and lack of precision with using county-level data, and recommended the use of an alternative methodology to define the ACO's regional service area (such as CBSAs, MSAs, and CSAs). Some commenters requested clarification of what the proposed methodology for establishing an ACO's regional service area would mean for ACOs that use a model of geographically distant providers to aggregate to the required minimum number of 5,000 assigned beneficiaries.

Response: We are finalizing as proposed the policy of weighting an ACO's regional expenditures relative to the proportion of its assigned beneficiaries in each county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries. For the reasons discussed in the proposed rule and raised by commenters who supported this approach, we believe that weighting county-level FFS expenditures by the proportion of assigned beneficiaries in each county will accurately reflect expenditure levels in the ACO's market in regional FFS expenditure calculations.

We also note that the need to weight the expenditures is not necessarily specific to the choice of counties as the geographic unit in the regional definition. Some approach to weighting would be necessary in any methodology for calculating expenditures for an ACO's regional service area, since ACOs often serve beneficiaries in multiple counties within a state or across several states as discussed in the 2016 proposed rule (81 FR 5831). As a result, we disagree with the comment indicating that use of weighting in a methodology for calculating regional FFS expenditures is somehow indicative of a lack of precision with using county-level data.

Further, in response to the request for clarification on the application of the weighting methodology to smaller ACOs with geographically dispersed ACO participants, we note that the methodology for determining an ACO's regional service area and calculating regional FFS expenditures will be applied consistently across ACOs, regardless of ACO size, composition, or geographic location.

We did not receive comments specifically addressing how county-level FFS expenditures should be weighted for purposes of determining regional FFS expenditures for the ACO's regional service area. In the proposed rule, we outlined an approach in the proposed § 425.603(f). However, following further consideration of this issue, we now believe that the proposed provision should be revised to more clearly reflect our intended approach. We wish to clarify that when determining expenditures for an ACO's regional service area, we intend to calculate each county's expenditures by enrollment type, and to weight these expenditures by the ACO's proportion of assigned beneficiaries in the county for the applicable enrollment type. We will then aggregate these values, across counties within the ACO's regional service area, for each population by Medicare enrollment type. This will result in a separate value for each of the four populations identified by Medicare enrollment type, representing county-weighted regional FFS expenditures for that Medicare enrollment type. We will apply to each of these aggregate expenditure values (specific to a Medicare enrollment type) a weight reflecting the ACO's overall proportion of assigned beneficiaries in that Medicare enrollment type, as determined in relation to its entire assigned population for the relevant benchmark or performance year in order to determine the ACO's risk adjusted regional expenditures for that enrollment type. We are making clarifying revisions to the provision at § 425.603(f) to reflect this approach.

FINAL ACTION: We are finalizing our proposal to define the ACO's regional service area to include any county where one or more assigned beneficiaries reside, and to reflect this policy through the addition of a new definition of ''ACO's regional service

area'' to § 425.20. We are finalizing several proposals, among others described elsewhere in this final rule, on the calculation of county FFS expenditures and an ACO's regional FFS expenditures as reflected in new § 425.603 to: (1) Include expenditures for all assignable FFS beneficiaries (including ACO assigned beneficiaries) residing within the county to calculate the county's FFS expenditures; and (2) weight an ACO's regional expenditures relative to the ACO's proportion of its assigned beneficiaries in each county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries. As discussed in this section of this final rule, we are making revisions to § 425.603(f), to clarify the weighting of county-level expenditures by the ACO's proportion of beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) in each county for purposes of determining the ACO's regional expenditures. We will monitor the effects of this methodology on calculations of regional FFS expenditures, particularly for bias in the calculations among ACOs that are dominant in their regions, as well as in ACO-heavy regions, and will address any necessary adjustments to this methodology through future rulemaking.

c. Applying Regional Expenditures to the ACO's Rebased Benchmark

(1) Background

In the 2016 proposed rule (81 FR 5832), we summarized our discussion of benchmark alternatives in recent rulemaking, indicating there is an array of options for incorporating regional expenditures in ACO benchmarks. We explained our agreement with commenters on the previous rulemaking regarding the benefits of incorporating regional expenditures in rebased benchmarks, and indicated our interest in moving to an alternative rebasing approach that builds on the program's existing benchmarking methodology established under the authority of section 1899(d)(1)(B)(ii) of the Act and codified in the Shared Savings Program regulations at § 425.602.

As we stated in the proposed rule, over 400 ACOs have voluntarily entered the Shared Savings Program under the financial models (Track 1 and Track 2) established in the November 2011 final rule and as modified by the June 2015 final rule (adding a choice of Track 3 for agreement periods beginning January 1, 2016). Furthermore, 147 ACOs with 2012 and 2013 agreement start dates elected to continue their participation in the program for a second 3-year agreement period effective January 1, 2016, to which the current rebasing methodology, finalized in the June 2015 final rule applies. We explained that the value proposition of the program's financial models, which is largely determined by the methodology used to establish ACO benchmarks, is an important consideration for organizations deciding whether to engage (or continue to engage) in this new approach to the delivery of health care. Therefore, in considering how to incorporate regional expenditures into the benchmarking methodology, we expressed our belief that building from the existing benchmarking methodology will help maintain the stability of the program and ultimately result in revised policies that are more easily understood by ACOs and program stakeholders, and more readily implemented by CMS.

Principally, we considered using the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate'' in order to incorporate regional FFS expenditures into the rebased historical benchmark. In the 2016 proposed rule (81 FR 5832 through 5836), we discussed two approaches to calculating an adjustment to an ACO's rebased historical benchmark to account for regional FFS expenditures for the ACO's regional service area, and described how the adjustment would be applied to the rebased historical benchmark.

We discussed our belief that although the plain language of section 1899(d)(1)(B)(ii) of the Act demonstrates Congress' intent that the benchmark established for a Shared Savings Program ACO would reflect the ACO's historical expenditures in the 3 most recent years prior to the start of the ACO's agreement period, Congress also recognized that this historical benchmark should be adjusted ''for beneficiary characteristics and such other factors as the Secretary determines appropriate.'' Therefore, to the extent an ACO's rebased benchmark continues to be based on the ACO's historical expenditures in the 3 years preceding the start of the new agreement period, we expressed our belief that adjusting those historical expenditures to account for regional FFS expenditures for the ACO's regional service area falls within the Secretary's discretion to make adjustments to the historical benchmark for ''other factors'' under section 1899(d)(1)(B)(ii) of the Act.

We explained that we currently make several adjustments to an ACO's historical benchmark under the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act, including to: (1) Adjust benchmark year expenditures to exclude IME and DSH payments (§ 425.602(a)(1)(i)); (2) adjust the historical benchmark for the addition and removal of ACO participants (§ 425.602(a)(8)); (3) adjust the rebased historical benchmark to account for the average per capita amount of savings generated during the ACO's previous agreement period (§ 425.602(c)(2)(ii)); and (4) adjust the historical benchmark for changes in demographics and health status of the ACO's performance year assigned beneficiary population (§§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), 425.610(a)(1) through (3)). We expressed our belief that it is appropriate to further adjust ACO historical benchmarks to reflect FFS expenditures in the ACO's regional service area. Furthermore, in relation to the use of regional FFS expenditures in developing the ACO's rebased benchmark, we explained our belief that it is appropriate to forgo making an additional adjustment to account for savings generated by the ACO in its prior agreement period (81 FR 5832).

(2) Adjusting the Reset ACO Historical Benchmark To Reflect Regional FFS Expenditures

In the 2016 proposed rule we described two options for calculating the regional FFS adjustment and the ACO's rebased historical benchmark. The first option would be to calculate a regional adjustment based on a regionally-trended version of the ACO's prior historical benchmark. The second option would be based on a regional average determined using county FFS expenditures (81 FR 5832 and 5833). We proposed to adopt the second option.

Specifically, we proposed to calculate the ACO's rebased historical benchmark using the current rebasing methodology established in the June 2015 final rule under which an ACO's rebased benchmark is calculated based on the 3 years prior to the start of its current agreement period. Consistent with the current policy we would equally weight the 3 benchmark years. However, in trending forward benchmark year (BY) 1 and BY2 expenditures to BY3 dollars, we proposed to use regional growth rates (instead of national growth rates) for Parts A and B FFS expenditures (81 FR 5833 and 5838).

Furthermore, in calculating the ACO's rebased historical benchmark, we proposed not to apply the current adjustment to account for savings generated by the ACO under its prior agreement period. We explained our

observation that for ACOs generating savings, a rebasing methodology that accounts for regional FFS expenditures would generally leave a similar or slightly greater share of measured savings in an ACO's rebased benchmark for its ensuing agreement period. By contrast, for ACOs generating losses, a rebasing methodology that accounts for regional FFS expenditures would tend to carry forward a significant portion of measured losses into their rebased benchmarks and push benchmarks lower than the current rebasing policy. We expressed our belief that in transitioning to a benchmark rebasing methodology that incorporates an adjustment for regional FFS expenditures, it is important to forgo the current adjustment to account for shared savings generated by the ACO under its prior agreement period.

We proposed to calculate the regional FFS adjustment to the ACO's rebased historical benchmark based on a regional average determined using county FFS expenditures. The calculation of regional average expenditures would generally involve the following key steps:

- Calculate risk adjusted regional per capita FFS expenditures using county level Parts A and B expenditures for the ACO's regional service area for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible); weighted based on the proportion of ACO assigned beneficiaries residing in each county for the most recent benchmark year. We also proposed a risk adjustment approach that would be used in these calculations to adjust for differences in health status between an ACO and its regional service area (81 FR 5846 through 5848; and as discussed in detail elsewhere within this section of this final rule).
- Weight the resulting regional expenditures by the proportion of assigned beneficiaries for the most recent benchmark year for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

We described in detail and sought comment on the alternative option, under which we would calculate the regional FFS adjustment based on a regionally-trended version of the ACO's prior historical benchmark (81 FR 5833). In comparing the features of the two options, we expressed our belief that using regional average expenditures offered a preferred approach. While we believed both options would avoid penalizing ACOs that improve their spending relative to that of their region, the approach of using regional average expenditures would not depend on older historical data in calculations as would be required under the alternative involving calculation of a regionally-trended amount. In general, from an operational standpoint, we anticipated that using a regional average as part of calculating regional FFS expenditures for an ACO's regional service area would be easier for ACOs and other stakeholders to understand as well as for us to implement in comparison to the alternative considered, and would more closely align with the MA ratesetting methodology.

We also considered how the adjustment based on regional FFS expenditures should be applied to the ACO's rebased historical benchmark. Our preferred approach was to use the following steps to adjust the ACO's rebased historical benchmark:

- Calculations of the ACO's rebased historical benchmark and regional average expenditures, as described previously in this section of the final rule, would result in average per capita values of expenditures for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).
- For each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) we would determine the difference between the average per capita regional amount and the average per capita amount of the ACO's rebased historical benchmark. These values may be positive or negative. For example, for a particular Medicare enrollment type, if the value of the ACO's rebased historical benchmark is greater than the regional average amount, the difference between these values will be expressed as a negative number.
- Multiply the resulting difference, for each Medicare enrollment type by a percentage determined for the relevant agreement period. The value of this percentage is described in detail later in this section of the final rule. The products (one for each Medicare enrollment type) resulting from this step are the amounts of the regional adjustments that will be applied to the ACO's historical benchmark.
- Apply the adjustment to the ACO's rebased historical benchmark by adding the adjustment amount for the Medicare enrollment type to the truncated, trended and risk adjusted average per capita value of the ACO's rebased historical benchmark for the same Medicare enrollment type.
- Multiply the adjusted value of the ACO's rebased historical benchmark for each Medicare enrollment type by the proportion of the ACO's assigned beneficiary population for that Medicare enrollment type, based on the ACO's assigned beneficiary population for benchmark year 3 of the rebased historical benchmark.
- Sum expenditures across the four Medicare enrollment types to determine the ACO's adjusted rebased historical benchmark.

In a separate section of the 2016 proposed rule, we considered issues related to risk adjustment when using regional expenditures in resetting ACO benchmarks, including considerations raised in prior rulemaking (see 81 FR 5846 through 5848). We discussed our concern that using CMS–HCC risk scores for an ACO's assigned beneficiary population in resetting the ACO's benchmark has the potential to benefit ACOs that have systematically engaged in coding initiatives during their prior agreement period. We explained that this effect would have been limited in the corresponding performance years due to the application of our current approach to risk adjusting during the agreement period according to the ACO's newly and continuously assigned beneficiary populations. We noted that initial financial performance results (for the performance years ending December 31, 2013 and 2014) do not show strong evidence that concerns about systematic coding practices by ACOs have materialized, but complete data are not yet available to analyze the effect of coding initiatives in the initial rebasing of ACO benchmarks, as initial program entrants (ACOs with 2012 and 2013 agreement start dates) only began their second agreement periods on January 1, 2016.

To balance our concerns regarding ACO coding practices with the recommendations of commenters received through earlier rulemaking, we proposed to risk adjust to account for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area as part of the methodology for determining the adjustment to the ACO's rebased historical benchmark to reflect regional FFS expenditures, and indicated we would rigorously monitor for the impact of coding initiatives on ACO benchmarks and make necessary refinements to the program's risk adjustment methodology through future rulemaking if program results show adverse impacts due to increased coding intensity. We outlined the methodology of the proposed risk adjustment approach. We indicated that we would compute for each Medicare enrollment type a measure of risk-adjusted regional expenditures that would account for the differences between the average CMS–

HCC risk scores of the ACO's assigned beneficiaries and the average CMS–HCC risk scores in the ACO's regional service area. This adjustment would also capture differences in patient mix between the ACO's assigned population and the FFS population in the ACO's regional service area. We noted our belief that this combined approach (risk adjustment in combination with monitoring for coding intensity) was reasonable given the lack of strong evidence to date that ACOs are engaging in more intensive coding practices and given a number of factors, described in the 2016 proposed rule (81 FR 5847 through 5848), that we believe would mitigate the potential impact of coding intensity on ACO financial calculations. We noted that the proposed approach would not apply in the calculation of benchmarks for ACOs in their first agreement period or in the second agreement period for ACOs that started the program in 2012 and 2013 and started a new agreement period on January 1, 2016. We also noted that for all ACOs we would continue to use the current methodology to adjust the ACO's benchmark annually to account for the health status and demographic factors of the ACO's performance year assigned beneficiaries (according to the newly and continuously assigned populations).

We sought comment on this proposed approach and on the alternatives considered that might be employed in the future to limit the impacts of intensive coding while still accounting for changes in health status within an ACO's assigned beneficiary population, including: (1) Applying the methodology currently used to adjust the ACO's benchmark annually to account for the health status and demographic factors of the ACO's performance year assigned beneficiaries (according to newly and continuously assigned populations) when rebasing the ACO's historical benchmark; or (2) developing a coding intensity adjustment by looking at risk score changes over time for beneficiaries assigned to the ACO for at least two consecutive years, as well as in each respective diagnosis collection year (similar to the population referred to as stayers under the MA methodology) relative to the greater FFS population.

In another section of the 2016 proposed rule, we proposed program-wide changes to the methodology used to adjust the ACO's benchmark for changes in ACO participant (TIN) composition (81 FR 5850 and 5851). In that discussion, we proposed to redetermine the regional FFS adjustment to account for changes to the ACO's certified ACO Participant List. Specifically, we would redetermine the ACO's regional service area during the reference year (benchmark year 3 (BY3)) based on the residence of the ACO's assigned beneficiaries for the reference year determined using the new ACO Participant List. We would also use this assigned population to determine the ACO's proportion of beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) to be used in calculating the regional adjustment. We would then redetermine the regional FFS adjustment to the ACO's rebased historical benchmark, based on regional average expenditures for the ACO's updated regional service area. In redetermining the regional FFS adjustment, we would also adjust for differences between the health status of the ACO's assigned beneficiaries determined using the new ACO Participant List and the population of assignable beneficiaries in the ACO's regional service area based on the reference year (BY3). Although we will discuss our proposed revisions to the methodology for adjusting benchmarks to account for changes in ACO participant composition in more detail in section II.B of this final rule, we believe it is appropriate to address the issue of redetermining the regional FFS adjustment based on changes in the ACO's participant composition in this section of this final rule.

Consistent with our proposal to incorporate an adjustment for regional expenditures into an ACO's rebased benchmark, we proposed to revise § 425.602 in order to limit the scope of the provision to establishing, adjusting, and updating the benchmark for an ACO's first agreement period. We proposed to explain how the benchmark would be reset for a subsequent agreement period, including the methodology for adjusting an ACO's rebased historical benchmark to reflect FFS expenditures in the ACO's regional service area in the ACO's second or subsequent agreement period starting on or after January 1, 2017, in a new provision of the Shared Savings Program regulations at § 425.603. We also proposed to include the risk adjustment approach to account for differences in health status between the ACO's assigned beneficiary population and the broader FFS population in the ACO's regional service area in the revised benchmark rebasing methodology under § 425.603. In addition, we proposed to specify in the new provision at § 425.603 that CMS will redetermine the regional adjustment amount annually based on the ACO's assigned beneficiaries for BY3 determined using the most recent certified ACO Participant List for the relevant performance year.

Furthermore, we proposed to make conforming and clarifying revisions to the provisions of § 425.602, including to: Revise the title of the section; remove paragraph (c) and incorporate this paragraph in the new § 425.603; and add a paragraph that describes the adjustments made to the ACO's historical benchmark during an ACO's first agreement period to account for changes in severity and case mix for newly and continuously assigned beneficiaries as presently specified under § 425.604, § 425.606, and § 425.610. We also proposed to specify in § 425.20 that the acronym ''BY'' stands for benchmark year.

We sought comments on our proposals for incorporating regional expenditures into rebased ACO benchmarks and on the alternative approach of using a regionally-trended amount developed from the ACO's historical benchmark for a prior agreement period instead of regional average expenditures to adjust the ACO's rebased historical benchmark. In particular, we welcomed comments on the design of the approaches for calculating the regional adjustment to the ACO's rebased historical benchmark described in the 2016 proposed rule, as well as any concerns about implementing the regional adjustment.

Comment: A few commenters supported the proposal to eliminate the adjustment to the ACO's historical benchmark for savings achieved by the ACO in the previous agreement period. However, most commenters strongly opposed the proposal to discontinue the current adjustment to the ACO's rebased benchmark for savings generated in the prior agreement period. Commenters explained that eliminating the adjustment makes it harder for ACOs that have successfully met the goals of the program in a prior agreement period to achieve future savings. These commenters were critical of CMS' explanation that incorporating regional expenditures sufficiently offsets the loss of the adjustment for savings in the prior agreement period. Some commenters specified that removing the adjustment would undermine the sustainability of the program, citing concerns including the following:

- Further reducing benchmarks for ACOs with higher historical costs compared to their region that would be negatively affected by the introduction of a regional adjustment. Several commenters suggested that retaining the

adjustment could have the effect of more gradually lowering the rebased benchmarks for ACOs harmed by the integration of regional expenditures over subsequent agreement periods.

- Discouraging successful ACOs from remaining in the program as they face increasingly lower benchmarks and diminishing returns, with a commenter indicating that the current adjustment helps the many existing ACOs that have generated savings but not been eligible to share in those savings.
- The need to provide further incentives to retain ACOs with comparatively lower historical spending compared to their regions.

Some commenters pointed to CMS' rationale for the adjustment specified in earlier rulemaking as reason to retain it.[1] Several commenters pointed to the need to allow for additional time to evaluate the effects of the adjustment, which was applicable beginning in 2016, before changing the policy. Some commenters urged CMS to evaluate the rationale for accounting for savings in a prior agreement period separately from its consideration of incorporating regional cost data into benchmarks, believing these to be distinct issues that have distinguishable effects on ACOs. A commenter, urged that the adjustment be retained, pointing to the need for alignment between federal and state value based payment programs, citing as an example a state of New York initiative that has committed to including shared savings (or losses) when calculating its program benchmarks.

Many commenters favored CMS maintaining the current adjustment. Some commenters made suggestions, creating opposing alternatives, for CMS broadening or narrowing the amount of the adjustment. Although not discussed in the proposed rule, several commenters suggested incrementally lowering the adjustment amount over time. For example, a commenter suggested adding a percentage of prior savings that would be reduced in relation to the proposed phase-in to a higher weight in calculating the regional adjustment. A commenter, anticipating that ACOs in efficient, low-cost areas will be harmed by the proposed transition to benchmarks reflecting regional expenditures, encouraged CMS to abandon the proposed benchmark rebasing changes, including the removal of the adjustment for prior savings and the proposed regional FFS adjustment to the ACO's rebased benchmark, and recommended CMS continue to explore alternative methodologies for rebasing ACO benchmarks.

Some comments regarding the adjustment for savings generated in a prior agreement period seemed to reflect commenters' misunderstanding of the methodology for calculating the adjustment described in the June 2015 final rule (see 80 FR 32788 through 32791). For example, some commenters incorrectly described the methodology as based on savings earned (indicating only the amount of shared savings payments to eligible ACOs) as opposed to savings generated (accounting for savings by ACOs that may have lowered expenditures, but not by enough to earn a shared savings payment). A commenter stated that the current adjustment accounts for half of the savings achieved by the ACO. However, the adjustment takes into account the ACO's final sharing rate, which depends on the ACO's track as well as its quality performance.

Response: We believe our intent to propose eliminating the adjustment for prior savings was made clear in the discussion in the June 2015 final rule of moving to a rebasing approach that accounts for regional FFS costs and trends. In outlining our preferred methodology, we specified we would calculate the ACO's rebased historical benchmark—based on the 3 most recent years prior to the start of the ACO's new agreement period—including equally weighting these benchmark years but excluding the addition of a portion of savings generated over the same 3 most recent years (80 FR 32796). We also specified that in a future rule we would put forward details on a revised rebasing approach that would address, among other issues, how the revised benchmark rebasing methodology using ACO and regional cost trends fits in with the existing approach for establishing the ACO's historical benchmark for its first agreement period and the modifications to the rebasing methodology finalized in the June 2015 final rule. We also indicated that we would consider whether additional adjustment would be needed to transition ACOs to the revised benchmark rebasing methodology when they have been previously rebased under the methodology established with the June 2015 final rule (80 FR 32796).

We continue to believe that for ACOs generating savings, a rebasing methodology that accounts for regional FFS expenditures would generally leave a similar or slightly greater share of measured savings in an ACO's rebased benchmark for its ensuing agreement period. We disagree with comments suggesting that we either maintain the current adjustment without modification or broaden the scope of the adjustment for savings generated in the ACO's prior agreement period to make it more generous. We believe that as a result, benchmarks could become overly inflated for some ACOs (particularly those benefiting from the regional FFS adjustment) to the point where ACOs would need to do little to maintain or change their care practices to generate savings. Further, continued application of the current adjustment for savings generated in an ACO's prior agreement period, without modification, further ties an ACO's historical benchmark to its past performance, rather than making an ACO's benchmark more reflective of FFS spending in its region, an important aim of the revisions to the rebasing methodology in this final rule.

Therefore, as proposed, we will apply the revised rebasing methodology in the new regulation at § 425.603 to reset an ACO's historical benchmark for a second or subsequent agreement period beginning in 2017 and subsequent years, and will not include an adjustment for savings generated in the ACO's prior agreement period.

Comment: Most commenters discussing the regional adjustment to the ACO's rebased historical benchmark favored the proposed use of regional average expenditures in the calculation. Some commenters cited reasons for preferring the proposed approach instead of the alternative considered in the proposed rule, under which we would calculate the regional FFS adjustment using a regionally-trended amount based on an ACO's historical benchmark from a prior agreement period, including that the use of regional averages more closely aligns with the MA rate-setting methodology and would not depend on older historical data. A commenter explained that the reliance on older historical data under the regionally-trended approach would decrease the attainability and

[1] For example, in the June 2015 final rule we explained our belief that the adjustment for savings generated in the ACO's prior agreement period is important for encouraging ongoing program participation by ACOs that were successful in achieving the three-part aim in their first agreement, by lowering expenditures and improving both the quality of care provided to Medicare FFS beneficiaries and the overall health of those beneficiaries. Absent this adjustment, an ACO that previously achieved success in the program may elect to terminate its participation in the program rather than face a lower benchmark that reflects the lower costs for its patient population during the three most recent prior years (see 80 FR 32788). However, as noted elsewhere in this final rule, in the June 2015 final rule we stated our belief that it would be critical to revisit the policy of accounting for an ACO's savings generated in a prior agreement period when resetting its benchmark in conjunction with any future changes to the benchmarking methodology to incorporate regional FFS expenditures (see 80 FR 32791). See also discussion of the policy in the December 2014 proposed rule (79 FR 72838 through 72839).

accuracy of the resulting benchmarks over time. In particular, the commenter indicated that the: (1) Comparison of ACO assigned beneficiaries to non-ACO assigned beneficiaries will not remain stable over time as ACO participation in the Shared Savings Program grows or declines in a region; and (2) risk adjustment under this approach may not be adequate to account for changes in the ACO's composition over time in relation to its region.

A few commenters expressed support for the alternative (use of a regionally-trended amount) or a somewhat similar approach. For example, a commenter cited concerns that use of regional averages would disadvantage ACOs with historically high-cost providers, such as skilled nursing facilities, and ultimately incent ACOs to remove these providers as participants in order to generate savings below their benchmark. Another commenter, detailing findings based on extensive modeling, favored an approach under which the historical benchmark for the initial agreement period would be updated for subsequent agreement periods to account for regional spending growth and for compositional changes in ACO beneficiaries or providers without rebasing it to reflect the historical costs for the ACO from the most recent years prior to the start of the subsequent agreement period.

Some commenters addressed the anticipated effects of the regional FFS adjustment on benchmarks of ACOs with spending relatively lower and higher than their region. Commenters explained that the proposed approach rewards an ACO with lower spending than its region by increasing the ACO's benchmark value. For an ACO with higher spending than its region, the proposed approach was anticipated to decrease the ACO's benchmark value. Some commenters expressed particular concern about the latter group, explaining that the proposed policy could create a disincentive for continued participation by ACOs that were successful in earning shared savings payments in their initial agreement period, but have spending higher than the regional average for their regional service area.

Response: We are finalizing our proposal to calculate the regional adjustment to the ACO's historical benchmark as a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). We continue to believe there are benefits to using a regional average in calculating the adjustment, rather than the alternative approach of using a regionally-trended amount, including: greater alignment with the MA rate-setting methodology; lack of dependence on older historical data; greater transparency for ACOs and other stakeholders; and easier integration and alignment with our existing approach to adjusting the historical benchmark when an ACO makes ACO Participant List changes.

We agree with commenters that the regional FFS adjustment will have differing effects on an ACO's benchmark depending on whether the ACO's spending is relatively lower or higher than the spending for its regional service area. As discussed in this section of this final rule, we outlined our preferred approach to calculating the adjustment in the 2016 proposed rule (see 81 FR 5833 and 5834). We specified that we would determine the difference between the average per capita regional amount and the average per capita amount of the ACO's rebased historical benchmark for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). We indicated that the difference would be expressed as a negative number if the value of the ACO's rebased historical benchmark for a particular Medicare enrollment type is greater than the regional average amount for that enrollment type. The difference would be expressed as a positive number if the value of the ACO's rebased historical benchmark for a particular Medicare enrollment type is less than the regional average amount. We anticipate the regional adjustment value will differ by Medicare enrollment type for each ACO, and it will be possible to have a mix of positive and negative values for the regional adjustment amount across these Medicare enrollment types.

Generally, we anticipate several aspects of the revised rebasing methodology will mitigate concerns about the potential negative effects of the regional adjustment. First, as discussed in section II.A.2.b of this final rule, we believe the inclusion of ACO assigned beneficiaries in the calculation of regional FFS expenditures will be important in capturing the cost and health status of the beneficiary population served by the ACO. For example, for a high spending ACO operating in a lower spending region, including the ACO's assigned population in the regional FFS expenditures would likely result in a relatively higher regional adjustment value than if these beneficiaries were excluded. Second, we anticipate the risk adjustment methodology used in calculating the regional FFS adjustment will help mitigate the incentive for ACOs to avoid relatively higher cost providers and higher cost, higher acuity beneficiaries. As discussed in section II.A.2.e.2 of this final rule, we will use CMS–HCC scores to risk adjust county FFS expenditures when determining expenditures for the ACO's regional service area, thereby accounting for the severity of health status and case mix of this population. Additionally, as discussed elsewhere in this section of this final rule, we are finalizing our proposal to account for the difference in health status between the ACO's population and the ACO's regional service area in calculating the regional FFS adjustment. Under this approach, if an ACO's population is healthier than the assignable beneficiaries in the ACO's regional service area, with lower average risk scores for the relevant period, the risk adjustment would reduce the amount of the regional FFS adjustment. Similarly, if the ACO's assigned beneficiary population is comparably sicker than the assignable beneficiaries in the ACO's regional service area, with higher average risk scores for the relevant period, the risk adjustment would increase the amount of the regional FFS adjustment. Third, we believe our proposed phase-in approach, as described in section II.A.2.c.3. of this final rule, will ease the transition to this revised methodology for ACOs with historical spending higher than that of their region.

With respect to a more technical consideration for calculating the regional FFS adjustment, we note that the proposed regulations text specified that in calculating the regional adjustment we would determine the ACO's regional expenditures for benchmark year 3. We did not receive comments specifically addressing this proposal. We are finalizing the policy of using benchmark year 3 data in calculating the regional average used to determine the regional FFS adjustment as proposed. We believe that calculating the regional adjustment based on data from the most recent year prior to the start of the ACO's new agreement period will ensure the adjustment reflects the most recent historical expenditures. Although there were no comments directed specifically to the number of years of data used in calculating the regional adjustment, we believe comments suggesting CMS consider use of additional years of data in calculating county FFS expenditures (described in section II.A.2.e.2 of this final rule) raise

an important issue. These comments provoked our consideration of the possibility of using additional years of data in calculating the regional average, including what factors to use to trend the multiple years of data in computing the regional average. We anticipate continuing to explore this issue as we gain experience with the methodology described in this final rule. For example, we will consider whether use of additional years of data would add greater precision to calculation of regional averages. In the event we determine that any changes to the methodology would be appropriate, we would address this issue in future rulemaking, particularly in advance of applying a higher weight (70 percent) in the regional adjustment calculation as discussed in section II.A.2.c.3. of this final rule.

Comment: Many commenters expressed support for CMS' proposal to adjust for an ACO's risk relative to that of assignable beneficiaries in its region when determining the regional adjustment to the rebased historical benchmark. A commenter expressed support generally for a risk adjustment approach that adequately accounts for the higher costs of ACOs that include providers and health systems that care for the sickest patients and are providing medically necessary care to chronically-ill populations. Further, a commenter recommended that in blending regional FFS spending with ACO historical spending, the per capita spending for each should be similarly risk adjusted.

However, a commenter disagreed with CMS' proposal to compute a measure of risk-adjusted regional expenditures for each Medicare enrollment type that would account for differences in the average CMS–HCC score of the ACO's assigned beneficiary population and the average CMS–HCC risk scores in the ACO's regional service area, describing this as a change in methodology. This commenter expressed concern about the accuracy of using averages in risk adjustment calculations.

Some commenters raised a variety of concerns about the Shared Savings Program's use of the CMS–HCC prospective risk adjustment model, or offered alternative risk adjustment approaches. For example, some commenters encouraged CMS to consider factors beyond CMS–HCC risk scores when performing risk adjustment in the Shared Savings Program, including socio-economic and/or socio-demographic factors. Some commenters questioned whether the CMS–HCC risk adjustment model could effectively account for increasing acuity in a patient's condition over time, clinically complex patients, case mix among patient populations, and geographic variation. A commenter explained that concerns regarding the current risk adjustment methodology have the effect of discouraging participation in the program. A few commenters supported better aligning risk adjustment in the Shared Savings Program with MA, for example, suggesting that the Shared Savings Program adopt the proposed refinements to the MA risk adjustment model aimed at improving the accuracy of payments to plans serving low-income and dual eligible beneficiaries. Other commenters suggested greater transparency by CMS in regards to its use of CMS–HCC scores. For example commenters suggested making publicly available additional resources on the specifications of the CMS–HCC risk adjustment process and developing educational resources about improved coding for providers.

Response: We are finalizing our proposal to risk adjust to account for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area as part of the methodology for adjusting the ACO's rebased historical benchmark to reflect regional FFS expenditures in the ACO's regional service area as proposed. We will use full CMS–HCC risk scores in performing this adjustment. We agree with comments received in support of our proposal. We believe that failure to risk adjust regional FFS expenditures to reflect differences between the risk of the ACO's assigned beneficiary population and the risk of the broader FFS population in the ACO's regional service area would provide an incentive for ACOs to avoid serving sicker beneficiaries, an undesired result.

While the incorporation of risk-adjusted regional expenditures into historical benchmarks is a new approach, we disagree that the use of average risk scores when performing risk adjustment constitutes a change of methodology. Our current methodology risk-adjusts expenditures between years using mean CMS–HCC risk scores among an ACO's assigned beneficiaries within a particular enrollment type. We therefore believe that the approach for risk-adjusting the regional adjustment amount that we are adopting in this final rule is consistent with current risk-adjustment practices.

We appreciate the concerns raised by commenters and the suggestions offered for refining the Shared Savings Program's general risk adjustment methodology, which relies on the CMS–HCC prospective risk adjustment model. We consider these suggestions beyond the scope of this final rule. We decline at this time to adopt commenters' suggestions for use of alternative risk adjustment models, for example accounting for socio-economic or socio-demographic factors outside of the CMS–HCC risk adjustment model. To the extent that new information, such as social determinants of health, is incorporated into the CMS–HCC risk adjustment model in the future, we will account for this when using risk scores in the Shared Savings Program methodology.

Comment: Few commenters directly addressed CMS' plan to rigorously monitor for coding intensity efforts in combination with the agency's proposal to risk adjust for the health status of an ACO's assigned beneficiaries relative to the FFS population in its regional service area. A few commenters appreciated CMS' concerns about the potential for upcoding and a commenter explicitly supported the agency's monitoring plans, noting that differences in coding practices between ACO clinicians and other FFS clinicians should be taken into account when blending regional FFS spending into ACO benchmarks to ensure equity.

A number of commenters expressed the belief that additional coding intensity adjustments are not justified, given the various mitigating factors cited by CMS in the 2016 proposed rule such as routine changes in the assignment of beneficiaries to the ACO from year to year, and the inability of ACOs to submit supplemental codes as occurs in MA. Some commenters specified that the proposed use of regional trend calculations in resetting the benchmark served as a mitigating factor as well. Another commenter warned that even if high levels of coding are observed, this could be the direct result of providing more comprehensive, patient-centered care and that provider efforts to care for complex, chronically ill patients should not be penalized.

Several commenters expressed opinions, sometimes conflicting, on what type of coding intensity adjustment CMS should adopt for the Shared Savings Program if some type of adjustment is deemed necessary. Several commenters supported an approach similar to that used in MA in which a coding intensity adjustment is developed based on beneficiaries assigned for at least 2 consecutive risk adjustment data years. Another commenter expressed opposition to adopting a MA-like approach because they believe it unfairly penalizes

physician organizations engaged in accurate coding practices.

Although CMS sought comment on whether the methodology currently used to adjust the ACO's benchmark annually to account for the health status and demographic factors of the ACO's performance year assigned beneficiaries (according to newly and continuously assigned populations) should also be applied when rebasing the ACO's historical benchmark, many commenters expressed their opposition to the current use of this methodology in adjusting an ACO's benchmark for each performance year and requested that the agency revise the policy. A chief concern raised by many commenters is that the approach does not accurately reflect the potential for individuals to become sicker and more expensive to care for over time (circumstances referred to by some commenters as resulting in a higher ''disease burden''). Several commenters noted that it was unreasonable to assume that a provider organization, however effective, can manage a population such that patient conditions never worsen. Some commenters added that this policy particularly disadvantages ACOs that care for more complex patients, such as those that include tertiary care facilities or academic medical centers. A commenter noted that while it appreciated concerns about the potential for upcoding, it believed such concerns to be irrelevant relative to the negative impact it perceives the current policy for risk adjusting an ACO's benchmark for each performance year has on program participants.

A number of commenters also expressed the belief that the continued use of the newly/continuously assigned policy as a remedy for upcoding lacks justification. A commenter believed that CMS has not provided evidence that actual upcoding is occurring among ACOs, or that it would occur in the future. Another commenter opined that any adjustments for coding intensity should reflect actual, not perceived, coding intensity. Among other concerns raised about the methodology, a commenter opined that the approach transfers too much risk to ACOs and is responsible for deterring ACOs from entering two-sided risk models. Another commenter noted that the policy makes the role of the risk scores opaque to participating providers, making it difficult to anticipate how risk scores may affect performance.

In light of the previously noted concerns, many commenters urged CMS to allow risk scores to increase year-over-year within an agreement period for the continuously assigned beneficiary population, or to allow them to increase within limits. A commenter recommended that if CMS is unwilling to allow risk scores to increase year-over-year for all ACOs, the agency should consider allowing increases for participants in two-sided risk models, which could encourage progression to higher levels of risk. Another commenter thought that CMS should, at a minimum, develop a list of conditions that are high cost and not subject to efforts to improve documentation and coding (for example, ESRD and cancer) and allow the CMS–HCC score for beneficiaries with these conditions to increase to reflect the increased illness of the beneficiary.

Some commenters suggested approaches for limiting the impact of intensive coding not discussed in the 2016 proposed rule. For example, some commenters recommended that if CMS deems a coding adjustment necessary, the agency should consider a method that compares CMS–HCC risk scores with changes in self-reported health status through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. Several other commenters thought CMS should consider approaches used by the Next Generation ACO model, including accounting for the difference in average CMS–HCC risk scores for the baseline and performance-year assigned beneficiaries, and limiting the change in an ACO's average risk score between the baseline and performance year to plus or minus 3 percent.

Response: We appreciate the suggestions made by commenters regarding the development of a coding intensity adjustment for the Shared Savings Program. We also appreciate commenters' feedback on the current policy for adjusting an ACO's historical benchmark for the health status of the ACO's performance year assigned population. At this time, we believe that continued use of this policy in the determination of an ACO's updated benchmark in combination with the use of full CMS–HCC risk adjustment in the calculation of the rebased historical benchmark strikes a balance between the need to recognize changes in beneficiary health status over time with the need to protect against intensive coding practices.

We plan to monitor for the impact of coding initiatives on ACO benchmarks, particularly as we gain more experience with the new rebasing methodology. In the event that a formal coding intensity adjustment is deemed necessary in the future, we would make necessary refinements to the program's risk adjustment methodology through future rulemaking.

FINAL ACTION: We are finalizing our proposals to revise the methodology used to rebase ACO benchmarks for new agreement periods starting on or after January 1, 2017 to incorporate a regional FFS adjustment to the ACO's rebased historical benchmark. We are finalizing the proposed approach to calculating the regional FFS adjustment using average per capita expenditures for benchmark year 3 for assignable beneficiaries in the ACO's regional service area, and to risk adjust to account for the health status of the ACO's assigned population in relation to the assignable FFS beneficiaries in the ACO's regional service area in determining the regional FFS adjustment. We are also finalizing our proposal to add new § 425.603 that incorporates our policies for resetting, adjusting and updating the benchmark for a second or subsequent agreement period.

We did not receive any comments on the specific proposal to redetermine the regional FFS adjustment to account for changes to the ACO's certified ACO Participant List. We believe this redetermination is necessary to ensure that the regional FFS adjustment reflects the ACO's participant composition under the new ACO Participant List. Therefore, we are finalizing our proposal to redetermine the regional FFS adjustment, consistent with the current approach to adjusting an ACO's historical benchmark to account for changes in the ACO's certified ACO Participant List during the agreement period. This policy is also incorporated in new § 425.603.

We are also finalizing as proposed the conforming and clarifying revisions to the provisions of § 425.602, including to: Revise the title of the section; remove paragraph (c) and incorporate this paragraph in new § 425.603 to address the methodology for establishing, adjusting, and updating the historical benchmark for ACOs that entered a second agreement period in 2016; and to add a paragraph that describes the adjustments made to the ACO's historical benchmark during an ACO's first agreement period to account for changes in severity and case mix for newly and continuously assigned beneficiaries as presently specified under § 425.604, § 425.606, and § 425.610. We are also finalizing as proposed a change to § 425.20, to specify that the acronym ''BY'' stands for benchmark year.

(3) Transitioning to a Higher Weight in Calculating the Adjustment for Regional FFS Expenditures

In the 2016 proposed rule, we considered both the potential positive and negative consequences of quickly transitioning to use of a greater weight (70 percent) in calculating the regional adjustment to ACOs' rebased historical benchmarks. We explained our belief that placing a greater weight on regional expenditures in adjusting an ACO's historical benchmark will encourage existing low spending ACOs in higher spending and/or higher growth regions to enter and continue their participation in the Shared Savings Program. We reiterated our view, expressed in the June 2015 final rule, that the benchmarking methodology should be revised to help ensure that an ACO that has previously achieved success in the program will be rebased under a methodology that encourages its continued participation in the program (see 80 FR 32788). Further, we again noted the importance of quickly moving to a benchmark rebasing approach that accounts for regional FFS expenditures and trends in addition to the ACO's historical expenditures and trends (see 81 FR 5834).

We also explained our concern that existing low spending ACOs operating in regions with relatively higher spending and/or higher growth in expenditures may be positioned to generate savings under the proposed revisions to the rebasing methodology because of the regional adjustment to their rebased historical expenditures rather than as a result of actual gains in efficiency, creating an opportunity for arbitrage. In particular, we expressed concern about the potential for ACOs to alter their healthcare provider and beneficiary compositions or take other such actions in order to achieve more favorable performance relative to their region without actually changing their efficiency. We anticipated these effects would be more pronounced the larger the percentage that is applied to the difference between the average expenditures for the ACO's regional service area and the ACO's rebased historical expenditures when calculating the regional adjustment. However, we expressed our belief that there is uncertainty around the magnitude of these possible negative consequences of adjusting the ACO's rebased benchmark based on regional expenditures in the ACO's regional service area which have yet to be observed. We noted that we believed these concerns are likely to be outweighed by the benefits of encouraging more efficient care through a benchmark rebasing methodology that encourages continued participation by ACOs that are efficient relative to their regional service area by placing greater weight on regional expenditures when resetting the ACO's benchmark over subsequent agreement periods. We explained that the use of a higher percentage in calculating the regional adjustment would create strong incentives for higher spending ACOs to be more efficient relative to their regional service areas while also improving the quality of care provided to their beneficiaries. Furthermore, we explained that this approach would also ensure that ACOs' rebased benchmarks continue to reflect in part their historical spending.

To balance these concerns, we proposed to adopt a phased approach to transitioning to greater weights in calculating the adjustment amount, expressed as a percentage of the difference between regional average expenditures for the ACO's regional service area and the ACO's rebased historical expenditures. Under this approach we would increase the weight used in calculating the adjustment over time, making an ACO's benchmark gradually more reflective of expenditures in its region and less reflective of the ACO's own historical expenditures. This proposed phase-in approach included the following features:

- Maintain the current methodology for establishing the benchmark for an ACO's first agreement period in the Shared Savings Program based on the historical expenditures for beneficiaries assigned to the ACO with no adjustment for expenditures in the ACO's regional service area in order to provide continued stability to the program and the momentum for attracting new organizations. As over 400 ACOs have voluntarily entered the program under this methodology, we believe the current methodology is an important part of facilitating entry into the program by organizations located throughout the nation that have differing degrees of experience with accountable care models and have varying provider compositions.
- Increase the percentage used in calculating the regional adjustment amount, applied to the ACO's rebased historical benchmark, over subsequent agreement periods.

++ We proposed to calculate the regional adjustment in the ACO's second agreement period by applying a weight of 35 percent to the difference between regional average expenditures for the ACO's regional service area and the ACO's rebased historical benchmark expenditures.

++ We proposed that in the ACO's third and subsequent agreement periods, the percentage used in this calculation would be set at 70 percent unless the Secretary determines a lower weight should be applied as specified through future rulemaking.

We discussed that in making a determination of whether a lower weight should be used in calculating the adjustment, the Secretary would assess what effects the regional adjustment (and other modifications to the program made under this rule) are having on the Shared Savings Program, considering factors such as, but not limited to: The effects on net program costs; the extent of participation in the Shared Savings Program; and the efficiency and quality of care received by beneficiaries. As part of this determination, the Secretary may also take into account other factors, such as the effect of implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) on the Shared Savings Program by incentivizing physicians and certain other practitioners to participate more broadly in alternative payment models (APMs).

We noted that such a determination could potentially occur in advance of the first application of this higher percentage. For example, the determination could be made in advance of the agreement period beginning January 1, 2020, which is the start of the third agreement period for ACOs that entered the program in January 2014 and the first group of ACOs to which the revised rebasing methodology being adopted in this final rule will apply. Any necessary modifications to program policies as a result of the Secretary's determination, such as reducing the long-term weight used in calculating the regional adjustment below 70 percent or making other program changes (for example, refinements to the risk adjustment methodology) would be proposed in future rulemaking, such as through the calendar year (CY) 2020 Physician Fee Schedule rule. Subsequently, we would periodically assess the effects of the regional adjustment over time and address any needed modifications to program policies in future rulemaking.

- For ACOs that started in the program in 2012 and 2013 and started their second agreement period on January 1, 2016, we proposed to apply this phased approach when rebasing for their third and fourth (and subsequent) agreement periods, as discussed in section II.A.2.f. of this final rule.

We explained our belief that this phased approach to moving to a higher percentage in calculating the adjustment for regional expenditures would give ACOs sufficient notice of the transition to benchmarks that reflect regional expenditures. Furthermore, we believed this approach to phasing in the use of a greater percentage to calculate the regional adjustment provides a smoother transition for ACOs to benchmarks reflective of regional FFS expenditures, giving ACOs more time to prepare for this change and therefore ultimately maintaining the stability of ACOs, the Shared Savings Program and the markets where ACOs operate. Accordingly, we proposed to incorporate these policies regarding the transition to greater weights in calculating the regional adjustment amount in the new regulation at § 425.603.

We sought public comment on our proposed approach to phase in the weight used in calculating the regional adjustment. We were particularly interested in understanding commenters' thoughts and suggestions about the percentage that should be used in calculating the adjustment for regional FFS expenditures. We also sought comment on the alternatives we considered in the proposed rule including: (1) Limiting the weight used in the calculation of the adjustment to 50 percent (instead of 70 percent) in the ACO's third and subsequent agreement period; (2) a more gradual transition to use of a higher percentage in calculating the adjustment (such as 35 percent in the second agreement period, 50 percent in the third agreement period, and 70 percent in the fourth and subsequent agreement period); and (3) a phase-in approach that uses regional (instead of national) FFS expenditures to trend benchmark year expenditures when establishing and updating the benchmark during an ACO's first agreement period (for agreement periods beginning on or after January 1, 2017). We also sought comment on alternative approaches to address our concerns about selective program participation and arbitrage opportunities that would facilitate our use of a higher percentage in calculating the amount of the adjustment.

Comment: A few commenters shared CMS' concerns about the potential for negative consequences that could result from transitioning to use of factors based on regional FFS expenditures in resetting ACO historical benchmarks, including selective participation creating an opportunity for arbitrage. These commenters were somewhat divided as to the ultimate outcome of these changes. For example, a commenter explained that benchmarking ACOs against their region will have the effect of more seamlessly encouraging transformative physician care, while simultaneously discouraging agreements with entities unwilling or unable to make meaningful changes in care delivery. Further, this commenter encouraged CMS to implement safeguards that deter the negative consequences of transitioning to the use of factors based on regional FFS expenditures in resetting ACO benchmarks (for instance, protecting against ACOs that increase their spending to lock in a higher benchmark, and protecting against benchmarks becoming overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings). Another commenter, concerned about discouraging participation by ACOs with expenditures higher than their regions and those with losses in their first agreement period, and behavioral responses by providers to the revised methodology (for example, ACO avoidance of high-cost beneficiaries), encouraged CMS to delay finalizing the proposed modifications. A commenter identified the availability of traditional FFS, under which providers and suppliers can continue to be paid based on the quantity of services provided (thereby maintaining their status quo for reimbursement rather than entering value based payment models), as being a greater concern for the Trust Funds than the potential threat of arbitrage by ACOs under the revised rebasing methodology. The commenter also noted that the fact that only a portion of ACOs have actually been eligible to share in savings to date is an indication that there is little reason for concern about arbitrage by ACOs. Another commenter counseled that the arbitrage concerns overestimate the flexibility of markets, pointing to the existence of ongoing relationships between healthcare providers, tied to a range of risk bearing contracts, as an example of a mitigating factor. A few commenters specifically encouraged CMS to engage in ongoing monitoring of the effects of the changes, if implemented, with a commenter suggesting CMS address arbitrage concerns by requiring additional reporting by ACOs regarding their use of shared savings payments.

Response: We greatly appreciate commenters' careful consideration of the concerns we specified in the 2016 proposed rule, including the participation incentives that could result from the transition to a rebasing methodology that places a greater weight on a regional FFS adjustment over time. We decline to delay finalizing the changes to rebasing methodology altogether because of concerns about the potential negative effects that could result from these changes, as recommended by a commenter. For the reasons we described in the 2016 proposed rule (and reiterated in this final rule), we believe a phased approach to transitioning to a higher weight in calculating the regional adjustment offers the appropriate balance between our concerns about the potential negative effects of a revised rebasing approach that places a greater weight on regional FFS expenditures and the anticipated benefits of the revised rebasing policies for the sustainability of the program. Elsewhere in this section of this final rule, we discuss in detail issues related to the application of the revised rebasing methodology to ACOs with higher spending than their region. In addition, we will consider the concerns raised in the comments as we monitor the effects of the revised rebasing methodology and as we consider whether further modifications to the rebasing policies are necessary. Any changes to the rebasing methodology would be addressed in future rulemaking.

Comment: Most of the commenters discussing the phase-in of the weights used in calculating the adjustment, generally expressed support for taking an incremental approach to incorporating regional elements when resetting an ACO's benchmark. Some commenters expressed support for the proposed phased-approach to applying an increasing weight in calculating the regional adjustment: To initially calculate the adjustment using a 35 percent weight in rebasing the ACO's second agreement period benchmark and then increase to using a 70 percent weight for subsequent agreement periods. A commenter explained that the proposed phased approach to incorporating regional spending into the benchmark gives ACOs ample time to adjust to the methodological changes. Several commenters were supportive of monitoring the weight (percentage) used in calculating the regional adjustment over time, to assure balance is struck in setting benchmarks. A commenter expressed support for examining the results of the adjustment before switching to a higher weight for the regional spending component. A commenter emphasized the need to assess the effects of the modifications to the benchmarking methodology and to make needed revisions to the policies in

future rulemaking in order to ensure small entities and hospitals (more generally), particularly those in rural and underserved areas, are not placed at a disadvantage.

Many commenters urged CMS to provide more options and greater flexibility to ACOs (referred to by some as establishing a ''glide path'') as they transition to benchmarks containing regional cost data. A few commenters cited the importance of this flexibility to encourage continued participation by small and rural ACOs. Commenters' suggestions focused on allowing ACOs the choice of the proposed approach, as well as options for a faster or slower phase-in, ultimately reaching a weight of 70 percent, over the course of one to three agreement periods (beginning with the ACO's first agreement period), including options for incremental increases in the weight used to calculate the regional adjustment within an agreement period.

Some commenters suggested that CMS apply the phase-in differently for individual ACOs depending on certain characteristics, such as their historical spending, financial performance in the program, or their participation in performance-based risk tracks (Tracks 2 and 3). Some commenters suggested phasing-in the weight differently depending on whether an ACO's historical expenditures were above or below the regional average, encouraging adoption of faster phase-in options to more quickly benefit ACOs with low spending compared to their region, and slower phase-in options to mitigate the anticipated benchmark reductions for ACOs with high spending compared to their region. Commenters suggested allowing additional flexibility on the pace of the phase-in for high performing ACOs and ACOs entering a performance-based risk model (Track 2 or 3).

Many commenters suggested a variety of alternatives to afford ACOs greater choice over the timing of applicability (in particular for ACOs that entered the Shared Savings Program in 2012 and 2013 and started their second agreement period January 1, 2016, as discussed in greater detail in section II.A.2.f of this final rule), and the phase-in to the proposed maximum percentage (for example, within an agreement period).

Commenters supporting incorporation of regional cost data into an ACO's benchmark for its first agreement period in the Shared Savings Program cited perceived benefits including: consistent application of the benchmarking methodology across the program; the potential to create more equitable benchmarks within a market (noting that urban and suburban ACOs tend to have overlapping service areas); and attracting new participants to the Shared Savings Program. When discussing the weight that should be applied when calculating the regional adjustment for an ACO's first agreement period, commenters suggested a range of options, typically with a maximum weight of either 30 or 35 percent. Some commenters suggested applying an increasing weight when calculating the adjustment for the ACO's first agreement period, such as 10 percent in year 1, 20 percent in year 2, and 30 percent (or 35 percent) in year 3.

Several commenters suggested alternative approaches to the methodology proposed, such as: (1) Applying a 100 percent weight when calculating the regional FFS adjustment for ACOs with costs lower than their region, and zero percent weight when calculating the adjustment for ACOs with costs higher than their region; (2) an alternative methodology for calculating the adjustment that would both lower the weight on the regional component and slow its rate of increase; and (3) setting limits on the amount of reduction in the benchmark value that could occur as a result of the regional FFS adjustment.

Response: We are finalizing with modifications our proposal to phase-in a higher weight in calculating the regional adjustment over time starting in an ACO's second agreement period beginning in 2017 and subsequent years and to apply this phased approach to ACOs that entered the program in 2012 and 2013 (that started a second agreement period on January 1, 2016) when rebasing for their third and subsequent agreement periods (as discussed in section II.A.2.f of this final rule). We are persuaded by commenters' concerns that the phase-in outlined in the proposed rule would be too rapid for ACOs with relatively higher spending compared to their region, for which the regional FFS adjustment will be negative and result in lower benchmark values. We are especially concerned that the revised benchmarking methodology could result in attrition from the Shared Savings Program by ACOs that are striving to meet the program's goals, including ACOs that have been previously successful in generating shared savings. We agree with comments suggesting a phase-in approach that applies differing weights in the regional adjustment calculation depending on whether an ACO's historical expenditures were above or below the regional average for the same period. Specifically, we agree with the commenters that suggested use of a lower weight in calculating the adjustment for ACOs with higher spending compared to their region.

Accordingly, we are finalizing an approach that will apply a lower weight in calculating the regional adjustment the first and second time that an ACO's benchmark is rebased under the revised rebasing methodology, for those ACOs determined to have spending higher than their region. However, we will ultimately apply a weight of 70 percent in calculating the adjustment for all ACOs beginning no later than the third time the ACO's benchmark is rebased using the revised methodology. Under this approach, we will make an initial determination about whether the ACO has higher spending compared to its regional service area as part of establishing the ACO's rebased historical benchmark for the applicable agreement period. Consistent with the approach we are finalizing for redetermining the regional FFS adjustment when an ACO makes changes to its certified ACO Participant List within an agreement period, we will also redetermine whether the ACO has higher spending compared to its region, and therefore whether the lower weight should be used in calculating the regional adjustment.

The determination of whether to apply the lower weight in calculating the regional FFS adjustment will include the following steps:

- For each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) we will determine the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark. We will multiply the difference for each Medicare enrollment type by the proportion of the ACO's assigned beneficiary population for that Medicare enrollment type, based on the ACO's assigned beneficiary population for benchmark year 3 of the rebased historical benchmark.
- Take the sum of the differences weighted by the ACO's proportion of assigned beneficiaries by Medicare enrollment type (determined in the previous step). As summarized in Table 2, the result of this step will determine the percentage weight applied in calculating the regional FFS adjustment:

++ If this sum is a net positive value, we will apply the proposed weights for calculating the regional FFS adjustment for the agreement period: 35 percent the first time the benchmark is rebased using the revised methodology; 70 percent the second time the benchmark

is rebased under this methodology, and in all subsequent agreement periods.

++ If this sum is a net negative value, we will apply a relatively lower weight in calculating the regional FFS adjustment in the first two rebasings for which the regional adjustment applies: 25 percent the first time the benchmark is rebased under the revised methodology; and 50 percent the second time the benchmark is rebased under this methodology. A weight of 70 percent will be used in the calculation of the regional adjustment for ACOs that are determined to have higher spending compared to their regional service area during the third rebasing in which this regional adjustment is applied, and in all subsequent agreement periods.

TABLE 2—PERCENTAGE WEIGHT APPLIED IN CALCULATING THE REGIONAL FFS ADJUSTMENT

Agreement period (for example, 2014 starters renewing for 2017)	ACO's spending relative to its region	Weight used to calculate regional adjustment (percent)
Performance year within an agreement period to which regional adjustment is applied for the first time (for example, second agreement period beginning in 2017).	ACO spending is higher than its regional service area.	25
	ACO spending is lower than its regional service area.	35
Performance year within an agreement period to which regional adjustment is applied for the second time (for example, third agreement period beginning in 2020).	ACO spending is higher than its regional service area.	50
	ACO spending is lower than its regional service area.	70
Performance year within an agreement period to which regional adjustment is applied for the third time (for example, fourth agreement period beginning in 2023 and subsequent years).	ACO spending is higher than its regional service area.	70
	ACO spending is lower than its regional service area.	70

After making the determination of the weight to be applied in calculating the regional FFS adjustment, we follow the remaining steps for calculating the regional FFS adjustment described in section II.A.2.c.2 of this final rule:

- Multiply the difference between the average per capita expenditure amount for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark for each Medicare enrollment type by the applicable percentage shown in Table 2. This is the adjustment amount for each Medicare enrollment type.
- Apply the adjustment to the ACO's rebased historical benchmark by adding the adjustment amount for the Medicare enrollment type to the truncated, trended and risk adjusted average per capita value of the ACO's rebased historical benchmark for the same Medicare enrollment type.
- Multiply the adjusted value of the ACO's rebased historical benchmark for each Medicare enrollment type by the proportion of the ACO's assigned beneficiary population for that Medicare enrollment type, based on the ACO's assigned beneficiary population for benchmark year 3 of the rebased historical benchmark.
- Sum expenditures across the four Medicare enrollment types to determine the ACO's adjusted rebased historical benchmark.

We reiterate that, as we explained in the 2016 proposed rule, the Secretary will assess what effects the regional adjustment (and other modifications to the program made under this rule) are having on the Shared Savings Program to determine whether a lower weight (than 70 percent) should be used in calculating the regional adjustment. Any necessary modifications to program policies as a result of the Secretary's determination, such as reducing the long-term weight used in calculating the regional adjustment below 70 percent or making other program changes would be proposed in future rulemaking.

We believe this phased approach represents a middle ground between the comments supporting the proposal, as well as recommendations for relatively faster or slower phase-in of the adjustment based on the historical costs of the ACO compared to its region. We chose the lower weights of 25 percent (compared to 35 percent) and 50 percent (compared to 70 percent) to balance providing a more gradual phase in to ACOs with higher spending compared to their region with our projected estimates of the impact of this policy on the Medicare Trust Funds. We believe these lower weights align with commenters' suggestions for application of a weight less than 35 percent (for example, between 10 percent and 30 percent), as well as our consideration of a more gradual phase-in of the adjustment by applying weights of 35 percent, 50 percent, and 70 percent in calculating the regional adjustment over the course of 3 agreement periods under the revised rebasing methodology as discussed in the 2016 proposed rule.

Incrementally lowering benchmarks for ACOs determined to have higher spending than their region over the course of multiple agreement periods will afford these ACOs time to adapt to the revised rebasing methodology. This gradual phase in may be especially important for successful ACOs with relatively higher costs that may otherwise leave the program if faced with a more rapid phase-in to a rebased benchmark reflecting factors based on regional FFS expenditures. We decline to forgo applying the regional adjustment altogether to ACOs with costs higher than their region, as recommended by the comment suggesting use of a zero percent weight in calculating the regional adjustment for these ACOs. We believe such an approach, which would ensure that the benchmark for these ACOs would continue to be based largely on their own historical spending, would undermine the purpose of a policy that seeks to incrementally make an ACO's benchmark less dependent on its own historical spending and more reflective of spending in its regional service area.

We also continue to believe this phased approach mitigates our concerns about the opportunity for arbitrage that could result from establishing higher benchmarks for ACOs with relatively lower spending compared to their region; a concern that is heightened when considering a more rapid phase-in to a higher weight in calculating the regional adjustment. Specifically, an approach that would more quickly produce more generous benchmarks for ACOs could hasten organizations to alter their behavior or composition to

better position themselves to achieve favorable performance relative to their region under this methodology without actually changing their efficiency. For this reason, we decline to adopt alternative approaches recommended by commenters that would apply higher weights in the regional adjustment calculation for ACOs that are lower spending compared to their regions (such as applying a 100 percent weight in calculating the adjustment).

The approach we are finalizing recognizes that changes in the ACO's certified ACO Participant List during an agreement period could result in changes in the ACO's historical spending patterns and accordingly would result in a change to the weight used in calculating the regional adjustment. We believe this approach is responsive to commenters' requests for a flexible approach, particularly because it would ensure that we always apply the most advantageous weight in calculating the adjustment for each performance year within the agreement period according to whether the ACO's historical spending based on its most recent certified ACO Participant List is relatively higher or lower compared to spending in its regional service area.

We decline at this time to adopt commenters' suggestions to apply differing weights in the calculation of the regional adjustment depending on other characteristics of ACOs, such as past performance in the Shared Savings Program, or participation in a performance-based risk track. At this time, we believe the most significant consideration in determining the weight applied in the calculation of the regional adjustment is the level of the ACO's historical spending compared to its regional service area. Consistent with our decision to finalize the proposal to remove the adjustment for savings generated under the ACO's prior agreement period in calculating the ACO's rebased historical benchmark, as we discuss in section II.A.2.c.2 of this final rule, we also decline to otherwise account for an ACO's prior savings in determining the regional FFS adjustment that is applied to the ACO's rebased historical benchmark.

We are concerned that offering the broader flexibility suggested by commenters, including allowing ACOs to choose from a menu of options for when the revised rebasing methodology would apply and the weight that would be used to calculate the regional adjustment, may invite selective participation by those ACOs that would be most advantaged by the new benchmarking methodology, thereby increasing the opportunity for arbitrage. As previously noted in this final rule, we do not believe it would be operationally feasible to apply customized benchmarking methodologies to ACOs across the program.

In contrast, we believe commenters make a convincing argument for a phased approach to incorporating regional factors into ACO benchmarks beginning with the ACO's initial agreement period in the Shared Savings Program. We find particularly persuasive the suggestion that this approach may offer the optimal glide-path for ACOs, and also result in greater consistency across program benchmark calculations. However, given the diversity of comments suggesting faster and slower phase-in of the regional adjustment, we believe it will be important to gain experience with the use of the regional adjustment as part of the rebasing methodology before seeking to adopt the adjustment as part of the methodology used to establish the ACO's first agreement period benchmark. Therefore, we plan to explore, the possibility of extending the phase-in by applying the regional adjustment to an ACO's first agreement period benchmark with a weight equal to or lower than 35 percent, in combination with using alternative factors to trend the ACO's historical benchmark (BY1 and BY2 to BY3) and to update the benchmark during the agreement period (discussed in section II.A.2.d. of this final rule). Any changes to the methodology used to establish an ACO's benchmark for its first agreement period would be addressed in future rulemaking.

FINAL ACTION: We are finalizing with modifications a phased approach to transitioning to greater weights in calculating the regional adjustment amount, which is expressed as a percentage of the difference between regional average expenditures for the ACO's regional service area and the ACO's rebased historical expenditures. This approach maintains the current methodology for establishing the benchmark for an ACO's first agreement period in the Shared Savings Program based on the historical expenditures for beneficiaries assigned to the ACO with no adjustment for expenditures in the ACO's regional service area, and the current methodology for resetting the historical benchmark for the second agreement period for ACOs that entered the program in 2012 and 2013 and started a new agreement period on January 1, 2016.

We will apply the regional adjustment to the ACO's rebased historical benchmark for ACOs entering a second or subsequent agreement period in 2017 and subsequent years. We will use the following phased-approach to determine the weight used in calculating the adjustment, which includes applying a lower weight the first and second time the ACO's benchmark is rebased using the regional adjustment if the ACO is determined to have spending higher than its region:

- The first time that an ACO's benchmark is rebased using the regional adjustment:

++ CMS uses a weight of 35 percent of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's rebased historical benchmark amount, if the ACO is determined to have lower spending than its regional service area;

++ The percentage used in this calculation will be set at 25 percent if the ACO is determined to have higher spending than its regional service area.

- The second time that an ACO's benchmark is rebased using the regional adjustment:

++ CMS uses a weight of 70 percent of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's rebased historical benchmark amount if the ACO is determined to have lower spending than the ACO's regional service area, unless the Secretary determines a lower weight should be applied, as specified through future rulemaking;

++ The percentage used in this calculation will be set at 50 percent if the ACO is determined to have higher spending than the ACO's regional service area.

- The third or subsequent time that the ACO's benchmark is rebased using the regional adjustment, the percentage used in this calculation will be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking.
- If CMS adjusts the ACO's benchmark during the term of the agreement period to reflect the addition or removal of ACO participants or ACO providers/suppliers, CMS will redetermine whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage to be used in calculating the regional adjustment.

We are incorporating this phased approach to transitioning to greater weights in calculating the regional adjustment in new § 425.603.

As discussed in section II.A.2.f of this final rule, this phased approach will apply to ACOs that entered the program

in 2012 and 2013 and started their second agreement period on January 1, 2016, for the first time in calculating their rebased historical benchmark for their third agreement period (beginning in 2019).

d. Parity Between Establishing and Updating the Rebased Historical Benchmark

(1) Background

In the 2016 proposed rule we provided background on policies regarding the historical benchmark trend factors and annual benchmark updates during the agreement period, including our previous consideration of whether to base these trend and update factors on State, local or regional expenditures instead of national FFS expenditures (see 81 FR 5836 through 5838).

In the initial rulemaking to establish the Shared Savings Program, we identified the need to trend forward the expenditures in each of the 3 years making up the historical benchmark. As explained in earlier rulemaking, because the statute requires the use of the most recent 3 years of per-beneficiary expenditures for Parts A and B services for FFS beneficiaries assigned to the ACO to estimate the benchmark for each ACO, the per capita expenditures for each year must be trended forward to current year dollars before they are averaged using the applicable weights to obtain the benchmark (see 76 FR 19609). In the November 2011 final rule, we finalized an approach under § 425.602(a)(5) for trending forward benchmark expenditures based on national FFS Medicare growth rates for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (76 FR 67924 and 67925). We also explained that making separate calculations for specific groups of beneficiaries—specifically the aged/dual eligible, aged/non-dual eligible, disabled, and ESRD populations—accounts for variation in costs of these groups of beneficiaries, resulting in more accurate calculations (76 FR 67924). We considered using national, State or local growth factors to trend forward historical benchmark expenditures (76 FR 19609 through 19610 and 76 FR 67924 through 67925).

Among other considerations, we explained that the anticipated net effect of using the same trending factor based on the national growth rate for all ACOs would be to provide a relatively higher benchmark for low growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. ACOs in high cost, high growth areas would therefore have an incentive to reduce their rate of growth more to bring their costs more in line with the national average; while ACOs in low cost, low growth areas would have an incentive to continue to maintain or improve their overall lower spending levels (see 76 FR 67925). We also explained that use of the national growth rate could also disproportionately encourage the development of ACOs in areas with historical growth rates below the national average (see 76 FR 19610). These ACOs would benefit from having a relatively higher benchmark, which would increase the chances for shared savings. On the other hand, ACOs in areas with historically higher growth rates above the national average would have a relatively lower benchmark, and might be discouraged from participating in the program (see 76 FR 19610).

In contrast, as we explained in the initial rulemaking to establish the Shared Savings Program, trending expenditures based on State or local area growth rates in Medicare Parts A and B expenditures may more accurately reflect the experience in an ACO's area and mitigate differential incentives for participation based on location (see 76 FR 19610). We considered, but did not finalize, an option to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate (see 76 FR 19610 and 76 FR 67925). This option balanced providing a more accurate reflection of local experience with not rewarding historical growth higher than the national average. We believed this method would instill stronger saving incentives for ACOs in both high growth and low growth areas (see 76 FR 19610).

Section 1899(d)(1)(B)(ii) of the Act states that the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Further, the Secretary's authority under section 1899(i)(3) of the Act, for implementing other payment models, allows for alternatives to using national expenditures for updating the benchmark, as long as the Secretary determines the approach improves the quality and efficiency of items and services furnished under Medicare and does not to result in additional program expenditures.

In the initial rulemaking, we finalized our policy under § 425.602(b) to update the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as specified under section 1899(d)(1)(B)(ii) of the Act. Further, consistent with the final policies for calculating the historical benchmark (among other aspects of the Shared Savings Program's financial models) the calculations for updating the benchmark are made for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (76 FR 67926 and 67927). In developing this policy, we also considered using our authority under section 1899(i)(3) of the Act to update the benchmark by the lower of the projected absolute amount of growth in national per capita expenditures and the projected absolute amount of growth in local/state per capita expenditures (see 76 FR 19610 and 19611).

Among other considerations, we explained that using a flat dollar increase, which would be the same for all ACOs, provides a relatively higher expenditure benchmark for low growth, low spending ACOs and a relatively lower benchmark for high growth, high spending ACOs. Therefore, ACOs in high spending, high growth areas must reduce their rate of growth more (compared to ACOs in low spending, low growth areas) to bring their costs more in line with the national average (see 76 FR 19610). We also indicated that these circumstances could contribute to selective program participation by ACOs favored by the national flat-dollar update, and ultimately result in Medicare costs from shared savings payments that result from higher benchmarks rather than an ACO's care coordination activities (see 76 FR 19610 through 19611 and 19635). Incorporating more localized growth factors reflects the expenditure and growth patterns within the geographic area served by ACO participants, potentially providing a more accurate estimate of the updated benchmark based on the area from which the ACO derives its patient population (76 FR 19610).

In the June 2015 final rule, we discussed comments received on benchmark rebasing alternatives discussed in the December 2014 proposed rule that would include using regional FFS expenditures, instead of national FFS expenditures, to develop the historical benchmark trend factors and to update the benchmark during the agreement period (79 FR 72839; 79 FR 72841 through 72843; 80 FR 32792, 32794). We indicated our plan to consider further what additional

adjustments should be made to the benchmarking methodology when moving to a rebasing approach that accounts for regional FFS trends, including whether to incorporate regional FFS expenditures in updating an ACO's historical benchmark each performance year or to maintain the policy under which we update an ACO's benchmark based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program (80 FR 32796).

(2) Regional Growth Rate as a Benchmark Trending Factor

We proposed to replace the national trend factors currently used for trending an ACO's BY1 and BY2 expenditures to BY3 in calculating an ACO's rebased historical benchmark with regional trend factors derived from a weighted average of risk adjusted FFS expenditures in the counties where the ACO's assigned beneficiaries reside. Further, we proposed to calculate and apply these trend factors for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. We proposed to incorporate these changes in a new regulation at § 425.603.

To align with the proposed methodology for calculating regional FFS expenditures for an ACO's regional service area, we considered the following approach for calculating regional FFS trend factors:

- For each benchmark year, calculate risk adjusted county FFS expenditures for the ACO's regional service area. County FFS expenditures would be determined consistent with other proposals discussed in the 2016 proposed rule, by using total county-level FFS Parts A and B expenditures for assignable beneficiaries, excluding IME, DSH, and uncompensated care payments, but including beneficiary identifiable payments made under a demonstration, pilot or time limited program; regional expenditures would be calculated for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible);
- For each benchmark year, compute a weighted average of risk adjusted county-level FFS expenditures using weights that reflect the proportion of an ACO's assigned beneficiaries residing in each county within the ACO's regional service area. Calculations would be done by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) based on the ACO's benchmark year assigned population.
- Compute the average growth rates from BY1 to BY3, and from BY2 to BY3, using the weighted average of risk-adjusted county level FFS expenditures for the respective benchmark years, for each Medicare enrollment type.

We explained that we would apply these regional trend factors to the ACO's historical benchmark expenditures, which are also adjusted based on the CMS–HCC model, to account for the severity and case mix of the ACO's assigned beneficiaries in each benchmark year.

We discussed that using regional trend factors, instead of national trend factors to trend forward expenditures in the benchmark period, would further incorporate regional FFS spending and population dynamics specific to the ACO's regional service area in the ACO's rebased benchmark. We explained our belief that there are number of relevant considerations for moving to use of regional trend factors, including the following:

- Regional trend factors would more accurately reflect the cost growth experience in an ACO's regional service area compared to use of national trend factors.
- Regional trend factors would reflect the change in the health status of the FFS population that makes up the ACO's regional service area, the region's geographic composition (such as rural versus urban areas), and socio-economic differences that may be regionally related.
- Regional trend factors could better capture location-specific changes in Medicare payments (for example, the area wage index) compared to use of national trend factors.

We also considered how use of regional trend factors in resetting ACO benchmarks could affect participation by relatively high- and low-growth ACOs operating in regions with high and low growth in Medicare FFS expenditures. We anticipated the following:

- Using regional trend factors would result in relatively higher benchmarks for ACOs that are low growth in relation to their region compared to benchmarks for ACOs that are high growth relative to their region. Therefore, use of regional FFS trends could disproportionately encourage the development of and continued participation by ACOs with rates of growth below that of their region. These ACOs would benefit from having a relatively higher benchmark, which would increase their chances for shared savings. On the other hand, ACOs with historically higher rates of growth above the regional average would have a relatively lower benchmark and may be discouraged from participating if they are not confident of their ability to bring their costs in line with costs in their region.
- In using regional growth rates specific to an ACO's regional service area and composition (by Medicare enrollment type), there would likely be significant variation in the growth rates between health care markets in different regions of the country and even between ACOs operating in the same markets. This approach would be a departure from the current methodology, which applies a single set of national growth factors calculated for each benchmark year by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). However, ACOs familiar with the composition of their assigned population and cost trends in their regional service area may find they can more readily anticipate what these trend factors may be. We indicated that stakeholders may find it helpful to observe differences in county FFS expenditures using the data files made publicly available in conjunction with the 2016 proposed rule.

We sought comment on the proposed change to the rebased historical benchmark trend factor. We also considered and sought comment on several alternative approaches, including:

- Using regional trend factors for trending forward an ACO's BY1 and BY2 expenditures to BY3 in establishing and resetting historical benchmarks under the approach to resetting ACO benchmarks established with the June 2015 final rule (under which we equally weight the benchmark years, and account for savings generated under the ACO's prior agreement period), as an alternative to adopting the approach to adjusting rebased benchmarks to reflect FFS expenditures in the ACO's regional service area, as discussed in the 2016 proposed rule.
- Applying regional trend factors for trending forward BY1 and BY2 expenditures to BY3 in establishing the benchmark for an ACO's first agreement period under § 425.602(a), allowing this policy to be applied consistently program-wide beginning with an ACO's first agreement period.

Comment: Some commenters discussed issues relevant both to the proposal to replace national growth rates with regional growth rates for trending the rebased benchmark (BY1 and BY2 expenditures to BY3) and the proposed use of regional growth rates instead of a national flat dollar amount to update the benchmark each performance year. The following

summary reflects these more general considerations, while later in this section of this final rule we discuss comments specific to each of these proposals. Comments were somewhat divided between support for and concerns about the proposals on using regional FFS expenditures instead of national FFS expenditures in calculating trend and update factors. Broader considerations reflected in the comments, relevant to both proposals include the following:

- Among commenters supporting the proposed use of regional growth rates instead of factors based on national FFS expenditures in benchmark calculations, some believed this approach generally would result in benchmarks that better reflect the regional patterns in spending and costs. Additionally, several commenters explained that the use of national FFS expenditures as a component of the benchmark does not accurately reflect what is possible for ACOs to achieve, in terms of controlling growth in Medicare spending, within their geographic area or with respect to their assigned patient population.
- Some commenters disagreed with the proposed use of regional growth rates in benchmark calculations, perceiving that these modifications could negatively impact benchmarks by, for example: (1) Allowing individual provider anomalies to have a material impact on an ACO's benchmark; (2) lowering benchmarks (compared to the current methodology) for ACOs in low growth regions, with a commenter noting that ACOs in higher-growth areas would be rewarded with higher benchmarks; (3) lowering benchmarks in regions where ACOs have been successful in reducing growth in expenditures (particularly for successful ACOs that are dominant in a region, or ACO-heavy regions).
- Some commenters were concerned about the discussion in the proposed rule indicating that the proposed changes could have mixed effects, increasing and decreasing benchmarks for ACOs depending on their circumstances.
- Several commenters expressed support for adopting the use of regional trend and update factors across all ACOs, including ACOs within their first agreement period. A commenter explained that applying different methodologies in the first and subsequent agreement periods adds complexity and reduces predictability of the benchmark values.

A few commenters noted CMS' larger goal of reducing regional variation in health care utilization and costs. A commenter expressed concern that using regional factors to formulate benchmarks for Shared Savings Program ACOs may exacerbate geographic variation and is antithetical to CMS' broader goal of reducing this variation. However, another commenter stated that use of regional expenditure growth rates rather than national expenditure growth rates in benchmark calculations will better facilitate CMS' goal of encouraging Shared Savings Program ACOs to transition to risk bearing arrangements.

Response: We appreciate commenters' support of the proposed use of growth rates based on regional FFS expenditures to trend forward BY1 and BY2 expenditures to BY3 when establishing the ACO's rebased historical benchmark and to annually update the ACO's rebased historical benchmark, as well as comments describing concerns with use of regional growth rates in these calculations. We agree with comments indicating the use of regional growth rates for the trend and update factors will have mixed effects on ACOs' rebased benchmarks, increasing or decreasing the benchmark values depending on the growth rates determined for the ACO's regional service area as we described in the 2016 proposed rule and reiterate in this final rule. As discussed in greater detail in section II.A.2.d.3 of this final rule, we plan to explore through future rulemaking alternative approaches to calculating the trend and update factors that may help mitigate concerns raised by some commenters about the potential disadvantages for some ACOs of transitioning from national to regional trend and update factors. We also plan to explore through future rulemaking suggestions by some commenters to begin to incorporate regional factors in the ACO's first agreement period.

On the whole, for the reasons described in the 2016 proposed rule and echoed in some comments, we believe these policy changes are an important step towards making an ACO's rebased historical benchmark more reflective of the ACO's regional service area including better reflecting the region's cost experience, location-specific Medicare payment changes, as well as the health status of the region's FFS population. We believe these changes to the methodology are responsive to stakeholders' requests that we incorporate regional FFS expenditures into the ACO's rebased historical benchmark, and therefore are critical to ensuring the sustainability of the program.

Comment: Commenters also offered suggestions specific to the proposed use of regional growth rates for trending the rebased benchmark. Although some commenters were supportive of the proposed methodology for calculating the growth rates to be used as trend factors in establishing an ACO's rebased historical benchmark, a commenter conditioned support for use of regional trend factors on the ACO's spending being compared to spending for the regional Medicare FFS population excluding beneficiaries assigned to the ACO or any other ACO in the region. Some commenters disagreed with the proposed change from using national FFS expenditures to using regional FFS expenditures to calculate the trend factors used to establish an ACO's rebased historical benchmark, for reasons previously described in this section of this final rule.

Response: We are finalizing as proposed the use of regional growth rates to calculate the trend factor for establishing an ACO's rebased historical benchmark. We appreciate commenters' support for this approach, which we believe will more quickly transition the program to benchmark calculations reflecting spending, and spending growth, in the ACO's regional service area and is consistent with the approach we are finalizing for calculating the annual update to the ACO's rebased historical benchmark. For these reasons, we decline the suggestion by some commenters to continue using trend factors based on national FFS expenditures in establishing an ACO's rebased historical benchmark.

In section II.A.2.b of this final rule, we discuss comments suggesting exclusion of ACO assigned beneficiaries from the population used to determine expenditures for the ACO's regional service area, and the reasons why we believe it is appropriate to include ACO assigned beneficiaries when calculating regional FFS expenditures. For the same reasons, we believe it is appropriate to include expenditures for these ACO assigned beneficiaries when determining regional trend and update factors.

Comment: A few commenters recommended alternative approaches to using regional growth rates for trending benchmark expenditures to establish an ACO's rebased historical benchmark not discussed in the proposed rule. For example, a commenter suggested a methodology that would account for both national and regional FFS expenditure trends, expressing concern that replacing the national trend factor with only a regional trend factor would pose additional challenges for ACOs in low-cost regions to meet the benchmark. Another commenter suggested allowing

ACOs a choice of regional or national trend factors, explaining that this choice would allow each ACO to take into consideration the many competitive factors driving change within its local market.

Response: We decline to adopt any of the alternative approaches recommended by commenters for calculating the trend factors. Elsewhere in this section of this final rule we discuss concerns that use of regional growth rates in benchmark calculations for the trend factors and the annual update will result in relatively lower benchmarks for ACOs in regions where spending growth is limited compared to areas with higher spending growth. In section II.A.2.d.3 of this final rule, we discuss our plan to explore an alternative approach to calculating the annual update, and also the benchmark trend factors, using standardized national FFS expenditures. We believe this approach has the potential to address the concerns raised by the commenter that suggested using an approach to determining trend factors that accounts for both national and regional FFS expenditure trends. We also decline at this time to adopt the commenter's suggestion for an approach that (by design) would allow ACOs the choice between trend factors (national or regional). Such an approach could lead to opportunities for arbitrage and may dull incentives for ACOs to improve their performance under the Shared Savings Program, as well as create additional operational complexities for implementing the policy.

Comment: Some commenters supported using a similar approach to calculate both the trend factors used in establishing the ACO's rebased historical benchmark and the annual update to the rebased benchmark, as described in the 2016 proposed rule. A commenter expressed concern that the descriptions of the calculations for the proposed regional trend factors and annual update were based on different parameters but arrived at the same outcome.

Response: In the 2016 proposed rule (81 FR 5838 and 5839), we outlined the steps for calculating the regional growth rates for the regional trend factors used in establishing the ACO's rebased benchmark and for the annual update to the ACO's rebased benchmark. We appreciate the commenter's attention to the details in the descriptions of our proposed methodologies for trending and updating the benchmark. The methodologies used to calculate the growth rates for the trend factor and annual update are the same: for both the trend factor and the annual update, we will determine risk-adjusted county FFS expenditures for the ACO's regional service area, calculated by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) for the relevant reference years, and determine the percentage change in regional FFS expenditures for the ACO's regional service area. However, there are certain necessary differences in the reference years used for purposes of trending and updating the benchmark. Specifically, the trend factors represent the growth rates between the ACO's historical benchmark years (trend factor of BY1 and BY2 to BY3), whereas the annual update represents the growth rate between benchmark year 3 and the performance year. Therefore, both growth rates will reflect changes in expenditures for the ACO's regional service area (according to the counties of residence of the ACO's assigned beneficiaries) for each of the 2 reference years used in determining the applicable growth rate. We believe that the approaches are generally consistent and together they will result in a benchmark that consistently reflects the rate of growth in expenditures for the ACO's region.

FINAL ACTION: We are finalizing as proposed the use of regional growth rates, derived from a weighted average of risk adjusted FFS expenditures for the ACO's regional service area, determined by the counties where the ACO's assigned beneficiaries reside, to trend forward an ACO's BY1 and BY2 expenditures to BY3 in calculating an ACO's rebased historical benchmark. We will calculate and apply these trend factors for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. We are incorporating this methodology at § 425.603(c)(5).

(3) Updating the Reset Benchmark During the Agreement Period

Using the authority of section 1899(i)(3) of the Act, we proposed to include a provision in a new regulation at § 425.603 to specify that for ACOs in their second or subsequent agreement period whose rebased historical benchmark incorporates an adjustment to reflect regional expenditures, the annual update to the benchmark will be calculated as a growth rate that reflects growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area. Further, we proposed to calculate and apply separate update factors based on risk adjusted regional FFS expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. We proposed that this approach would replace the annual update to the historical benchmark for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program under section 1899(d)(1)(B)(ii) of the Act. We explained our considerations in developing this proposal and sought comment on the proposed methodology.

We considered the following issues in developing our proposed modification to the methodology for updating the ACO's rebased historical benchmark:

- Using an update factor based on the regional FFS expenditures for the ACO's regional service area to update an ACO's rebased historical benchmark during the ACO's second or subsequent agreement period would align with our proposal to use regional FFS expenditures in developing the trend factors for the rebased historical benchmark (to trend BY1 and BY2 expenditures to BY3) and our proposal to adjust the ACO's rebased historical benchmark to reflect regional FFS expenditures.
- Updating the benchmark based on regional FFS expenditures annually, during the course of the agreement period, would result in a benchmark used to determine shared savings and shared losses for a performance year that reflects trends in regional FFS growth for the ACO's regional service area for the corresponding year. We explained that calculating the update factor using regional FFS expenditures would better capture the cost experience in the ACO's region, the health status and socio-economic dynamics of the regional population, and location-specific Medicare payments, when compared to using national FFS expenditures.
- Adopting this approach would require our use of authority under section 1899(i)(3) of the Act as it is a departure from the methodology for annually updating the benchmark specified under section 1899(d)(1)(B)(ii) of the Act.

We considered using the following approach to calculate the regional update amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible):

- For each calendar year corresponding to a performance year, calculate risk adjusted county FFS expenditures for the ACO's regional service area. As described in the 2016 proposed rule, county FFS expenditures would be determined using total county-level FFS Parts A and B

expenditures for assignable beneficiaries, excluding IME, DSH, and uncompensated care payments, but including beneficiary identifiable payments made under a demonstration, pilot or time limited program, truncated and risk adjusted for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). The ACO's regional service area would be defined based on the ACO's assigned beneficiary population used to perform financial reconciliation for the relevant performance year.

- Compute a weighted average of risk adjusted county-level FFS expenditures with weights based on the proportion of an ACO's assigned beneficiaries residing in each county of the ACO's regional service area. Calculations would be done by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) based on the ACO's assigned population used to perform financial reconciliation for the relevant performance year.
- Although not specified in the 2016 proposed rule, a necessary step in this calculation is computing the growth rates as the ratio of weighted average risk-adjusted county level FFS expenditures for the applicable 2 years. To clarify, we would determine the regional growth rates by comparing expenditures determined in the previous step for the relevant performance year with expenditures for BY3.

We considered whether to calculate a flat dollar equivalent of the projected absolute amount of growth in regional per capita expenditures for Parts A and B FFS services, or whether to calculate the percentage change in growth in regional FFS expenditures for the ACO's regional service area. We discussed issues related to use of a growth rate or a flat dollar amount in the initial rulemaking to establish the Shared Savings Program, including our view that a growth rate would more accurately reflect each ACO's historical experience, but could also perpetuate current regional differences in medical expenditures (see 76 FR 19609 through 19610 and 76 FR 67924). Based on the reasons discussed in the earlier rulemaking, we noted our belief that using growth rates to determine the annual update would more effectively capture changes in the ACO's regional service area expenditures and changes in the health status of the ACO's population in comparison to the health status of the population of the ACO's regional service area over time. We explained that using a growth rate to update ACOs' benchmarks would also result in proportionately larger updates for higher spending ACOs in the region and lower updates for lower spending ACOs in the region and would strike a balance with the flat-dollar average regional expenditures used to adjust the ACOs historical benchmark.

We further described the anticipated effects of the proposed change to the methodology for calculating the update to an ACO's rebased historical benchmark, including:

- The use of an update factor based on regional FFS spending offers different incentives compared to an update factor reflecting only growth in national FFS spending. For instance, accounting for national FFS spending in an ACO's benchmark update would provide a relatively higher expenditure benchmark for low spending ACOs in low growth areas and a relatively lower benchmark for high spending ACOs in high growth areas. In contrast, accounting for changes in regional FFS spending between the benchmark and the performance year by updating the benchmark according to changes in regional FFS expenditures would ensure that the benchmark continues to reflect recent trends in FFS spending growth in the ACO's region throughout the duration of the ACO's agreement period.
- The use of an update factor based on regional FFS spending will likely result in significant variation in annual benchmark updates for individual ACOs, reflecting the cost experience in each ACO's individualized regional service area along with changes in the health status of the population of patients served by the ACO as well as changes in the types of Medicare entitlement status in the ACO's assigned beneficiary population. The degree of year-to-year change in expenditures will likely vary in both existing low- and high-growth regions and could also vary significantly from expectations. We explained, based on our past experience with calculating the 2012 national FFS growth factors (as used for interim reconciliation for the 2012 starters), the potential for negative updates and corresponding decreases in benchmark values.

We also considered how to apply the update to the ACO's rebased historical benchmark adjusted for expenditures in the ACO's regional service area. We specified that the update would be applied after all adjustments are made to the ACO's rebased benchmark. We detailed a sequence for these adjustments and the application of the update that would maintain the overall structure of the program's current methodology, and align with the other revisions to the methodology used to calculate an ACO's rebased historical benchmark described in the 2016 proposed rule.

We explained it would be necessary to use the discretionary authority in section 1899(i)(3) of the Act to adopt a policy under which we would calculate the benchmark update using regional FFS expenditures. Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models in place of the payment model outlined in section 1899(d) of the Act as long as the Secretary determines these other payment models will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. We explained our belief that updating an ACO's rebased historical benchmark based on regional FFS spending, rather than national FFS spending, would have positive effects for the Shared Savings Program and Medicare beneficiaries. As described in the regulatory impact analysis of the 2016 proposed rule, we noted the proposed changes to the payment model used in the Shared Savings Program, including updating the ACO's rebased historical benchmark based on regional FFS spending, were anticipated to increase overall participation in the program, improve incentives for ACOs to invest in effective care management efforts, and increase the accuracy of benchmarks in capturing the experience in an ACO's regional service area compared to the use of national FFS expenditures. Therefore, we believed these changes would result in improved quality of care furnished to Medicare beneficiaries, and greater efficiency of items and services furnished to these beneficiaries, as more ACOs enter and remain in the Shared Savings Program and continue to work to meet the program's three-part aim of better care for individuals, better health for populations and lower growth in expenditures.

We noted that section 1899(i)(3)(B) of the Act provides that the requirement that the other payment model not result in additional program expenditures ''shall apply . . . in a similar manner as [subparagraph (b) of paragraph (2) of section 1899(i)] applies to the payment model under [section 1899(i)(2)].'' Section 1899(i)(2) of the Act provides discretion for the Secretary to use a partial capitation model rather than the payment model described in section 1899(d) of the Act. Section 1899(i)(2)(B) of the Act provides that payments to an ACO for items and services for beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such

beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary.

We explained that we had not previously addressed this provision in rulemaking. We stated our belief that we could use a number of approaches to address this statutory requirement, for example: Through an initial estimation that the model does not result in additional expenditures that spans multiple years of implementation; by a periodic assessment that the model does not result in additional program expenditures; or by structuring the model in a way such that CMS could not spend more for an ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented. However, because section 1899(i)(3)(B) of the Act states only that the requirement that the payment model not result in additional program expenditures must be applied in ''a similar manner'' to the requirement under section 1899(i)(2)(B) of the Act, we explained our belief that we have some discretion to tailor this requirement to the payment framework that is being adopted under the other payment model.

The regulatory impact analysis of the 2016 proposed rule discussed our analysis of the requirement under section 1899(i)(3)(B) of the Act that the other payment model must not result in additional program expenditures, and our initial assessment of the costs associated with a payment model that includes changes to the manner in which we update the benchmark during an ACO's agreement period. We compared all current policies and proposed policies to policies that could be implemented under section 1899(d)(1)(B)(ii) of the Act, and assessed that for the period spanning 2017 through 2019 there would be net federal savings. Therefore, we believed that the proposed alternative payment model under section 1899(i)(3) of the Act, which includes the use of regional FFS expenditures to update an ACO's rebased historical benchmark and the use of FFS expenditures of assignable beneficiaries to calculate the national benchmark update for ACOs in their first agreement period and those ACOs that started a second agreement period on January 1, 2016, as well as policies established using the authority of section 1899(i)(3) of the Act in earlier rulemaking, meets the requirement under section 1899(i)(3)(B) of the Act. We anticipated that the costs of this alternative payment model would be periodically reassessed as part of the impact analysis for subsequent rulemaking regarding the payment models used under the Shared Savings Program. However, we explained that in the event we do not undertake additional rulemaking, we intend to periodically reassess whether a payment model established under authority of section 1899(i)(3) of the Act continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. If we determine the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the alternative payment model results in net program costs, we would undertake additional notice and comment rulemaking to make adjustments to our payment methodology to assure continued compliance with the statutory requirements.

We clarified that the current methodology for calculating the annual update would continue to apply in updating an ACO's historical benchmark during its first agreement period, as well as in updating the rebased historical benchmark for the second agreement period for ACOs that started in the program in 2012 or 2013, and entered their second agreement period on January 1, 2016. That is, for these ACOs, we would continue to update the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. Consistent with the discussion in section II.A.2.e.3 of this final rule, these calculations will be performed based on assignable beneficiaries.

We also discussed and sought comment on alternatives to the proposed approach, including: (1) Calculating the update factor as the flat dollar equivalent of the projected absolute amount of growth in regional per capita expenditures for Parts A and B services for the ACO's regional service area; and (2) using regional FFS expenditures, instead of national FFS expenditures, to update an ACO's historical benchmark beginning with its first agreement period.

Comment: In section II.A.2.d.2 of this final rule, we describe and respond to comments regarding the use of regional growth rates in trending the ACO's rebased historical benchmark and updating the ACO's rebased historical benchmark annually during the agreement period. Commenters also offered suggestions specific to the proposed use of regional growth rates for updating the rebased benchmark. Some commenters expressed support for the proposed use of growth rates based on regional FFS expenditures to annually update the ACO's rebased historical benchmark. A commenter seemed to support this approach because it would yield larger update amounts for ACOs in higher growth regions, compared to the current use of an update factor based on national FFS expenditures.

Of the few comments discussing whether the annual update should be calculated using regional growth rates or regional flat dollar amounts, commenters expressed a preference for the use of regional growth rates. Some commenters explained their preference for CMS to use the same formula to determine the regional trend and update factors. Because CMS proposed that regional trend factors would be calculated as growth rates, these commenters opposed use of regional flat dollar amounts in calculating the annual update in order to assure a consistent methodology would be used to trend and update the ACO's rebased historical benchmark using factors based on regional FFS expenditures.

Some commenters opposed the proposed use of regional FFS expenditures, instead of national FFS expenditures, to determine the annual update to the ACO's rebased historical benchmark. Some commenters expressed concern that the proposed approach would have a variable impact on ACOs across the country, increasing and decreasing benchmarks for ACOs depending on the circumstances. A principal concern expressed by these commenters was that the proposed methodology would result in relatively lower update amounts for ACOs in low growth areas (including as a result of ACOs' success in lowering growth in expenditures) compared to the update amounts for ACOs in higher growth areas. A commenter further explained that the wrong incentives will result because for regions where there is a substantial amount of managed care, or a dominant, successful ACO, the rate of FFS spending growth per capita in the region would be limited and the update to ACO benchmarks would be lowered by the success of risk-based coordinated care. Another commenter indicated a similar concern specific to ACO-heavy regions, pointing to a discussion of the issue in the 2016 proposed rule regulatory impact analysis (81 FR 5859).

Some commenters suggested CMS forgo the proposed modification, and some recommended alternative

approaches to use of regional growth rates for updating the ACO's rebased benchmark, including the following:

• Several commenters (including MedPAC) expressed support for modifying the benchmark update methodology to better account for changes in factors outside the ACO's control that affect regional spending, but expressed concern about the proposal to move to use of regional FFS expenditures in calculating the annual update. MedPAC explained that ACOs' incentives to control spending growth would be limited if the update to the benchmark would be reduced by their success in reducing spending growth, particularly in circumstances where an ACO is dominant in its region. MedPAC suggested CMS investigate continuing to use a national update amount, and excluding IME, DSH and uncompensated care payments as provided under our current regulations, but also adjusting for changes in factors outside the ACO's control that affect regional spending such as area wage index changes (for example the region's hospital wage index). Along similar lines, another commenter suggested CMS adopt the Next Generation ACO model methodology. The Next Generation ACO Model is currently testing a benchmarking method that includes use of a prospectively calculated trend-adjustment factor, applied to baseline claims, which includes a national projected trend adjusted for regional changes in geographic adjustment factors (such as area wage index (AWI) and geographic practice cost index (GPCI)). See Next Generation ACO Model Benchmarking Methods (December 15, 2015), available online at *https://innovation.cms.gov/Files/x/nextgenaco-methodology.pdf*).

• Allow ACOs a choice between the higher of the national or regional update amount, particularly in the agreement period when the rebasing methodology including factors based on regional FFS expenditures is applied to the ACO for the first time.

• Reduce the frequency of, or eliminate altogether, the benchmark update.

Response: We are finalizing as proposed the use of regional growth rates to calculate the annual update to the ACO's rebased historical benchmark. We believe this approach will more quickly transition the program to benchmark calculations reflecting spending and spending growth in the ACO's regional service area.

However, we do share commenters' concerns about creating significant variation in the update amount across ACOs participating in the Shared Savings Program. We are also concerned about the longer term effects on participation resulting from relatively lower benchmark updates for regions with lower growth rates, reflecting ACOs' success in lowering growth in expenditures in those regions or a more general pattern of lower growth in the regions. We considered the approach suggested by MedPAC, under which the benchmark update would be calculated using standardized national FFS expenditures, adjusted for factors including the area wage index, to be an elegant alternative to use of regional growth rates in calculating the benchmark update. We are not adopting this approach in this final rule because this option was not discussed in the proposed rule, and therefore ACOs and other stakeholders have not had an opportunity to comment on this approach. Further, we would need to undertake additional analysis and modeling of this approach before deciding whether to propose it.

We anticipate exploring an alternative approach to calculating the update similar to MedPAC's recommendation, and may address the details of this approach in future rulemaking. Under this approach we would consider standardizing national FFS expenditures, for example: By calculating the benchmark update using a national growth rate adjusted for factors including IME, DSH, uncompensated care, as well as the AWI and GPCI; or by removing all geographic based payments and other add on payments similar to the approach for standardizing claims under the Physician Value Based Payment Modifier and Hospital Value-Based Purchasing programs. See for example, Basics of Payment Standardization (June 2015) and Detailed Payment Standardization Methods (updated May 2015), available at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*. We also believe the Innovation Center's experience with the Next Generation ACO Model methodology will be informative when evaluating use of geographic adjustments within the Shared Savings Program benchmarking methodology.

We would also explore, through future rulemaking, how broadly to apply an alternative approach, including whether to apply the same methodology consistently in calculating both the trend factors and the annual update. We would also consider whether to apply the same methodology consistently across the program for benchmark calculations, regardless of whether the ACO is participating in its first, or a subsequent agreement period. For example, we may consider calculating the trend and update factors using regional growth rates, as provided in this final rule, in benchmark calculations for an ACO's first agreement period. Alternatively, we may consider applying consistently across the program an alternative approach to calculating the regional trend and update factors, such as using standardized national FFS expenditures. Another consideration would be whether to apply an alternative approach to calculating the trend and update factors, such as using standardized national FFS expenditures, only in calculating an ACO's first agreement period benchmark, as a means of facilitating ACOs' transition to a benchmarking methodology in subsequent agreement periods that includes use of regional growth rates to trend and update the benchmark.

FINAL ACTION: Under the authority of section 1899(i)(3) of the Act, we are finalizing our proposal that for ACOs in their second or subsequent agreement period whose rebased historical benchmark incorporates an adjustment to reflect regional expenditures, the annual update to the benchmark will be calculated as a growth rate that reflects growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area, for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. We are incorporating this methodology at § 425.603(d). We note that this final provision includes some minor revisions to the proposed regulatory language in order to ensure that the final methodology for updating the rebased benchmark is described accurately and consistently.

We note that section IV.E of this final rule contains an updated assessment of all policies that are being implemented under the authority of section 1899(i)(3). Specifically, we compared all current policies along with the policies that are being adopted in this final rule to policies that could be implemented under section 1899(d)(1)(B)(ii) of the Act, and concluded that for the period from 2017 to 2019 there would be net federal savings. As discussed in the proposed rule, we anticipate that the costs of this alternative payment model will be periodically reassessed as part of the impact analysis for subsequent rulemaking regarding the payment models used in the Shared Savings Program. However, in the event we do

not undertake additional rulemaking, we intend to periodically reassess whether the payment model established under the authority of section 1899(i)(3) of the Act continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. If we determine the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the alternative payment model results in net program costs, we will undertake additional notice and comment rulemaking to make adjustments to our payment methodology to assure continued compliance with the statutory requirements. In adopting this approach, we believe that the alternative payment model under section 1899(i)(3) of the Act that is set forth in this final rule, which includes using regional FFS expenditures to update an ACO's rebased historical benchmark, using FFS expenditures of assignable beneficiaries to calculate the national benchmark update for ACOs in their first agreement period and those that started a second agreement period on January 1, 2016, as well as existing policies established using the authority of section 1899(i)(3) of the Act, meets the requirement of section 1899(i)(3)(B) of the Act.

e. Parity Between Calculation of ACO, Regional and National FFS Expenditures

(1) Background

In the November 2011 final rule, we established a methodology for determining ACO benchmark and performance year expenditures for Medicare FFS beneficiaries assigned to the ACO. Under that methodology, we take into account payments made from the Medicare Trust Funds for Parts A and B services for assigned Medicare FFS beneficiaries, including individually beneficiary identifiable payments made under a demonstration, pilot or time limited program, when computing average per capita Medicare expenditures under the ACO. We exclude IME payments and DSH and uncompensated care payments from both benchmark and performance year expenditures. This adjustment to benchmark expenditures falls under the Secretary's discretion established by section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate. However, section 1899(d)(1)(B)(i) of the Act only provides authority to adjust expenditures in the performance period for beneficiary characteristics and does not provide authority to adjust for ''other factors.'' Therefore, to remove IME and DSH payments from performance year expenditures, we used our authority under section 1899(i)(3) of the Act, which authorizes use of other payment models, in order to make this adjustment (see 76 FR 67920 through 67922). We allow for a 3-month run out of claims data and apply a claims completion factor (percentage), to more accurately determine an ACO's benchmark and performance year expenditures (76 FR 67837 and 67838). To minimize variation from catastrophically large claims we truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark year and performance year (76 FR 67914 through 67916).

We perform many of these calculations separately for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. For example, we calculate benchmark and performance year expenditures, determine truncation thresholds, and risk adjust ACO expenditures separately for each of these four Medicare enrollment types. As part of this methodology, we account for circumstances where a beneficiary is enrolled in a Medicare enrollment type for only a fraction of a year, through a process that results in a calculation of ''person years'' for a given year. We calculate the number of months that each beneficiary is enrolled in Medicare in each Medicare enrollment type, and divide by 12. When we sum the fraction of the year enrolled in Medicare for all the beneficiaries in each Medicare enrollment type, the result is total person years for the beneficiaries assigned to the ACO.

We currently apply these policies consistently across the program, as specified in the provisions for establishing, updating and resetting the benchmark under § 425.602, and for determining performance year expenditures under § 425.604 for Track 1 ACOs and under § 425.606 for Track 2 ACOs. Further, in developing Track 3, we determined that it would be appropriate to calculate expenditures consistently program-wide (see 80 FR 32776 through 32777). Accordingly, the provisions in § 425.602 governing establishing, updating, and resetting the benchmark also apply to ACOs under Track 3, and we adopted the same approach for determining performance year expenditures as is used in Track 1 and Track 2 in § 425.610 for Track 3 ACOs.

(2) Calculation of County FFS Expenditures

As part of our proposal to adjust the historical benchmark to reflect regional FFS expenditures, we expressed our belief that it is important to calculate FFS expenditures for an ACO's region in a manner consistent with the methodology used to calculate the ACO's benchmark and performance year expenditures. Several sections of the 2016 proposed rule discussed proposals related to calculating county FFS expenditures: one section described proposals for determining county FFS expenditures (see 81 FR 5831 and 5832); a separate section described related proposals for adjusting county FFS expenditure data to assure parity between regional FFS expenditure calculations and other program expenditure calculations (81 FR 5841 through 5843). Further, the discussion of the definition of the ACO's regional service area included a proposal to use statewide (instead of county level) values for the ESRD population (81 FR 5829 and 5830). We are consolidating our discussion of these proposals within this section of this final rule.

Consistent with our proposed definition of regional service area, we proposed to define regional costs as county FFS expenditures for the counties in which the ACO's assigned beneficiaries reside. We proposed that the calculations of county FFS expenditures would be undertaken separately according to the following populations of beneficiaries (identified by Medicare enrollment type): ESRD, disabled, aged/dual eligible, aged/non-dual eligible (see 81 FR 5830). We explained that consistent with the use of beneficiary person years in calculating ACO benchmark and performance year expenditures for each Medicare enrollment type, we would also calculate beneficiary person years when determining county FFS expenditures for each Medicare enrollment type (see 81 FR 5841 through 5843).

We proposed to compute per capita expenditures and average risk scores for the ESRD population at the state level, and to apply those state-level values to all counties in the state. We explained that this approach would address issues associated with small numbers of ESRD beneficiaries in certain counties that can lead to statistical instability in expenditures for this complex population, and is consistent with the approach used in MA. We explained that our concern about small numbers of ESRD beneficiaries was particularly acute for ACOs operating in rural areas

that tend to be more sparsely populated (see 81 FR 5830).

To increase predictability and stability, and avoid bias, we proposed to apply the same approach to calculating county FFS expenditures for factors based on regional expenditures as is currently used in calculating benchmark and performance year expenditures. We explained consistent application of program methodology in calculating FFS expenditures would result in more predictable and stable calculations across the program over time, for example as ACOs transition from a benchmarking methodology that incorporates factors based on national FFS expenditures to one that incorporates factors based on regional FFS expenditures. In addition, use of an alternative approach to calculating regional FFS expenditures could introduce bias because different types of payments could be included in or excluded from these expenditures, as compared to historical benchmark expenditures and performance year expenditures.

Therefore, we proposed to take the following steps in calculating county FFS expenditures used to determine expenditures for an ACO's regional service area:

- Determine county FFS expenditures based on the expenditures of the assignable population of beneficiaries in each county, where assignable beneficiaries are identified for the 12-month period corresponding to the applicable calendar year (see section II.A.2.e.3 of this final rule). We will make separate expenditure calculations according to the following populations of beneficiaries (identified by Medicare enrollment type): ESRD, disabled, aged/dual eligible, aged/non-dual eligible.
- Calculate assignable beneficiary expenditures using the payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, allowing for a 3-month claims run out and applying a completion factor. The completion factor will be calculated based on national FFS assignable beneficiary expenditures (see section II.A.2.e.3 of this final rule).

++ These calculations will exclude IME, DSH, and uncompensated care payments.

++ These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

- Truncate a beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS assignable beneficiary expenditures as determined for the relevant year, in order to minimize variation from catastrophically large claims (see section II.A.2.e.3 of this final rule). We would determine truncation thresholds separately for each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).
- Adjust county FFS expenditures for severity and case mix of assignable beneficiaries in the county using prospective CMS- Hierarchical Condition Category (HCC) risk scores. We would determine average risk scores separately for each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

We explained our plan to make county level data used in Shared Savings Program calculations publicly available annually. For example, a publicly available data file would indicate for each county: Average per capita FFS assignable beneficiary expenditures and average risk scores for all assignable beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). In response to requests from ACOs and other stakeholders for data to allow for modeling of the proposed changes to the benchmark rebasing methodology, CMS made new data files available through the Shared Savings Program Web site, to coincide with the issuance of the 2016 proposed rule (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Statutes-Regulations-Guidance.html*). These files included: average per capita county-level FFS spending and risk scores for three historical years; and ACO-specific data on the total number of assigned beneficiaries residing in each county where at least 1 percent of the ACO's assigned beneficiaries reside, for three historical years. We described these data files and considerations for their use, including comparability of ACO-specific data across programmatic datasets in the proposed rule (81 FR 5867 through 5868).

We proposed to incorporate this methodology for calculating county FFS expenditures in a new regulation at § 425.603. We sought comment on this proposed methodology as well as any additional factors we would need to consider in calculating risk adjusted county FFS expenditures for an ACO's regional service area.

Comment: The few commenters addressing the sections of the rule containing proposals for determining county FFS expenditures, as well as the related section describing parity between regional FFS expenditure calculations and other program expenditure calculations, were generally supportive of the proposed approach. However, a commenter expressed concerns that the proposed approach to calculating regional expenditures will incorporate historical geographic payment disparities that have never been adequately addressed in fee schedule and wage index rulemaking. Commenters offered specific suggestions regarding the proposals, as described in the remaining comment and response summaries within this section of this final rule.

Several commenters expressed support for the proposal to calculate expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). Commenters generally shared CMS' concern about small numbers of ESRD beneficiaries at the county-level. While a few commenters believed that the proposed use of state level data would adequately address this concern as well as align with the methodology used in MA, many commenters expressed uncertainty about whether using state-level data for the ESRD population would be the best solution. These commenters urged CMS to release additional data and further explain how use of state-level data is the optimal solution, with some suggesting CMS revisit this issue in future rulemaking. Commenters offered a variety of alternatives, including: approaches similar to alternatives for ensuring a sufficiently large regional population, and several approaches that would rely on an ACO's historical costs for its assigned ESRD population. Some commenters preferred use of county-level data for the ESRD population. A commenter suggested use of statewide values only if county level values did not meet a threshold of sufficient statistical stability. A commenter explained that applying state-level data for all counties within a state may skew results for certain ACOs, in particular those ACOs operating only in certain areas of a state.

Response: We are finalizing as proposed the use of county level data to determine regional FFS expenditures for the assignable beneficiary population in the ACO's regional service area. We will perform these calculations separately according to the following populations of beneficiaries (identified by Medicare enrollment type): ESRD, disabled, aged/dual eligible, aged/non-dual eligible. However, we are making a modification to the methodology for calculating county FFS expenditures.

Based on commenters' recommendations, we carefully

considered alternatives to the proposed approach of aggregating the expenditures for the ESRD population at the state level and applying this value consistently to each county within the State. Specifically, we reconsidered the option of using county-level data for the ESRD population, and determined that it would be appropriate to finalize a policy of calculating expenditures for the ESRD population at the county level. We believe there are a number of advantages of calculating expenditures for the ESRD population at the county level, consistent with the approach we proposed and are finalizing for determining county level expenditures for the other populations of beneficiaries (disabled, aged/dual eligible, aged/non-dual eligible). We believe a consistent approach to calculating expenditures for each Medicare enrollment type will be less operationally burdensome compared to an approach that calculates expenditures for the ESRD population differently than the expenditures for the disabled, aged/dual eligible, and aged/non-dual eligible populations. We also anticipate this consistency will allow for greater comparability between the values for each Medicare enrollment type to facilitate analysis by CMS and ACOs of expenditure trends for these populations over time. Further, this approach will reflect the variation in expenditures within states and the regional service areas that ACOs serve, a concept supported by comments underscoring the importance of reflecting regional spending variation in the methodology for resetting the ACO's historical benchmark.

We believe our concern about the small numbers of ESRD beneficiaries at the county level will be mitigated by certain factors. For one, while ESRD beneficiaries exhibit higher mean expenditures, they also exhibit significantly lower variation due in part to the stability of regular dialysis services for which payments are bundled in a highly standardized fashion. Second, we are finalizing an approach of weighting regional FFS expenditures by the proportion of assigned beneficiaries by Medicare enrollment in each county as discussed in section II.A.2.b.2 of this final rule. Specifically, for ACOs with a small proportion of ESRD beneficiaries within their assigned beneficiary population, the county-level ESRD expenditures will have a relatively low weight within the ACO's regional FFS expenditures. On the other hand, in the case of ACOs serving a large proportion of ESRD beneficiaries within a county, this approach could accommodate commenters' requests that the regional FFS expenditures more directly reflect the historical costs for the ACO's assigned ESRD beneficiaries. Additionally, we believe that the methodology for truncating the assignable beneficiary expenditures used to determine county FFS expenditures at the 99th percentile of national Medicare FFS assignable beneficiary expenditures will help reduce the potential for variation in county expenditure values with respect to the ESRD population in the same way as for the disabled, aged/dual eligible and aged/non-dual eligible populations.

We appreciate commenters' support for a methodology for determining regional FFS expenditures for use in the Shared Savings Program benchmark rebasing methodology that aligns with the MA rate-setting methodology. Although the approach we are finalizing does not follow the MA methodology for aggregating expenditures for the ESRD population statewide, and applying these values to each county in the state, we believe our overall approach for calculating county level expenditures risk adjusted using CMS–HCC prospective risk scores is a substantial step towards aligning with the MA rate-setting approach.

We decline at this time to adopt an alternative approach that (by design) only bases regional FFS expenditures for the ESRD population on the ACO's assigned ESRD beneficiaries, because it would systematically tie an ACO's rebased historical benchmark to its past performance, rather than allowing an ACO's benchmark to be more reflective of FFS spending in its region.

With respect to the commenter's concern that the proposed methodology for calculating regional expenditures would incorporate geographic payment disparities, we recognize there are geographic variations in Medicare payments. However, it is beyond the scope of this final rule, as well as the Shared Savings Program in general, to address broader Medicare payment policies regarding geographic adjustments.

Comment: Some commenters suggested increasing the number of years of data included in the calculations of county FFS expenditures, for example, using a 5-year rolling average for county-level spending estimates, along the lines of the approach used by MA.

Response: We are finalizing without modification our proposal to calculate county FFS expenditures for assignable beneficiaries residing in a county using the payment amounts included in Parts A and B FFS claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, allowing for a 3-month claims run out and applying a completion factor, and adjusted for other factors as described elsewhere in this section of this final rule. We believe that use of a single year of data in calculating county FFS expenditures will be approximately equivalent to using multiple years of data that have been trended using regional growth factors developed using historical FFS expenditures for the county. We believe using growth factors to trend forward historical county data would be approximately equivalent to the use of county level expenditures for the applicable year because each growth factor would be derived from the same historical county data it would be tasked with inflating.

Comment: Some commenters expressed support for the proposed adjustment to exclude IME, DSH and uncompensated care payments from the calculation of county FFS expenditures. Although a commenter suggested further normalizing payment methodologies to account for differences in payment policies for certain rural providers, for example rural health clinics (RHCs) and hospitals receiving the status of sole community hospital. A commenter also expressed support for including individually beneficiary identifiable payments made under a demonstration, pilot or time limited program in the determination of county FFS expenditures. This commenter underscored the importance of including these payments to give an accurate representation of actual FFS payments during the measurement period, and urged that we allow adequate time for other CMS payment demonstrations to complete final reconciliation to ensure that our calculation of county FFS expenditures accounts for actual FFS expenditures.

Response: We appreciate commenters' support for adjusting county FFS expenditures for IME, DSH and uncompensated care payments and for including individually beneficiary identifiable payments made under a demonstration, pilot, or time limited program, to remain consistent with the methodology used in calculating ACO and national FFS expenditures. We are finalizing these policies, as proposed.

Currently, the Shared Savings Program coordinates across initiatives within CMS to obtain the most recent available, final non-claims based beneficiary-identifiable payments for use in program financial calculations and informational reports.

We decline to adopt the commenter's recommendations to account for differences in cost and payment among providers and suppliers, such as RHCs and sole community hospitals, in calculating county FFS expenditures. As explained in response to related considerations in the November 2011 final rule, we continue to believe this approach would create an inaccurate and inconsistent picture of ACO spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies (76 FR 67919 and 67920).

Comment: A commenter expressed support, in general, for an approach that minimizes the impact of catastrophically large claims in the calculation of the benchmark. Several commenters offered alternatives to the proposal to truncate a beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS assignable beneficiary expenditures as determined for the relevant year. A commenter disagreed with limiting the population used to calculate the truncation threshold to assignable beneficiaries (instead of all FFS beneficiaries). Another commenter, concerned about the potential for year-to-year variability in threshold amounts, suggested CMS explore approaches that would provide greater predictability for these values, such as fixed absolute dollar thresholds.

Response: We are finalizing without modification our proposal to truncate a beneficiary's total annual Parts A and B FFS per capita expenditures when determining county FFS expenditures, and to define the truncation threshold as the 99th percentile of national Medicare FFS assignable beneficiary expenditures as determined for the relevant year for the applicable Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). We do not believe the concern raised by the commenter about the increase in the truncation thresholds as a result of using expenditures for assignable beneficiaries instead of all FFS beneficiaries is sufficient to warrant modification to the proposal. We estimate that the approach of using expenditures for assignable beneficiaries would result in approximately a 0.1 percent increase in the amount of the truncation thresholds. We believe this differential is small and therefore does not warrant either a change in approach or a delay in adopting a policy change that we believe will result in less biased calculations. We also decline at this time to revise the methodology for calculating the thresholds to specify a fixed amount that would not vary based on year-to-year changes in population and payment amounts, as suggested by a commenter. In the 2016 proposed rule we did not propose or seek comment on an alternative basis for truncating claims such as using a flat dollar amount (that does not vary year to year) instead of an annually determined percentile, and at this time we do not believe this alternative would be a preferred approach. As we explained in the November 2011 final rule, we believe that truncating claims at the 99th percentile (as opposed to alternative suggestions for differing threshold amounts) achieves an appropriate balance between limiting catastrophic costs and continuing to hold ACOs accountable for those costs that are likely to be within their control (see 76 FR 67914 and 67915).

Comment: A number of commenters expressed general support for CMS' proposed approach for calculating risk-adjusted county expenditures using CMS–HCC risk scores. While no commenters explicitly opposed this proposal, several commenters raised concerns about CMS–HCC risk adjustment more broadly and some offered suggestions for improving or refining the program's general risk adjustment methodology. For a more detailed description of these comments, see section II.A.2.c.2. of this final rule.

Response: We are finalizing our proposal to risk adjust county FFS expenditures by Medicare enrollment type, using the CMS–HCC risk scores. We appreciate the general support received from commenters on our proposed approach for calculating risk-adjusted county expenditures. We acknowledge the concerns raised by commenters about the program's general risk adjustment methodology, which relies on CMS–HCC risk scores, and appreciate the suggestions for improvement. As we gain more experience in the Shared Savings Program we will continue to evaluate the appropriateness and effectiveness of our risk adjustment methodology and, as necessary, will propose refinements through future notice and comment rulemaking.

Comment: While commenters applauded the release of data to support modeling of the proposed benchmarking changes, some voiced dissatisfaction with the data and pointed to concerns indicating a ''persisting lack of transparency.'' For instance, some commenters believed that too little time was allowed for ACOs and other stakeholders to model the proposed changes, and that insufficient data were released (for example, requesting county level instead of statewide ESRD data, and citing a lack of data to support modeling of the proposed revisions to the methodology for adjusting an ACO's benchmark for changes in ACO participant composition). Some comments included analyses based on publicly available data and other data sources, as described in more detail in section IV.G. of this final rule. Several commenters pointed to the complexity of the proposed changes and difficulty in accessing complete data to support modeling as reasons for CMS to provide resources and tools to help ACOs and other stakeholders understand the impact of the changes adopted in this final rule.

Some commenters applauded CMS' stated intention to release annual data files. Some commenters underscored the need for these annual files to be comprehensive (for example, ACO assigned beneficiary data should include counties with less than 1 percent of the assigned population to align with the definition of the ACO's regional service area, if finalized as proposed) and timely (for example, data should be made available in time to be used to support organizations' participation decisions). A commenter encouraged CMS to provide comparable data, to the extent feasible, for beneficiaries enrolled in MA plans, as a step towards aligning Medicare payments across ACOs and MA. A commenter further urged CMS to supply data related to benchmark calculations directly to ACOs, including data on the performance of other providers in the ACO's region, change over time, and risk adjustment.

Response: We appreciate commenters' feedback on the release of the data to support modeling of the proposed changes to the Shared Savings Program benchmark rebasing methodology. It is our goal to encourage transparency and understanding of program calculations. To this end we provided detailed descriptive information in the 2016 proposed rule on our proposed approach for implementing the proposed revisions to the rebasing methodology, and made publicly available informational data files as well as descriptive details on the parameters for and limitations in using these data.

We anticipate releasing annual data files to support our goal of transparency in program calculations, as well as to allow ACOs and other stakeholders to model impacts. We believe it is important for these data to be as complete and accurate as possible and, consistent with our methodology for performing financial reconciliation, will include claims data with a 3-month claims run out. As a result, we

anticipate releasing county-level expenditure and risk score data following the conclusion of the calendar year to which the data relate. We believe this dataset will provide ACOs and other program stakeholders the inputs needed to calculate the regional adjustment to their historical benchmark as well as to understand the level of county level expenditures in their regional service area, including any changes to that level once multiple years of data are available.

In addition, we plan to make public ACO-specific, aggregate data on counties of residence for the ACO's assigned population for each performance year so the public at large has a better understanding of the ACOs in various counties and regions across the country. We anticipate including these details on county of residence for ACO assigned beneficiaries as part of the annual Shared Savings Program public use files on ACO financial and quality performance.

In response to the commenter's request for release of comparable MA data, we note that MA rates and statistics are publicly available through the CMS Web site (available at *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/*). We encourage stakeholders to review these data in combination with the informational data files that CMS plans to release related to the revised Shared Savings Program benchmark rebasing methodology we are finalizing in this final rule.

We also anticipate updating the operational guidance documents available to the public and ACOs, to facilitate understanding by ACOs, other stakeholders, and the public (more generally) of the changes to the Shared Savings Program's benchmarking methodology resulting from this final rule.

We recognize there may be additional opportunities to improve program transparency. Therefore, we thank the commenters for their suggestions and will continue to look for ways we can engage with ACOs and other program stakeholders.

FINAL ACTION: We are finalizing our proposed methodology for calculating county FFS expenditures in new § 425.603, with one modification. We are finalizing as proposed the use of county level data to determine regional FFS expenditures for the assignable beneficiary population in the ACO's regional service area, and to perform these calculations separately according to the following populations of beneficiaries (identified by Medicare enrollment type): ESRD, disabled, aged/dual eligible, aged/non-dual eligible. However, we are not finalizing our proposal to aggregate the expenditures for the ESRD population at the state level and to apply this value consistently to each county within the State. Instead, we are finalizing a policy of calculating expenditures for the ESRD population at the county level. We are also finalizing our proposal to calculate county FFS expenditures in the same way that is currently used to calculate ACO expenditures in order to assure parity with the calculation of ACO benchmark and performance year expenditures as specified under the Shared Savings Program regulations.

(3) Modifying the Calculation of National FFS Expenditures, Completion Factors, and Truncation Thresholds Based on Assignable Beneficiaries

In the 2016 proposed rule we explained our belief that it is timely to reconsider the beneficiary population that should be used in program calculations for the national FFS population at the same time as we are establishing our policies for determining regional FFS expenditures, including the beneficiary population that will be used in those calculations. Several elements of the existing Shared Savings Program financial calculations are based on expenditures for all Medicare FFS beneficiaries regardless of whether they are eligible to be assigned to an ACO, including: The national growth rates used to trend forward expenditures during the benchmark period; the projected absolute amount of growth in national per capita expenditures for Parts A and B services used to update the benchmark; the completion factors applied to benchmark and performance year expenditures; and the truncation thresholds set at the 99th percentile of national Medicare FFS expenditures. In calculating these factors based on national FFS expenditures, we take into account Parts A and B expenditures for all Medicare FFS beneficiaries, and exclude IME payments and DSH and uncompensated care payments to align with our methodology for calculating benchmark and performance year expenditures.

We explained our concern that using expenditures for all Medicare FFS beneficiaries, including beneficiaries ineligible for assignment, in calculating factors that are based on the expenditures of the broader FFS population as opposed to using only expenditures for the narrower population of FFS beneficiaries eligible for assignment to an ACO, can bias those calculations. There may be differences in the health status and health care cost experience of Medicare beneficiaries excluded from the assignment ''pre-step'' compared to those who are eligible for assignment, based on their health conditions and the providers from whom they receive care. Thus, including the expenditures for non-assignable beneficiaries, such as non-utilizers of health care services, can result in lower overall per capita expenditures. These biases may have a more pronounced effect in calculations of regional FFS expenditures, which are based on relatively smaller populations of beneficiaries, as compared to calculations based on the national FFS population.

We described how we identify the pool of ''assignable'' Medicare beneficiaries (a subset of the larger population of Medicare FFS beneficiaries) as a pre-step to the two-step assignment process under § 425.402 for determining the beneficiaries who will be assigned to an ACO. We explained our preferred approach would be to apply a similar logic to identify the beneficiary population that would be used in program calculations for both national and regional FFS populations. As part of this pre-step, we determine if a beneficiary received at least one primary care service from a physician within the ACO whose services are used in assignment:

- For performance year 2016 and subsequent performance years, the beneficiary must have received a primary care service, as defined under § 425.20, with a date of service during the 12-month assignment window, as defined under § 425.20.
- The service must have been furnished by a primary care physician as defined under § 425.20 or by a physician with one of the primary specialty designations included in § 425.402(c). Therefore, beneficiaries who have not received any primary care service, or who have only received primary care services from physicians with a primary specialty code not specified in § 425.402(c) (see 80 FR 32753 through 32754, Table 5 Physician Specialty Codes Excluded From Assignment Step 2), or from non-physician practitioners are excluded from assignment to an ACO.

This pre-step is designed to satisfy the statutory requirement under section 1899(c) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians (80 FR 32756; § 425.402(b)(1)).

We discussed that one factor related to calculating expenditures for assignable beneficiaries is the assignment window used to identify

this population, with options including: The 12-month period used to assign beneficiaries to Track 1 and 2 ACOs based on a calendar year, and an off-set 12-month period used to assign beneficiaries prospectively to an ACO in Track 3. (See definition of assignment window under § 425.20 and related discussion in the June 2015 final rule at 80 FR 32699.) We expressed our belief that it is important to calculate regional and national FFS expenditures consistently across the three tracks of the program, so as not to advantage or disadvantage an organization simply on this basis. This consistency would help to ensure a level playing field in markets where multiple ACOs are present, and would also simplify program operations. Accordingly, we proposed to calculate county FFS expenditures and average risk scores, as well as factors based on national FFS expenditures, using the assignable beneficiary population identified using the assignment window for the 12-month calendar year corresponding to the benchmark or performance year. This is the same assignment window that is currently used to assign beneficiaries under Track 1 and Track 2. We specified our plan to monitor for observable differences in the health status (for example, as identified by CMS–HCC risk scores) and expenditures of the assignable beneficiaries identified using the 12-month calendar year assignment window, as compared to assignable beneficiaries identified using an assignment window that is the off-set 12-month period prior to the benchmark or performance year (for example, October through September preceding the calendar year). In the event that we conclude that additional adjustments (for instance, as part of risk adjusting county FFS expenditures) are necessary to account for the use of assignable beneficiaries identified using an assignment window that is different from the assignment window used to assign beneficiaries to the ACO, we would address this issue through future rulemaking.

We clarified that we will continue to apply an update based on national FFS expenditures to ACOs in their first agreement period and for ACOs that entered their second agreement period on January 1, 2016. However, to the extent that we were proposing to change our methodology in order to use only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures, we believed we would need to use the authority under section 1899(i)(3) of the Act to adopt other payment models to implement this change.

Section 1899(d)(1)(B)(ii) of the Act states that the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. The plain language of section 1899(d)(1)(B)(ii) of the Act demonstrates Congress' intent that the benchmark update be calculated based on growth in expenditures for the national FFS population, as opposed to a subset of this population. Therefore, in order to allow us to use only assignable beneficiaries in determining the amount of growth in per capita expenditures for Parts A and B services for purposes of determining the benchmark update for ACOs in their first agreement period and those ACOs that started a second agreement period on January 1, 2016, we believed it was necessary to rely upon our authority under section 1899(i)(3) of the Act. Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models in place of the payment model outlined in section 1899(d) of the Act as long as the Secretary determines these other payment models will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures.

We explained our belief that using our authority under section 1899(i)(3) of the Act to adopt a payment model that includes calculating the benchmark update for ACOs in their first agreement period and for ACOs that started a second agreement period on January 1, 2016, using national FFS expenditures for assignable beneficiaries, rather than for all FFS beneficiaries, would improve the quality and efficiency of items and services furnished to Medicare beneficiaries. We believed this approach would increase the accuracy of benchmarks, by determining the national update using a population that more closely resembles the population that could be assigned to ACOs. Further, we believed using assignable beneficiaries across all program calculations based on national and regional FFS expenditures would result in factors that are generally more comparable. As a result, these calculations will be more predictable and stable across the program over time, for example as ACOs transition from a benchmarking methodology that incorporates national FFS expenditures to one that incorporates factors based on regional FFS expenditures. Ultimately, we believed this policy could increase overall participation in the program, thereby resulting in more organizations working to meet the program's three-part aim of better care for individuals, better health for populations and lower growth in expenditures.

As explained in section II.A.2.d.3 of this final rule, section 1899(i)(3)(B) of the Act also specifies that the other payment model must not result in additional program expenditures. We discussed our analysis of this requirement, and our initial assessment that for the period spanning 2017 through 2019 there would be net federal savings associated with a payment model under section 1899(i)(3) of the Act that includes the proposed changes to the manner in which we update the benchmark during an ACO's agreement period as part of the regulatory impact analysis for the proposed rule.

Taking these considerations into account, we believed applying a payment methodology that includes calculating the benchmark update consistently based on assignable FFS beneficiaries, instead of all FFS beneficiaries, would meet the requirements under section 1899(i)(3) of the Act that the payment model improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. However, we also discussed our intention to revisit this determination periodically. If we determine the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the model results in net program costs, we would undertake additional notice and comment rulemaking to make adjustments to the model to assure continued compliance with the statutory requirements.

Accordingly, we proposed to use the authority under section 1899(i)(3) of the Act to revise the regulation at § 425.602(b)(1) to specify that the annual update to the benchmark will be based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries. We further proposed to specify in this provision of the regulations that we would identify assignable beneficiaries for the purpose of calculating the update based on national FFS expenditures using the 12-month calendar year corresponding to the year for which the update is being calculated. We sought comment on these proposed provisions.

We also proposed to make conforming changes to the regulations to specify that assignable Medicare FFS beneficiaries, identified based on the 12-

month period corresponding to the calendar year for which the calculations are being made, will be used to perform the following calculations: (1) Truncation thresholds for limiting the impact of catastrophically large claims on ACO expenditures under § 425.602(a)(4), § 425.604(a)(4), § 425.606(a)(4), § 425.610(a)(4); and (2) national growth rates used to trend forward expenditures during the benchmark period under § 425.602(a)(5). We specified that we would provide additional information through subregulatory guidance regarding the process for using assignable beneficiaries to perform these calculations, as well as the calculation of the claims completion factor applied under § 425.602(a)(1), § 425.604(a)(5), § 425.606(a)(5), § 425.610(a)(5).

Similarly, as discussed in sections II.A.2.b. and II.A.2.e.2 of this final rule, we proposed to specify in a new provision of the Shared Savings Program regulations at § 425.603 that would govern the methodology for resetting, adjusting, and updating an ACO's benchmark for a second or subsequent agreement period starting on or after January 1, 2017, that county FFS expenditures would be based on assignable Medicare FFS beneficiaries determined using the 12-month period corresponding to the calendar year for which the calculations are being made.

We proposed that regulatory changes regarding use of assignable beneficiaries in calculations based on national FFS expenditures would apply for the 2017 performance year and all subsequent performance years. Under this proposed provision, these changes would apply to ACOs that are in the middle of an agreement period, specifically ACOs that started their first agreement period in 2015 or 2016 and ACOs that started their second agreement period on January 1, 2016. We would adjust the benchmarks for these ACOs at the start of the first performance year in which these changes apply so that the benchmark for the ACO reflects the use of the same methodology that would apply in expenditure calculations for the corresponding performance year.

We sought comment on these proposals. We also sought comment on whether expenditures for all Medicare FFS beneficiaries should be used to calculate these elements for ACOs in their first agreement period or a second agreement period that started on January 1, 2016, while expenditures for assignable Medicare FFS beneficiaries are used to calculate these elements for an ACO's second and subsequent agreement period starting on or after January 1, 2017, in combination with the use of the assignable beneficiary population to determine expenditures for the ACO's regional service area.

Comment: Among the comments addressing this aspect of our proposed methodology, almost all commenters were supportive of the proposal to use assignable beneficiaries, rather than all FFS beneficiaries, when calculating both national and regional expenditures. A commenter generally agreed with all proposed modifications described in the relevant section of the proposed rule (81 FR 5843 through 5845). As discussed in section II.A.2.b.2 of this final rule, some commenters disfavored including ACO assigned beneficiaries within the population of assignable beneficiaries that would be the basis for calculating these factors. As discussed in section II.A.2.e.2 of this final rule, a commenter disagreed with limiting the population to assignable beneficiaries (instead of all FFS beneficiaries) when calculating the truncation thresholds.

Response: We appreciate the commenters' support for our proposed approach. We are finalizing, with one modification, our proposal to calculate factors based on national and regional FFS expenditures using the population of assignable Medicare FFS beneficiaries, identified based on the 12-month period corresponding to the calendar year for which the calculations are being made. See previous discussion in this final rule of related comments and responses, specifically: Section II.A.2.b.2 for comments concerning the inclusion of ACO assigned beneficiaries within the assignable population; and section II.A.2.e.2 for discussion of the comment concerning calculation of truncation thresholds based on expenditures for assignable beneficiaries instead of the broader FFS population.

As specified in the 2016 proposed rule, we plan to monitor for observable differences in the health status (for example, as identified by CMS–HCC risk scores) and expenditures of the assignable beneficiaries identified using the 12-month calendar year assignment window, as compared to assignable beneficiaries identified using an assignment window that is the off-set 12-month period prior to the benchmark or performance year (for example, October through September preceding the calendar year). In the event that we conclude that additional adjustments (for instance, as part of risk adjusting county FFS expenditures) are necessary to account for the use of assignable beneficiaries identified using an assignment window that is different from the assignment window used to assign beneficiaries to the ACO, we would address this issue through future rulemaking.

Although commenters did not discuss in detail their consideration of our proposal to determine completion factors based on assignable Medicare FFS beneficiaries instead of all Medicare FFS beneficiaries, we have reconsidered the need for this proposed change. The completion factors are determined based on multiple years of Medicare FFS claims submission data, and reflect claim submission patterns across the Medicare program. The concern about potential bias resulting from calculations based on beneficiaries that are not eligible for assignment, such as non-utilizers, is not prominent in the calculation of a claims completion factor. For instance, in the case of non-utilizers, there would be no relevant data to consider on the timing of receipt of claims data, because there would be no claims with dates of service for these beneficiaries in the relevant period examined for the purpose of calculating the completion factor. Further, in calculating the completion factors, the use of more comprehensive data based on the timing of submission of claims across the entire Medicare FFS population, as is reflected in our current approach, would result in the most accurate factors as compared to use of a subset of Medicare FFS beneficiaries (such as assignable beneficiaries under the Shared Savings Program) for these calculations. For these reasons, we are not finalizing our proposal to replace the current approach for calculating the claims completion factors using all Medicare FFS beneficiaries with an approach to calculating these factors based on assignable Medicare FFS beneficiaries at this time.

Comment: A commenter noted that beneficiaries receiving only services provided by allied providers (non-physician practitioners) are excluded from the proposed definition of assignable beneficiary. This commenter suggested that these providers be included in determining assignable beneficiaries because of the increasing role of non-physician practitioners in efforts to lower the cost of care for patients with low acuity healthcare needs.

Response: We continue to believe it is important to align the definition of assignable beneficiary with the statutory requirement that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians and with the methodology for identifying assignable beneficiaries described in the 2016 proposed rule and also discussed earlier in this section of the final rule. Applying the same

definition of assignable beneficiary as is used in the assignment process will help to ensure that program calculations based on national and regional FFS expenditures reflect the expenditures and acuity of patients that could be assigned to ACOs. Therefore we decline at this time to adopt the commenter's suggestion to also use services furnished by non-physician providers as a basis for identifying assignable beneficiaries.

Comment: Several commenters addressed the timing of applicability of the revised methodology for determining factors based on national FFS expenditures using the assignable beneficiary population instead of all FFS beneficiaries. A commenter noted support for the proposal that this methodology would apply for the 2017 performance year and all subsequent performance years and would apply to ACOs that are in the middle of an agreement period. One comment, which seemed to reflect the commenter's misunderstanding of the proposed policy, interpreted the proposal as failing to address the applicability of the proposed changes to ACOs with 2014 agreement start dates.

Response: We are finalizing with modifications our proposal that regulatory changes regarding the use of assignable beneficiaries in calculations based on national FFS expenditures would apply for the 2017 performance year and all subsequent performance years. The proposed rule specified revisions to the provisions at § 425.602(b), § 425.604(a)(1) through (3), § 425.606(a)(1) through (3), and § 425.610(a)(1) through (3) in order to differentiate between the methodology that applied for performance years before 2017 and the methodology that would apply for the 2017 performance year and all subsequent performance years. We believe it is important to clarify the timing of applicability of these changes, which will be reflected in the regulations finalized with this final rule:

- In establishing or resetting an ACO's historical benchmark for agreement periods beginning in 2017 and subsequent years, we will apply the methodology for use of assignable beneficiaries in determining factors based on national FFS expenditures and regional FFS expenditures.
- In calculations made during a performance year, including updating an ACO's historical benchmark and determining an ACO's performance year expenditures, for performance year 2017 and subsequent years, we will apply the methodology for use of assignable beneficiaries in determining factors based on national FFS expenditures and regional FFS expenditures.
- To ensure consistency in the way in which expenditure calculations are performed across the program, we will apply the revised methodology to ACOs that are in the middle of an agreement period, including: ACOs that started their first agreement period in 2015 or 2016; ACOs that entered the program in 2014 and elect the participation option established with this final rule to defer by 1 year entrance into a second agreement period under a two-sided model; and ACOs that started their second agreement period on January 1, 2016. We will adjust the benchmarks for these ACOs at the start of the 2017 performance year, the first performance year in which these changes apply, and in any subsequent years in the agreement period, so that the benchmarks established for these ACOs will reflect the use of the same methodology that will apply in expenditure calculations for the corresponding performance year, including determining the benchmark update and the ACO's expenditures for the performance year.

We wish to clarify that for any performance year prior to the applicability date for the regulatory change, we will continue to apply the current methodology under which factors based on national FFS expenditures are calculated using all FFS beneficiaries.

FINAL ACTION: We are finalizing our proposal to use assignable beneficiaries in all national and regional FFS calculations with one modification. We are not finalizing our proposal to determine completion factors based on assignable Medicare FFS beneficiaries, and will continue to determine these completion factors based on the timing of submission of claims across the entire Medicare FFS population. However, as proposed, we will limit the Medicare FFS population used in all other program calculations to ''assignable'' Medicare beneficiaries who meet the following requirements: (1) Received at least one primary care service, as defined under § 425.20, with a date of service during the 12-month assignment window; and (2) this primary care service was provided by a primary care physician, as defined under § 425.20, or by a physician with one of the primary specialty designations included in § 425.402(c). The assignable beneficiary population will be identified consistently across program tracks using the assignment window for the 12-month calendar year corresponding to the benchmark or performance year. This revised methodology will apply to all ACOs, including those ACOs with 2015 and 2016 agreement start dates that are in the middle of an agreement period, as well as ACOs that entered the program in 2014 and elect the participation option established with this final rule to defer by 1 year entrance into a second agreement period under a two-sided model. We will adjust the benchmarks for these ACOs at the start of the 2017 performance year and in any subsequent years in the agreement period so that the benchmarks established for these ACOs will reflect the methodology used in expenditure calculations for the performance year. We will provide additional information through subregulatory guidance regarding the process for using assignable beneficiaries to perform these calculations. We will revise the regulations to reflect these changes as follows:

- Revise the regulation at § 425.602(b)(1) using the authority under section 1899(i)(3) of the Act to provide that the historical benchmark will be updated annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is calculated. As discussed in section II.A.2.d.3 of this final rule, section IV.E of this final rule contains an updated assessment of all policies that are being implemented under the authority of section 1899(i)(3) of the Act. We anticipate that the costs of this alternative payment model will be periodically reassessed as part of the impact analysis for subsequent rulemaking regarding the payment models used in the Shared Savings Program. However, in the event we do not undertake additional rulemaking, we intend to periodically reassess whether the payment model established under the authority of section 1899(i)(3) of the Act continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. If we determine the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the alternative payment model results in net program costs, we will undertake additional notice and comment rulemaking to make adjustments to our payment methodology to assure continued compliance with the statutory requirements.

• Make conforming changes to the regulations on: (1) Truncation thresholds for limiting the impact of catastrophically large claims on ACO expenditures under § 425.602(a)(4), § 425.604(a)(4), § 425.606(a)(4), § 425.610(a)(4); and (2) growth rates used to trend forward expenditures during the benchmark period under § 425.602(a)(5) to specify that assignable Medicare FFS beneficiaries identified based on the 12-month period corresponding the calendar year for which the calculation is being made will be used to perform these calculations.

• Specify in a new provision of the Shared Savings Program regulations at § 425.603 that county FFS expenditures that are used in the methodology for resetting, adjusting, and updating an ACO's benchmark will be based on assignable Medicare FFS beneficiaries determined using the 12-month period corresponding to the calendar year for which the calculations are being made.

f. Timing of Applicability of Revised Rebasing and Updating Methodology

In the 2016 proposed rule, we discussed an approach under which the revised rebasing methodology could be applied to new agreement periods beginning on or after January 1, 2017, in a manner that allows for a phase-in to a greater percentage in calculating the regional adjustment for all ACOs:

• All ACOs would have the benchmark for their first agreement period set and updated under the methodology under § 425.602(a) and (b).

• The 2014, 2015, and 2016 starters and subsequent cohorts entering their second agreement periods on or after January 1, 2017, would be rebased under the new methodology for adjusting an ACO's rebased historical benchmark to reflect expenditures in the ACO's regional service area, and the ACO's rebased benchmark would be updated during the agreement period by growth in regional FFS expenditures. In calculating the regional adjustment to the rebased historical benchmark for an ACO's second agreement period, the percentage applied to the difference between the ACO's regional service area expenditures and the ACO's rebased historical benchmark expenditures would be set at 35 percent. In an ACO's third or subsequent agreement period this percentage would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking.

• With respect to the ACOs that started in the program in 2012 and 2013 and entered a second agreement period beginning in 2016, we applied the current rebasing methodology, under which we equally weight the benchmark years and account for savings generated during the ACO's prior agreement period, in rebasing their historical benchmark for their second agreement period. We would apply the methodology specified under § 425.602(b) for updating the benchmark annually for each year of their second agreement period. We would apply the new rebasing policies, including the phase in of the percentage used in calculating the regional adjustment, to these ACOs for the first time in calculating their rebased historical benchmark for their third agreement period (beginning in 2019), as if the ACOs were entering their second agreement period. Accordingly, the 2012 and 2013 starters would have the same transition to the use of a higher percentage in calculating the regional adjustment as all other ACOs.

We explained that this approach to phasing in the application of the new methodology for adjusting an ACO's rebased historical benchmark to reflect regional FFS expenditures would give ACOs and other stakeholders greater opportunity to prepare for, understand the effects of, and adjust to the application of benchmarks that incorporate regional expenditures.

Therefore, we proposed to make these changes applicable to ACOs starting a second or subsequent agreement period on or after January 1, 2017. These changes would initially apply in resetting benchmarks for the second agreement period for all ACOs other than those ACOs that started in the program in 2012 and 2013 (who entered their second agreement period on January 1, 2016). Furthermore, we proposed that 2012 and 2013 starters would have the same transition to regional adjustments to their rebased historical benchmarks as all other ACOs: In calculating the regional adjustment to the ACO's rebased historical benchmark for its third agreement period (in 2019), the percentage applied to the difference between the ACO's regional service area expenditures and ACO's rebased historical benchmark expenditures would be set at 35 percent; in its fourth or subsequent agreement period this percentage would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. We requested comment on this proposed approach to phasing in the application of the revised rebasing and updating methodology.

Comment: A commenter expressed support for the proposed phase-in of the new benchmark rebasing methodology based on an ACO's individual agreement renewal schedule rather than moving all ACOs to the new standard at one time. Many commenters opposed the proposal to phase-in the revised methodology to 2012 and 2013 starters beginning in their third agreement periods (starting January 1, 2019). Instead, commenters suggested options that would allow 2012 and 2013 starters the choice of the proposed approach or having the revised methodology apply during their second agreement period (for example, applying the methodology for performance year 2017 and onward, or allowing eligible ACOs to enter a new agreement period under the revised methodology that would begin in 2017). A commenter, in favor of applying the revised rebasing methodology to all ACOs in their second agreement period, suggested retroactively applying the changes to the first performance year (2016) of the 2012 and 2013 starters' second agreement period. Another commenter suggested allowing 2012 and 2013 starters that meet certain eligibility criteria (such as a quality performance threshold) to enter a new agreement period under the revised methodology beginning 2017, and permitting those ACOs participating under a performance-based risk model to have a weight greater than 35 percent applied in the calculation of the regional FFS adjustment. Alternatively, a commenter suggested applying the 70 percent weight (instead of 35 percent, as proposed) in calculating the regional adjustment for 2012 and 2013 starters beginning with their third agreement period.

Many commenters seemed to view the delay in applying the revised rebasing methodology to 2012 and 2013 starters until their third agreement period as a misfortune of timing. Commenters who perceived the proposed adjustment as beneficial explained that delaying application of the revised methodology would penalize 2012 and 2013 starters (or stated another way, unfairly advantage later entrants into the program) and perpetuate differences in benchmarks between ACOs in the same region. These commenters believed that this delay may cause attrition of these ACOs from the program. A commenter pointed out that applying the revised methodology to 2014 starters who begin a new agreement period in 2017, but delaying its application to 2012 and 2013 starters until 2019, could inadvertently lead to provider movement between ACOs depending on which benchmarking approach applies and is more financially favorable to the

ACO. A commenter suggested giving 2014 starters the option of delaying application of the revised methodology until their third agreement period, citing uncertainty about the policies to be finalized as these organizations decide whether to continue in the program.[2]

Response: In section II.A.2.c.3 of this final rule, we discuss our response to comments requesting broader flexibility to allow ACOs to choose from a menu of options on when the revised rebasing methodology would apply, and the weight with which the regional adjustment would be calculated.

ACOs that entered the Shared Savings Program in 2012 and 2013 renewed their agreements beginning January 1, 2016, with the understanding that the benchmark rebasing methodology finalized in the June 2015 final rule would be applied to their second agreement period. Under this rebasing methodology, described elsewhere in this final rule, we equally weight the ACO's historical benchmark years, and apply an adjustment for savings generated under the ACO's prior agreement period. While this methodology is substantially different from the rebasing approach we are establishing in this final rule, we are in fact applying to these ACOs a rebasing methodology that is intended to help mitigate the effects of an ACO's past successful performance on its current benchmark. The adjustment for savings generated in the ACO's prior agreement period increases the ACO's rebased historical benchmark by an amount that reflects the ACO's past financial and quality performance, and takes into account the size of the ACO's assigned beneficiary population. Equally weighting the benchmark years (corresponding to the three performance years of the prior agreement period) in resetting the ACO's historical benchmark mitigates reductions to the benchmark that would result from placing a higher weight on more recent prior benchmark years (corresponding to later years in the ACO's prior agreement period), in which ACOs are anticipated to show greater expenditure reductions. This methodology was designed to encourage continued participation in the Shared Savings Program and performance improvement by ACOs entering a second or subsequent agreement period, and therefore improve the overall sustainability of the program. These goals are consistent with the goals for the policies adopted in this final rule that incorporate regional FFS expenditures into the rebasing methodology.

Additionally, the 2016 proposed rule did not address the possibility of applying the revised rebasing methodology to these ACOs' second agreement periods spanning January 1, 2016 through December 31, 2018. As a result, we do not believe it would be appropriate to adopt a policy in this final rule under which we would apply the revised methodology to these ACOs prior to the start of their third agreement period in 2019. Applying this revised methodology in the middle of an ACO's second agreement period could prove disruptive to ACOs that have structured their operations and legal arrangements (including the ACO's Participant Agreements with ACO participant TINs) to reflect the application of the current benchmarking methodology. We also believe that more immediate application of the revised policies to 2012 and 2013 starters during their second agreement periods could undermine the ability of these ACOs to adapt to this change, possibly causing organizations to terminate their participation prior to the end of their second agreement period.

Furthermore, we do not believe it would be possible to allow these ACOs to terminate their current agreement period in order to start a new agreement period under the revised rebasing methodology, as suggested by some commenters. Section 425.222 addresses the circumstances under which an ACO may re-apply to participate in the Shared Savings Program after the ACO's agreement has been terminated. Section 425.222(a) specifies that an ACO that has been terminated from the Shared Savings Program under §§ 425.218 or 425.220 may participate in the Shared Savings Program again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated. We believe that this provision, without further modification, would prohibit CMS from allowing ACOs with 2012 and 2013 agreement start dates to terminate their current second agreement and re-enter the program under the revised benchmark rebasing methodology for a new second agreement period beginning January 1, 2017.

Taking these factors into consideration, we decline at this time to modify the Shared Savings Program regulations to offer the flexibility for 2012 and 2013 starters to terminate their agreements beginning January 1, 2016, and to reapply for a new second agreement period beginning January 1, 2017, under the revised rebasing methodology that is being adopted in this final rule.

Comment: Some commenters suggested alternatives not discussed in the proposed rule. Some commenters urged incorporating greater regulatory flexibility to apply the revised methodology when establishing the benchmarks for ACOs transitioning to the Shared Savings Program after completing a contract period under another CMS alternative payment methodology, including the Pioneer and Next Generation ACO Models. For example, with respect to the proposed phase-in approach, some commenters specified that former Pioneer ACOs and Next Generation ACOs entering their first agreement period under the Shared Savings Program should be allowed the option to be considered as entering a second or subsequent agreement period in order to allow their benchmark to be established using the regional benchmarking approach. A commenter explained that moving back to a benchmark calculated using national FFS factors would be taking a step backwards in terms of the evolution of the ACO model and unnecessarily expose these ACOs to additional risk.

Response: We greatly appreciate commenters' thoughtful suggestions for the transition of ACOs from other CMS ACO initiatives into the Shared Savings Program. We did not propose or discuss related changes to the Shared Savings Program regulations in the 2016 proposed rule. We agree with commenters that many organizations participating under other CMS ACO initiatives (such as the Pioneer ACO model and the Next Generation ACO model), which use factors based on regional FFS expenditures in setting ACO benchmarks, may find it disadvantageous to enter the Shared Savings Program under the methodology used to establish an ACO's benchmark for its first agreement period, and would prefer to be treated as if they were entering the program in a second or subsequent agreement period in order to receive a benchmark established using the rebasing methodology adopted in this final rule. We believe there are complexities to this issue that would need to be explored further, including the determination of which organizations would be eligible to be treated as entering the Shared Savings Program under a later agreement period and the applicability of other program requirements that relate to the agreement period in which an ACO is participating, including the selection of risk track and the quality performance

[2] The application/renewal cycle for the January 1, 2017 Shared Savings Program start date began in spring 2016. See the Shared Savings Program Web site, How to Apply Web page, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Application.html.*

standard. We anticipate considering these issues further in future rulemaking.

FINAL ACTION: We are finalizing our proposal to make the new benchmark rebasing policies described in this final rule, including the phase in of the percentage used in calculating the regional adjustment, applicable to ACOs entering into a second or subsequent agreement period in 2017 or subsequent years. With respect to ACOs that started in the program in 2012 and 2013 that have renewed their agreements for a second agreement period beginning in 2016:

- We applied the rebasing methodology established with the June 2015 final rule, under which we equally weight the benchmark years and account for savings generated during the ACO's prior agreement period, in rebasing their historical benchmark for their second agreement period (beginning in 2016). With the conforming changes made to the regulations text in this final rule, this methodology is incorporated in new § 425.603(b). We will apply the methodology specified under § 425.602(b) to update the benchmark annually for each year of the second agreement period for these ACOs.
- We will apply the new rebasing policies, including the revised phase in of the percentage used in calculating the regional adjustment that we are adopting in this final rule, to these ACOs for the first time in calculating their rebased historical benchmark for their third agreement period (beginning in 2019), as if the ACOs were entering their second agreement period. Accordingly, the 2012 and 2013 starters will have the same transition to the use of a higher percentage in calculating the regional adjustment as all other ACOs.

TABLE 3—CHARACTERISTICS OF BENCHMARKING APPROACHES BY AGREEMENT PERIOD

Source of methodology	Agreement period	Historical benchmark trend factors (trend BY1, BY2 to BY3)	Adjustment to the historical benchmark for regional FFS expenditures (percentage applied in calculating adjustment)	Adjustment to the historical benchmark for savings in prior agreement period?	Adjustment to the historical benchmark for ACO participant list changes	Adjustment to the historical benchmark for health status and demographic factors of performance year assigned beneficiaries	Update to the historical benchmark for growth in FFS spending
November 2011 final rule.	First	National	No	No	Calculated using benchmark year assignment based on the ACO's certified ACO Participant List for the performance year.	Newly assigned beneficiaries adjusted using CMS–HCC model; continuously assigned beneficiaries adjusted using demographic factors alone unless CMS–HCC risk scores result in a lower risk score.	National
As modified by June 2015 final rule.	Second (beginning 2016).	National	No	Yes	Same as methodology for first agreement period.	Same as methodology for first agreement period.	National
As modified by this final rule: Rebasing Methodology for second or subsequent agreement periods beginning 2017 and subsequent years.	Second (third for 2012/2013 starters).	Regional	Yes (35 percent, or 25 percent if ACO is determined to have higher spending compared to its region).	No	Same as methodology for first agreement period; regional adjustment redetermined based on ACO's certified ACO Participant List for the performance year.	No change	Regional
	Third (fourth for 2012/2013 starters).	Regional	Yes (70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking, or 50 percent if ACO is determined to have higher spending compared to its region).	No	Same as methodology for second agreement period beginning 2017 and subsequent years.	No change	Regional
	Fourth and subsequent (fifth and subsequent for 2012/2013 starters).	Regional	Yes (70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking).	No	Same as methodology for second agreement period beginning 2017 and subsequent years.	No change	Regional

B. Adjusting Benchmarks for Changes in ACO Participant (TIN) Composition

In the initial rulemaking establishing the Shared Savings Program, we acknowledged that the addition or removal of ACO participants or ACO providers/suppliers (identified by TINs and NPIs, respectively) during the term of an ACO's participation agreement could affect a number of different aspects of the ACO's participation in the Shared Savings Program. The 2016 proposed rule provided detailed background on the regulatory and subregulatory history of how CMS sets

and adjusts benchmarks to reflect ACO participant composition (see 81 FR 5848–5850).

We explained that under the current methodology, we set an ACO's historical benchmark at the start of an agreement period based on the assigned population in each of the three benchmark years by using the ACO Participant List certified by the ACO. The ACO must submit a new certified ACO Participant List at the start of each new performance year. CMS adjusts an ACO's historical benchmark at the start of a performance year if the ACO Participant List that the ACO certified at the start of the new performance year differs from the one it certified at the start of the prior performance year. We use the updated certified ACO Participant List to assign beneficiaries to the ACO in the benchmark period (the 3 years prior to the start of the ACO's agreement period) in order to determine the ACO's adjusted historical benchmark. As a result of changes to the ACO's certified ACO Participant List, we may adjust the historical benchmark upward or downward. Under this methodology, the historical benchmarks for ACOs with ACO Participant List changes from one performance year to the next continue to reflect the ACOs' historical costs in relation to the current composition of the ACO.

During the program's initial performance years, we experienced a high volume of change requests from ACOs, both adding and removing ACO participants. We adjusted the historical benchmarks for 162 of 220 ACOs (74 percent) with 2012 and 2013 start dates for the 2014 performance year to reflect changes in ACO participants. For the 2015 performance year, we adjusted benchmarks for 245 of 313 ACOs (78 percent) with 2012, 2013 or 2014 start dates to reflect changes in ACO participants.

While the current methodology ensures that a benchmark that has been adjusted based on changes in the ACO's participant composition accurately reflects benchmark year assignment using the most recent certified ACO Participant List, a primary drawback is that this methodology is operationally burdensome. To adjust benchmarks to account for ACO Participant List changes made by ACOs for each new performance year, we must repeat the assignment process for all 3 benchmark years for each starter cohort. Furthermore, with the addition of Track 3, we will need to perform two assignment runs for each benchmark year for a starter cohort, given that assignment for Track 3 ACOs is based on an offset beneficiary assignment window of the most recent 12-month period preceding the relevant calendar year for which data are available (for example, the period spanning October-September prior to the start of the benchmark year) that differs from the calendar year beneficiary assignment window used for Track 1 and Track 2 ACOs.

In light of the operational burden of adjusting benchmarks to reflect changes in ACO participants under the current policy, and the considerations associated with our proposals to adopt a benchmark rebasing methodology that requires additional calculations, we proposed to replace the current approach for calculating adjusted historical benchmarks for ACOs that make ACO Participant List changes with a more streamlined approach on a program-wide basis. The proposed approach would start with an ACO's historical benchmark based on the ACO's certified ACO Participant List for the most recent prior performance year and make adjustments using a ratio that is based on expenditures during a reference year for: (1) The ACO's beneficiaries assigned using both the ACO Participant List for the new performance year and the ACO Participant List for the most recent prior performance year (stayers); and (2) expenditures for the ACO's beneficiaries assigned using only the ACO Participant List for the ACO's most recent prior performance year (stayers and leavers) for the same reference year, defined as benchmark year 3 of the ACO's current agreement period. This figure would then be combined with reference year expenditures for beneficiaries assigned using only the ACO Participant List for the new performance year (joiners) to obtain the overall adjusted benchmark. Calculations of the adjustment would be made, and applied to the historical benchmark, for each of the following populations of beneficiaries, according to Medicare enrollment type: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. In the event an ACO's new ACO Participant List resulted in zero stayers, we proposed to continue to apply the current methodology for adjusting the ACO's historical benchmark for ACO Participant List changes.

We proposed to incorporate this adjustment to the historical benchmark for ACOs in their first agreement period and those ACOs that started a second agreement period on January 1, 2016, by adding a paragraph to § 425.602. In addition, we proposed to specify that the adjustment would apply to an ACO's rebased historical benchmark under the revised rebasing methodology in a new provision of the Shared Savings Program regulations at § 425.603. We also proposed to add definitions for ''stayers,'' ''joiners,'' and ''leavers'' to § 425.20.

We stated in the proposed rule that we believe that this approach would offer the right balance between approximating the accuracy of the current methodology for adjusting historical benchmarks (which requires performing beneficiary assignment for all 3 of an ACO's historical benchmark years with the new ACO Participant List) and operational ease. Initial modeling suggested that benchmarks calculated using this alternative methodology are highly correlated with those calculated using the current methodology.

We also examined and sought comment on a second alternative under which we would calculate the average per capita expenditures for leavers in the reference year and use this value, along with the relative person years for leavers and stayers, to impute average per capita reference year expenditures for stayers from the historical benchmark. The imputed expenditures for stayers would then be combined with average per capita reference year expenditures for joiners to obtain the overall adjusted benchmark.

Comment: While a few commenters expressed support for the proposed methodology to streamline adjustments for ACO Participant List changes, many commenters felt that CMS did not provide adequate information for stakeholders to properly evaluate the proposal, noting that the agency did not provide detailed results of its own modeling or sufficient data to allow others to perform their own analyses. A number of commenters urged the agency to make additional information available and to postpone finalization of the proposal at this time.

Response: In light of commenters' suggestions that we allow additional time to analyze the proposal, we are not finalizing the proposed new streamlined methodology at this time. We continue to believe the proposed approach has the potential to reduce operational burden without sacrificing accuracy. Therefore, we anticipate revisiting this issue in future notice and comment rulemaking. We believe that delaying adoption of a new approach to adjust historical benchmarks for ACO Participant List changes will allow CMS to gain more experience in the program and will allow more opportunity for the agency and stakeholders to evaluate the merits and tradeoffs associated with the proposed methodology or other alternatives. To that end, we anticipate

making more information available to aid stakeholder evaluation of this approach through future notice and comment rulemaking.

Comment: Some commenters expressed concerns about the accuracy of a ''proxy'' measure for adjusting benchmarks, or the potential for some ACOs to see large differences between the proposed and current methodologies for adjusting an ACO's benchmark for ACO Participant List changes, even if the two approaches produce similar results on average. Several commenters noted that differences of even one or two percentage points between the proposed and existing methodology could be quite substantial for an individual ACO. Some commenters also warned that using an expenditure ratio based on a single year of data could be less accurate or equitable than the current methodology that redetermines beneficiary assignment for each of an ACO's three benchmark years. A commenter stated CMS should not use a proxy method for adjusting the benchmark and that the agency should not let expediency threaten the accuracy of the program.

Response: We appreciate the concerns raised by commenters regarding the accuracy of the proposed streamlined approach for adjusting historical benchmarks for ACO Participant List changes and the potential for the proposed approach to have varied effects across ACOs. We believe that delaying finalization of this proposal will allow stakeholders further opportunity to study the implications of this or other alternatives, which may assuage some of the concerns initially raised about this proposal.

We want to take this occasion to clarify a statement in the proposed rule that referred to a magnitude of change for most ACOs of between −2 percent and +2 percent. Some commenters seemed to interpret this statement as referring to differences between the current methodology for computing adjusted benchmarks and the proposed streamlined methodology. In fact, the statement referred to differences between benchmarks calculated using the current methodology but based on different ACO Participant Lists (previous performance year and updated). In our modeling, comparing adjusted benchmarks computed under the proposed and current methodologies for 88 ACOs that began the program in 2014 and made ACO Participant List Changes for performance year 2015, we found that for close to two-thirds of these ACOs, the difference between the two methods was within half of a percentage point in either direction. For over 80 percent of these ACOs, the difference was within 1 percentage point. Only one ACO among the 88 saw a difference greater than two percentage points, with the proposed approach producing a benchmark that was 2.3 percent lower than the benchmark calculated under the current methodology. The mean difference between the two methods (proposed minus current) was −0.2 percent and the median was −0.1 percent.

Comment: Some commenters suggested other alternatives for CMS' consideration in conjunction with the proposed approach. A few commenters indicated that if CMS did decide to finalize the proposal to streamline the calculation of adjusted benchmarks, the agency should broaden the set of circumstances under which the current methodology would apply. Some commenters suggested that, rather than reverting to the current methodology only in the unlikely instance of zero ''stayers,'' the agency should adopt a low-volume threshold for stayers, below which the current methodology would be used to adjust for ACO Participant List changes. Another commenter called for adjusting benchmarks for ACO Participant List changes more frequently, such as within 30 days of an ACO notifying CMS of an ACO participant's resignation or removal from the list. Another commenter wanted to see the proposed methodology coupled with efforts by CMS to promote better data collection and information sharing.

Several commenters acknowledged that they understood CMS' desire to reduce operational complexity, but they expressed concern that CMS proposed a proxy method for adjusting benchmarks for ACO Participant List changes without first addressing other aspects of the existing methodology that commenters perceived to be flawed. Some commenters detailed alternative approaches. For example, some commenters suggested that adjustments to the ACO's benchmark for composition changes should be made for changes in ACO providers/suppliers, identified by National Provider Identifiers (NPIs), rather than for changes in ACO participants identified by TINs, or should account for changes in both NPIs and TINs. Their rationale was that only ACOs themselves can determine which physicians and non-physician practitioners are functioning as primary care providers and should be used in determining beneficiary assignment. Another commenter suggested that using NPIs instead of TINs could better account for changes in ACO composition over time. Some commenters also felt that CMS should address instability and inaccuracies introduced into benchmarks by ACO Participant List changes when such changes result in a difference in the acuity of patients assigned to the ACO in the benchmark period versus those assigned to the ACO for the performance year. A few commenters noted that some ACOs have had artificially low benchmarks due to innocuous changes in TINs, such as restructurings, where CMS did not make a correction or accommodation. These commenters further explained, for example, that when an ACO introduces a new service line for complex patients within an existing TIN during an agreement period, there would be no history of treating such patients in the baseline period and the benchmark would be understated. Another commenter opined that CMS should perform additional analysis and policy development on the fundamentals of benchmarking before developing a proxy process for making adjustments to benchmarks.

Response: We appreciate the suggestions raised by commenters and will take them into consideration when revisiting this issue in future rulemaking. However, we note that some of the suggestions offered, for example adjusting benchmarks for ACO Participant List changes more frequently, would likely offset, if not negate, the expected reduction in operational burden associated with the streamlined approach, which was the primary rationale behind its development. Thus it will be important to weigh the tradeoffs posed by any suggested modifications.

Further, in the 2016 proposed rule, CMS did not contemplate changes to the underlying methodology used to assign beneficiaries to ACOs, including how ACO participants are defined for purposes of assignment, or to policies surrounding when or under what circumstances CMS will make adjustments or corrections to an ACO's benchmark. We appreciate the concerns raised by commenters and will continue to review existing policies as we gain additional experience in the program. That being said, we do not believe that we should necessarily forgo opportunities to reduce administrative complexity in the near term if alternative methodologies have the potential to lower operational burden without sacrificing accuracy when calculating the adjustment for changes in the ACO's certified ACO Participant List.

FINAL ACTION: After consideration of the public comments received and

the concerns raised by many commenters, at this time, we are not finalizing our proposal to replace the current approach for calculating adjusted historical benchmarks for ACOs that make ACO Participant List changes with a new program-wide approach that would adjust an ACO's historical benchmark using an expenditure ratio based on single reference year. Relatedly, we are not finalizing the proposed definitions of ''stayers,'' ''leavers,'' and ''joiners'' in § 425.20 at this time. Although we are not finalizing the proposal to adopt a more streamlined approach for adjusting historical benchmarks for ACO Participant List changes in this rule, we continue to believe this alternative approach has merit as a means for reducing operational burden without sacrificing accuracy in ACO benchmarks. As such, we anticipate revisiting this proposal in future notice and comment rulemaking, and making more information available at that time to aid stakeholder evaluation. However, we are finalizing as proposed clarifying revisions to the description of the current approach to calculating adjusted historical benchmarks for ACOs that make ACO Participant List changes at § 425.602(a)(8), to specify that the benchmark is adjusted to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the most recent certified ACO Participant List for the relevant performance year. In addition, we will include a similar provision in new § 425.603 to provide that the same adjustment for ACO Participant List changes will be made to an ACO's rebased historical benchmark.

C. Facilitating Transition to Performance-Based Risk

1. Overview

As discussed in detail in the proposed rule (81 FR 5851 through 5853), we continue to believe that in order for the Shared Savings Program to be effective and sustainable over the long term, we need to further strengthen our efforts to transition the Shared Savings Program to a two-sided performance-based risk program in which ACOs share in both savings and losses. Currently, for its initial agreement period, an ACO applies to participate in a particular financial model or track of the program as specified under § 425.600(a). If the ACO's application is accepted, the ACO must remain under that financial model for the duration of its 3-year agreement. ACOs entering the program under the one-sided shared savings model (Track 1) that meet eligibility criteria may continue their participation under this model for a second 3-year agreement period as specified under § 425.600(b). In response to suggestions from ACOs and other stakeholders, and based on our experience with the first group of ACOs eligible for renewal for a second agreement period starting in 2016 in which nearly all such ACOs applied to remain in Track 1 for an additional agreement period, we further considered whether it would be appropriate to offer an additional participation option to encourage ACOs to move more quickly from the one-sided shared savings model to a performance-based risk model when renewing their agreements.

2. Additional Option for ACOs Participating Under Track 1 to Apply to Renew for a Second Agreement Period Under a Two-Sided Track

To respond to stakeholder concerns and to provide additional flexibility for ACOs that are willing to accept performance-based risk arrangements, we proposed to add a participation option that would allow eligible Track 1 ACOs to defer by 1 year their entrance into a performance-based risk model (Track 2 or 3) by extending their first agreement period under Track 1 for a fourth performance year. ACOs that would be eligible to elect this proposed new participation option would be those ACOs eligible to renew for a second agreement period under Track 1 but instead are willing to move to a performance-based risk track 2 years earlier, after continuing under Track 1 for 1 additional year. This option would assist ACOs in transitioning to a two-sided risk track when they need only one additional year in Track 1 rather than a full 3-year agreement period in order to prepare to accept performance-based risk. The additional year could allow such ACOs to further develop necessary infrastructure to meet the program's goals, such as further developing their care management services, adopting additional mechanisms for measuring and improving quality performance, finalizing implementation and testing of electronic medical records, and performing data analytics. We proposed to make this option available to Track 1 ACOs whose first agreement period is scheduled to end on or after December 31, 2016. Under this proposal, ACOs that elect this new participation option would continue under their first agreement period for a fourth year, deferring benchmark rebasing as well as deferring entrance to a two-sided risk track if they are approved for renewal.

More specifically, we proposed to provide an additional option for ACOs participating under Track 1 to apply to renew for a second agreement period under a two-sided track (Track 2 or Track 3) under the renewal process specified at § 425.224. If the ACO's renewal request is approved, the ACO would be able to defer entering the new agreement period under a performance-based risk track for 1 year. Further, as a result of this deferral, we would also defer rebasing the ACO's benchmark for 1 year. At the end of this fourth performance year under Track 1, the ACO would transition to the selected performance-based risk track for a 3-year agreement period. Accordingly, we proposed to amend the participation agreement requirements at § 425.200 to provide that an ACO that defers entering its new agreement period will be able to continue participating under its first agreement for an additional year (for an agreement period that would total 4 years).

An ACO electing this option would still be required to undergo the renewal process specified at § 425.224 prior to the end of its initial agreement (PY 3) and meet all other renewal requirements including the requirement that the ACO demonstrate that it is capable of repaying shared losses as required to enter a performance-based risk track. Because the ACO would be committing under the renewal application to transition to a performance-based risk track following completion of PY 4 under Track 1, the ACO would be required to demonstrate as part of its renewal application that it has established an adequate repayment mechanism as specified at § 425.204(f) to assure CMS of its ability to repay losses for which it may be liable during the new agreement period. We proposed to make this option available to Track 1 ACOs whose first agreement period is scheduled to end on or after December 31, 2016. Therefore, this proposed option would be available to ACOs with 2014 start dates seeking to renew their participation agreements in order to enter their second agreement period beginning in 2017. Under this proposal, we would update the ACO's benchmark as specified at § 425.602(b) for performance year 4 of the initial participation agreement. However, we would defer resetting the benchmark as specified at proposed § 425.603 until the beginning of the ACO's second agreement period (that is, the ACO's first agreement period under the selected performance-based risk track). The benchmark would be reset under the policies in place for that time

period, including the regional adjustment we are finalizing in this rule. Also, we proposed that the quality performance standard that would apply for performance year 4 of the initial participation agreement would be the same as for the ACO's performance year 3, consistent with § 425.502(a)(2). Specifically, we proposed that during the fourth performance year of the ACO's first agreement period, the ACO must continue to report all measures and the ACO will be assessed on performance based on the quality performance standard in place for the third performance year of the ACO's first agreement period.

In addition, we proposed that if a Track 1 ACO finishing its initial agreement period chooses to elect this option during the renewal of its participation in the Shared Savings Program, the ACO would be required to transition to the selected performance-based risk track at the end of the fourth performance year under Track 1. The term of the second agreement period would be 3 performance years.

If such an ACO subsequently decides during the fourth performance year that it no longer wants to transition to the performance-based risk track it selected in its application for a second agreement period, then the currently established close-out procedures and payment consequences of early termination under § 425.221 would apply. For example, if the ACO voluntarily terminates its agreement under § 425.221(a), effective December 31 of its fourth performance year, and completes all required close-out procedures, then as specified by § 425.221(b), the ACO would be eligible to share in any shared savings for its fourth performance year.

In addition, to provide some incentive for ACOs to honor their commitment to participate early in a performance-based risk track, we proposed that if an ACO that has been approved for an extension of its initial agreement period terminates its participation agreement prior to the start of the first performance year of the second agreement period, then the ACO would be considered to have terminated its participation agreement for the second agreement period under § 425.220. Such an ACO would not be eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

In the proposed rule, we also noted that if an ACO that goes on to participate under a two-sided track under this proposed option voluntarily terminates its agreement during its second agreement period, then the currently established close-out procedures and payment consequences of early termination under § 425.221 would apply. If an ACO terminates its agreement under its selected performance-based risk track and subsequently decides to reapply to participate in the Shared Savings Program, then the requirements under § 425.222 for re-application after termination would apply. For example, consistent with our current policy, such an organization would be required to apply to participate under a two-sided model and would have to wait the remaining duration of the agreement period before reapplying.

In developing this proposal to support our policy goal of providing additional flexibility to ACOs that are considering transitioning to two-sided risk, we also considered an alternative option that would permit the ACO to transition to a two-sided risk track during a subsequent 3-year agreement period under Track 1, instead of extending the first agreement period for an additional year. Under this alternative approach, we indicated that we would allow the ACO to remain in Track 1 for the first performance year of the second 3-year agreement period. The ACO would then be required to transition to Track 2 or 3 for the final 2 performance years of the agreement period. An ACO choosing this option would be required to satisfy all the requirements for a performance-based risk track at the time of renewal, including the requirement that the ACO demonstrate that it is capable of repaying shared losses as required to enter a performance-based risk track. Under this approach, we would rebase the ACO's benchmark as provided under proposed § 425.603, effective for the first year of the second 3-year agreement period. Further, we would calculate shared savings for the first year of the second 3-year agreement period under the one-sided model as specified at § 425.604. During the second and third performance years of the second agreement period, we would calculate shared savings and shared losses, as applicable, under either Track 2 (as determined at § 425.606) or Track 3 (as determined at § 425.610). We did not elect to propose this alternative option because we believed there could be a stronger incentive for some ACOs to transition to two-sided performance-based risk if we were to defer resetting the ACO's benchmark until the beginning of the ACO's second agreement period. Additionally, we noted that the alternative approach could raise concerns about risk selection since an ACO could participate for the first performance year of the second agreement period under this alternative, learn midway through the second performance year that its expenditures for the first performance year were below the negative MSR, and withdraw from the program before being subjected to reconciliation under performance-based risk.

We welcomed comments on our proposal and the alternative approach, as well as on other possible alternatives to provide flexibility and encourage ACOs to enter into and honor their participation agreements under performance-based risk tracks, and any related issues.

Comment: Commenters generally supported the proposed new participation option, believing that this additional participation option could assist some ACOs with transitioning to a two-sided risk track more quickly by giving eligible ACOs an additional year to further develop the infrastructure needed to achieve success under a performance-based risk track. Some commenters thought the alternative approach, in which we would allow the ACO to remain in Track 1 for the first performance year of its second 3 year agreement period before transitioning to a performance-based risk track in year 2, should also be offered, and might even be advantageous for ACOs in some situations. For example, some commenters suggested that this alternative participation option could be advantageous if it were integrated with the APM requirements under MACRA; that is, if the first year of a new two-sided risk contract under the alternative option could qualify as being ''more than nominal financial risk'' and therefore enable the ACO's physicians and other eligible clinicians to receive bonus payments equal to 5 percent of their covered Medicare professional services. A number of commenters also indicated that it was difficult for them to fully evaluate the proposed option and the alternative approach without first having policies in place for implementing MACRA, so that it would be clearer whether these new participation options might qualify as an APM under MACRA.

To provide yet even more flexibility for ACOs prepared to accept performance-based risk, some commenters recommended that CMS allow ACOs to ''move up'' the risk tracks (that is, to move from Track 1 to Track 2 or 3, or move from Track 2 to Track 3) between performance years without being required to wait for the

start of a new agreement period. These commenters suggested that allowing an ACO to accept varying degrees of risk within an agreement period would position the ACO to best balance its exposure to and tolerance for financial risk and would create a true glide path for providers.

However, many commenters indicated that while they supported adding one or more additional participation options, they also cautioned that adding such participation options might not have much impact on ACOs' willingness to participate under a performance-based risk track. These commenters suggested that if a Track 1 ACO is uncertain about its ability to successfully manage financial risk, the ACO would more likely simply choose to continue under Track 1 for a second agreement period. Another commenter stated that the anticipated impact of the proposed regional benchmark rebasing methodology is not as significant as hoped for and therefore the proposal to facilitate transition to performance-based risk by extending an ACO's agreement period into a fourth year without rebasing is not a meaningful incentive. This commenter recommended that CMS consider lowering the minimum savings rate of two percent under § 425.604(b) as a way to support ACOs by improving the probability that they will be eligible to share in any savings they achieve as they transition to performance-based risk, particularly for ACOs that demonstrate a commitment to the Shared Savings Program through their years of participation and meet sufficient size requirements for statistical reliability.

A commenter expressed concern that adding the proposed additional participation option could slow the move away from FFS payment arrangements. This commenter believes that the ultimate goal is for providers to take on full financial responsibility for caring for a population of patients for a fixed payment. On balance, however, the commenter preferred the proposed alternative for transition to participation under Track 2 or Track 3, over the option to renew for an additional 3-year agreement period under Track 1, as previously finalized in the June 2015 rule.

Response: We appreciate the general support received from commenters on our proposal to provide an additional option for ACOs participating under Track 1 to apply to renew for a second agreement period under a two sided track (Track 2 or Track 3), under which the ACO, if approved by CMS, may defer entering the new agreement period under a performance-based risk track, and extend participation under the initial participation agreement, for 1 year (that is, the initial agreement period would total 4 years). We acknowledge the concerns raised by commenters that this new participation option might not significantly affect ACOs' willingness to assume performance-based risk, but agree with commenters that such an option may influence some ACOs to transition to a performance-based risk track sooner than they otherwise might have.

As we gain experience with this new participation option in the Shared Savings Program, we will continue to evaluate the appropriateness and effectiveness of our incentives to encourage ACOs to transition to a performance-based risk track and, as necessary, may propose refinements through future notice and comment rulemaking. Although we are not adopting the alternative approach that we discussed in the proposed rule (that would permit the ACO to transition to a two-sided risk track during a subsequent 3-year agreement period under Track 1, instead of deferring entry into a new agreement period under a two-sided risk track and extending the first agreement period for an additional year), we may revisit it along with possible other approaches, including those suggested by commenters, in the future. As we gain additional experience under the Shared Savings Program, we may propose, if warranted, one or more additional participation options through future rulemaking to increase ACOs' willingness to assume performance-based risk. We would also note that the Department of Health and Human Services recently issued a Notice of Proposed Rulemaking that includes its proposals for implementation of the bonus payment for participants in eligible APMs under MACRA, 81 FR 28162 (May 9, 2016).

Comment: A commenter disagreed with our proposal that if an ACO that has been approved for an extension of its initial agreement period terminates its participation agreement prior to the start of the first performance year of the second agreement period, the ACO would be considered to have terminated its participation agreement for the second agreement period under § 425.220. We included this proposal because we believe it will provide an incentive for ACOs to honor their commitment to participate early in a performance-based risk track. The commenter believes that the proposed approach overlooks the fact that unanticipated changes can have a material impact on an ACO's readiness to assume risk. To illustrate, this commenter suggested that a significant change in the ACO's Participant List could have a material impact on the ACO's readiness and ability to follow through on its prior commitment to transition to a performance-based risk track. To address such situations, this commenter recommended that CMS create a ''hold harmless'' provision for ACOs that choose to renew their participation under the new participation option but then subsequently decide they are unable to assume performance-based risk due to a material change in their structure. Under this suggested hold harmless provision, an ACO that is unable to honor its commitment to participate in a performance-based risk track should have its benchmark rebased, so that it can be treated as being in PY1 of its second agreement period under Track 1. This commenter encouraged CMS to work with stakeholders to define a comprehensive list of material events that would enable an ACO to qualify for the hold harmless provision.

Response: We are not persuaded that it is necessary to revise the proposal to include a ''hold harmless'' provision. We continue to believe it would be appropriate under this new participation option to provide an incentive for ACOs to honor their commitment to participate early in a performance-based risk track. We would expect that ACOs considering this new participation option would share their process and systems knowledge with potential new ACO participants to increase the likelihood that new ACO participants could be successfully integrated in to the ACO, but ultimately ACOs should make their own determination as to whether a TIN is ready to join it in assuming performance-based risk. Alternatively, if the change in the ACO's composition is due the loss of one or more key ACO participant TINs, we believe it would be appropriate for the ACO to make its own determination as to whether to honor its commitment to assume performance-based risk or terminate its participation agreement. Also, we already have an adjustment to the historical benchmark in place that accounts for changes in an ACO's certified ACO Participant List, as discussed in section II.B of this final rule. This policy allows for more accurate benchmarks that reflect the historical spending patterns of the ACO and its assigned beneficiaries. Therefore, we are finalizing as proposed the policy that, if an ACO that has been approved for an extension of its initial

agreement period terminates its participation agreement prior to the start of the first performance year of the second agreement period, the ACO will be considered to have terminated its participation agreement for the second agreement period under § 425.220. Such an ACO will not be eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

Comment: Commenters provided a variety of other suggestions that they believe might also encourage ACOs to transition to a performance-based risk track earlier. For example, a commenter preferring retrospective beneficiary assignment under Track 2 rather than prospective assignment under Track 3, suggested that Track 2 could be made more attractive to participants if CMS were to make enhancements that are currently available only under Track 3, such as the waiver of the SNF 3-Day Rule, available under Track 2. Similar to comments we received in prior rulemaking, a number of commenters requested that CMS allow ACOs to include partial or ''split TINs'' among their ACO participants to allow large organizations, such as academic medical centers and their faculty practice plans, to participate in the program under a performance-based risk track with a subset of their providers.

Another commenter urged CMS to create stronger incentives for ACOs to assume downside risk in Track 2 and Track 3, such as by reducing the final sharing rate for eligible ACOs under Track 1 to perhaps 20 percent for the second agreement period, to minimize the number of ACOs renewing under Track 1. Otherwise, the commenter suggests many Track 1 ACOs may decide that Track 1 benefits, including having no risk of shared losses, exceed the marginal reduction of their shared savings payments during the second renewal term. This commenter also believes that CMS should provide a clearer and more certain path for ACOs willing to share in risk by, for example, also offering prospective beneficiary assignment for ACOs moving to Track 2 and providing more timely Part D expenditure data for assigned beneficiaries. The commenter believes that these changes would help ACOs predict the expected baseline Medicare spending and savings and reduce uncertainty.

Response: Although we are not addressing these additional suggestions as part of this rulemaking, we will further consider these and other suggestions from ACOs and other stakeholders that might encourage ACOs to enter performance-based risk arrangements earlier. As we discussed in the June 2015 final rule (80 FR 32810 and 32811), we appreciate the flexibilities that could be afforded to ACOs if a methodology could be developed that would permit ACOs to split ACO participants or ACO providers/suppliers into two different risk tracks. Under such a model, ACOs could progressively move providers participating in their organizations into risk in a step-wise fashion. Therefore, we continue to be interested in exploring operational processes that could permit such a design while also ensuring appropriate beneficiary protections. We intend to continue considering this issue and may revisit it in future rulemaking as infrastructure evolves to support this new alternative.

FINAL ACTION: We are finalizing our proposal to provide an additional option for ACOs participating under Track 1 to apply to renew for a second agreement period under a two-sided track (Track 2 or Track 3) under the renewal process specified at § 425.224. If the ACO's renewal request is approved, the ACO may defer entering the new agreement period under the performance-based risk track for 1 year and extend its first agreement period under Track 1 for a fourth performance year. Further, as a result of this deferral and extension, we will also defer rebasing the ACO's benchmark for 1 year. At the end of the fourth performance year under Track 1, the ACO will transition to the selected performance-based risk track for a 3-year agreement period. Accordingly, we are amending the participation agreement requirements at § 425.200 to provide that an ACO in its first agreement period under Track 1 that has applied and been approved for a second agreement period under a performance-based risk track that defers entering its new agreement period under the performance-based risk track will be able to continue participating under its first agreement for an additional year (for an agreement period that would total 4 years).

In addition, we are finalizing our proposal that if an ACO that has been approved for an extension of its initial agreement period terminates its participation agreement prior to the start of the first performance year of the second agreement period, then the ACO will be considered to have terminated its participation agreement for the second agreement period under § 425.220. Such an ACO will not be eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

D. Administrative Finality: Reopening Determinations of ACO Savings or Losses to Correct Financial Reconciliation Calculations, and a Conforming Change

1. Overview

ACOs enter into agreements with CMS to participate in the Shared Savings Program, under which ACOs that meet quality performance requirements and reduce the Medicare Parts A and B expenditures for their assigned beneficiaries below their benchmark by a specified margin are eligible to share a percentage of savings with the Medicare program. Further, ACOs participating under a two-sided risk track, whose Medicare Parts A and B expenditures for their assigned beneficiaries exceed their benchmarks by a specified margin, are liable for sharing losses with CMS. After each performance year, CMS calculates whether an ACO has generated shared savings by comparing its actual expenditures for its assigned beneficiaries in the PY with its updated benchmark. Savings are generated if actual Medicare Parts A and B expenditures for assigned beneficiaries are less than the updated benchmark expenditures and shared with the ACO if they exceed the ACO's minimum savings rate, and the ACO meets the minimum quality performance standards and otherwise maintains its eligibility to participate in the Shared Savings Program. For an ACO under a two-sided risk track, losses are generated if actual Medicare Parts A and B expenditures for assigned beneficiaries are greater than the updated benchmark expenditures and the ACO is liable for shared losses if the losses exceed the ACO's minimum loss rate.

To date, we have announced 2 years of financial performance results for ACOs participating in the Shared Savings Program, in Fall 2014 for 220 ACOs with 2012 and 2013 start dates for PY 1 (concluding December 31, 2013), and in August 2015 for 333 ACOs with 2012, 2013 and 2014 start dates for PY 2014. As discussed in detail in the proposed rule (81 FR 5853 through 5854), several months after the release of PY 1 financial reconciliation results and shared savings payments to eligible ACOs, we discovered that there was an issue with one of the source input data fields used in the final financial reconciliation calculations. As a result,

the PY 1 shared savings payments were overstated for some ACOs and shared losses were understated for some other ACOs. We ultimately determined this issue resulted in an estimated 5 percent overstatement of PY 1 shared savings payments to ACOs and an understatement of shared losses (81 FR 5853 and 5854). The impact on individual ACOs varied depending on the extent to which services provided to the ACO's assigned beneficiaries were furnished by providers that receive DSH payments. The issue did not result in understated PY 1 shared savings payments or overstated PY 1 shared loss recoupments for any ACO.

The financial reconciliation calculation/methodology and the amount of shared savings an ACO might earn, including all underlying financial calculations, are not appealable. That is, the determination of whether an ACO is eligible for shared savings under section 1899(d) of the Act, and the amount of such shared savings, as well as the underlying financial calculations are precluded from administrative and judicial review under section 1899(g)(4) of the Act and § 425.800(a)(4). However, under § 425.314(a)(4), if as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. (See also the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Reconsideration-Review-Process-Guidance.pdf*).

As noted in the proposed rule, we have not previously specified the actions that we would take under circumstances when we identify an error in a prior payment determination, such as the error that occurred in the calculation of PY 1 shared savings and shared losses. We are concerned that the current uncertainty regarding the timeframes and other circumstances in which we would reopen a payment determination to correct financial calculations under the Shared Savings Program could introduce financial uncertainty which could seriously limit an ACO's ability to invest in additional improvements (such as IT solutions and process development, staffing, population management, care coordination, and patient education) to increase quality and efficiency of care. This uncertainty could also limit an ACO's ability to get a clean opinion from its financial auditors, which could, for example, harm the ACO's ability to obtain necessary capital for additional program improvements. This could be especially challenging for ACOs seeking to enter or continue under a two-sided performance-based risk track since under the requirements at § 425.204(f)(2), such an ACO must, as part of its application for a two-sided performance-based risk track, demonstrate its ability to repay shared losses to the Medicare program, which it may do by placing funds in escrow, obtaining a surety bond, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing a combination of such repayment mechanisms, that will ensure its ability to repay the Medicare program. These arrangements can often require that an ACO or its financial supporters or both make an assessment of the ACO's level of financial risk for possible repayments. We are particularly concerned that uncertainty regarding past financial results could discourage ACOs from moving more quickly from the one-sided shared savings track to a performance-based risk track when renewing their agreements.

We considered an approach under which we would always reopen a determination of ACO shared savings or shared losses to correct any issue that might arise with respect to a financial calculation, identified within 4 years after the release of final financial reconciliation results. We did not propose this option because we were concerned that this approach of correcting even very minor errors might result in significant operational burdens for ACOs and CMS, including multiple financial reconciliation re-runs and off-cycle payment/recoupment activities that could have the potential for significant and unintended operational consequences, and could jeopardize the certainty of performance results for both ACOs and CMS. We also considered whether to adopt a policy under which we would never correct for errors after performing the financial calculations and making initial determinations of ACO shared savings and shared losses. However, we did not propose this option because we believed it would be appropriate to reopen financial calculations in certain circumstances, such as in the case of fraud or similar fault as defined at § 405.902, or for errors with a significant impact on the computation of ACOs' shared savings/shared losses. Therefore, we proposed a finality policy for financial calculations and shared savings payments or shared loss recoupments in which we would allow for corrections, under certain circumstances and within a defined timeframe, after financial calculations have been performed and the determination of ACO shared savings and shared losses has been made.

2. Circumstances for Reopening Initial Determinations and Final Agency Determinations of ACO Shared Savings or Shared Losses to Correct Financial Reconciliation Calculations

In developing the proposals in this section, we considered the following issues: (1) The type of issue/error that we would correct; (2) the timeframes for reopening a payment determination; and (3) whether we should establish a materiality threshold as an indicator of a material effect on shared savings and shared losses that would warrant a correction, and if so, at what level.

First, we proposed that CMS would have discretion to reopen a payment determination at any time in the case of fraud or ''similar fault,'' as defined in § 405.902. It is longstanding policy in the Medicare program that a determination may be reopened at any time if it was procured by fraud or ''similar fault,'' (see, for example, § 405.980(b)(3); 74 FR 65296, 65313 (December 9, 2009)). Second, we proposed that in certain circumstances we would reopen a payment determination for good cause. For consistency and to decrease program complexity, we proposed to follow the same approach to reopening for good cause as applies to the reopening of Parts A and B claims determinations under § 405.986. Specifically, we proposed that CMS would have the discretion to reopen a payment determination, within 4 years after the date of notification to the ACO of the initial determination of shared savings or shared losses for the relevant performance year, if there is good cause. We proposed that good cause may be established if there is new and material evidence that was not available or known at the time of the payment determination, and which may result in a different conclusion, or if the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

We indicated that new and material evidence or an obvious error could come to CMS' attention through a variety of means, such as identification by CMS through CMS program integrity reviews or audits, or identification through audits conducted by independent federal oversight entities such as the Office of Inspector General (OIG) or the Government Accountability

Office (GAO). CMS program integrity reviews and audits include reviews and audits conducted by CMS' contractors. We proposed to establish a 4-year time period (that is, 4 years from initial notification of the payment determination) for reopening Shared Savings Program payment determinations for good cause to provide sufficient time to initiate and complete CMS program integrity reviews or audits by oversight entities like OIG or GAO and to evaluate errors identified through those processes. We proposed that good cause would not be established by changes in substantive law or interpretative policy. A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, would not be a basis for reopening a payment determination under the proposal. Further, we proposed CMS would have sole discretion to determine whether good cause exists for reopening a payment determination under this section. Under the proposal, the determination of whether an error was made, whether a correction would be appropriate based on these proposed criteria, and the timing and manner of any correction would be within the sole discretion of CMS. We also indicated in the proposal that we did not intend to propose an exhaustive list of potential issues that would or would not constitute good cause, but instead intended to provide additional subregulatory guidance on this issue. We also noted that good cause would not be established by a reconsideration, appeal, or other administrative or judicial review of any determinations precluded under § 425.800.

In addition, we indicated we would not reopen a payment determination to consider, or otherwise consider as part of a reopening, additional claims information submitted following the end of the 3-month claims run out and the use of the completion factor. We would continue to use claims submitted prior to the end of the 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year, consistent with §§ 425.604(a)(5), 425.606(a)(5) and 425.610(a)(5). Also, consistent with established policy, under this proposed policy, we would not reopen a determination if an ACO's ACO participants submitted additional claims or submitted corrected claims after the 3-month claims run out period following the end of the performance year.

In order to provide an opportunity for CMS to consider updated information and make other adjustments to payment determinations across all ACOs, and to minimize program disruptions for ACOs resulting from multiple reopenings, we indicated that we would, to the extent feasible, make corrections for a given performance year in a unified reopening (as opposed to multiple reopenings). In addition, we indicated we would consider other ways to reduce operational burdens for both ACOs and CMS that could result from making payment adjustments.

In addition, in discussing the proposal regarding reopenings for good cause, we proposed that we would also consider whether the error is material and thus warrants a correction by reviewing the nature and particular circumstances of the error. We did not propose specific criteria for determining materiality but we indicated our intent to provide additional information for ACOs through subregulatory guidance, as appropriate. For example, in the case of technical errors by CMS such as CMS data source file errors and CMS computational errors, we stated we would consider limiting reopenings of payment determinations under the Shared Savings Program to issues/errors that have a material effect on the net amount of ACO shared savings and shared losses computed for the applicable performance year for all ACOs, and thus warrant a correction due to the magnitude of the error.

We also initially considered applying a materiality threshold for each ACO, rather than evaluating materiality based on the effect on total net shared savings and shared losses for all ACOs, in determining whether to exercise our reopening discretion to correct a CMS technical error. However, we indicated in the proposed rule that we believed it would be appropriate to limit reopenings to correct CMS technical errors that more widely affect the program rather than reopening determinations for specific issues for each of the hundreds of ACOs participating in the Shared Savings Program absent evidence of fraud or similar fault, or good cause established by evidence of other errors. Otherwise, a relatively broad scope and extended timeframe for reopening could seriously limit an ACO's ability to invest in additional improvements to increase quality and efficiency of care. This uncertainty could also limit an ACO's ability to get a clean opinion from its financial auditors, which could, for example, harm the ACO's ability to obtain necessary capital for additional program improvements. This could be especially challenging for ACOs seeking to enter or continue under a two-sided performance-based risk track since under the requirements at § 425.204(f), such an ACO must, as part of its application for a two-sided performance-based risk track, demonstrate its ability to repay shared losses to the Medicare program, which it may do by placing funds in escrow, obtaining a surety bond, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing a combination of such repayment mechanisms, that will ensure its ability to repay the Medicare program. These arrangements can often require that an ACO and/or its financial supporters make an assessment of the ACO's level of financial risk for possible repayments. Uncertainty over past financial results could significantly affect an ACO's ability to obtain and maintain these arrangements with financial institutions, and thus discourage ACOs from moving more quickly from the one-sided shared savings track to a performance-based risk track when renewing their agreements. (81FR 5854).

Therefore, after considering these issues, we proposed to revise § 425.314 to remove paragraph (a)(4) and add a new paragraph (e) to specify the circumstances under which we would reopen a payment determination under §§ 425.604(f), 425.606(h), 425.610(h), 425.804, or 425.806. Specifically, we proposed that, if CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS may reopen the earlier payment determination and issue a revised initial determination. We proposed that a payment determination may be reopened: (1) At any time in the case of fraud or similar fault, as defined in § 405.902; or (2) not later than 4 years after the date of notification to the ACO of the initial determination of shared savings or shared losses for the relevant performance year under § 425.604(f), § 425.606(h) or § 425.610(h), for good cause. We proposed that good cause may be established when there is new and material evidence of an error or errors, that was not available or known at the time of the payment determination and may result in a different conclusion, or the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination. Good cause would not be established by a change of legal

interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise. We would have sole discretion to determine whether good cause exists for reopening a payment determination under this section. Also, good cause would not be established by a reconsideration, appeal, or other administrative or judicial review of any determinations precluded under § 425.800.

Under the proposal, the determination of whether an error was made, whether a correction would be appropriate based on the proposed criteria, and the timing and manner of any correction would be within the sole discretion of CMS. We proposed that if CMS determines that the specified criteria were met and exercises its discretion to reopen, CMS would recompute the financial results for all ACOs affected by the error or errors. In light of this policy proposal, we indicated we would not reopen and revise the PY 1 payment determinations solely affected by the data source error described previously because we had not previously specified, either through regulations or program guidance, the criteria CMS would apply in determining whether to reopen a payment determination. However, we indicated we would reopen and revise these PY 1 payment determinations for other errors satisfying the proposed criteria for reopening for good cause or for fraud or similar fault (81 FR 5857). Finally, we proposed to amend § 425.800(a)(4), expressly to include a revised initial determination in the list of determinations that are precluded from administrative and judicial review.

We invited comments on this proposal, including the proposed criteria for reopening, on alternative approaches for defining the time period for reopenings of payment determinations, on the criteria for establishing good cause, whether the time period for reopenings for good cause should be longer or shorter than 4 years, and on any other criteria that we should consider for the final rule to address issues related to financial reconciliation calculations and the determination of ACO shared savings and shared losses.

Comment: Commenters generally appreciated efforts to further define parameters around reopening payment determinations within the Shared Savings Program. A few commenters concurred with the provisions as proposed; however, most commenters expressed concerns about one or more aspects of the proposal. In particular, many commenters suggested limiting the timeframe for good cause redeterminations to a shorter period such as 2 years, instead of 4, to provide ACOs with more financial certainty. These commenters stated that requiring ACOs to repay CMS for errors made potentially several years earlier would pose an excessive administrative burden on both ACOs and the Medicare program, create financial uncertainty and could discourage ACOs from participating in the program.

Response: We believe a 4 year time frame for reopenings for good cause, which is based on the timeframe for reopening of Parts A and B claims determinations under § 405.986, would also be appropriate under the Shared Savings Program. We acknowledge that a shorter timeframe for good cause determinations might provide more financial certainty for ACOs. However, based on a review of comments, we continue to believe the proposed approach carefully balances a desire to provide more financial certainty for ACOs while also addressing program integrity and other concerns. We are especially concerned that a shorter time period could make it difficult for CMS to make corrections based on program integrity reviews or audits by OIG or GAO. Similarly, a longer time period might make it feasible for CMS to make additional corrections based on program integrity reviews or audits by OIG or GAO, but could provide less financial certainty for ACOs.

Comment: Many commenters are concerned that CMS reserves for itself sole discretion to determine whether good cause exists for reopening. These commenters requested that CMS include a specific ''appeal process'' or other process in which individual ACOs could submit information and data to CMS regarding errors and other anomalies.

Response: As discussed earlier in this section, the financial reconciliation calculation/methodology and the amount of shared savings an ACO might earn, including all underlying financial calculations, are not appealable. That is, the determination of whether an ACO is eligible for shared savings under section 1899(d) of the Act, and the amount of such shared savings, as well as the underlying financial calculations are precluded from administrative and judicial review under section 1899(g)(4) of the Act and § 425.800(a)(4). Accordingly, we are not establishing an appeal process for ACOs to submit information to us regarding errors they believe were made in the financial reconciliation calculation or in determining the amount of shared savings earned by the ACO. We believe it is appropriate that the determination of whether an error was made, whether a correction would be appropriate based on these proposed criteria, and the timing and manner of any correction that would be made would be within the sole discretion of CMS. However, we also did not intend to imply that there would be no opportunity for ACOs to bring concerns about data errors or other anomalies to our attention. As noted in the June 2015 final rule (80 FR 32699), there are numerous existing processes through which ACOs can submit information and data to CMS regarding alleged data errors and other anomalies. For example, each ACO is assigned a CMS point of contact, we provide ACOs with a dedicated email box for ACOs to submit questions for subject matter experts to address, and we hold numerous webinars that include opportunities for ACOs to raise questions and concerns. CMS will consider information about potential errors or anomalies provided by ACOs in conducting its own reviews of prior payment determinations.

Comment: Some commenters requested that CMS propose the specific good cause criteria including a materiality threshold through rulemaking instead of through sub-regulatory guidance so that the criteria are transparent and available for public comment. Many commenters requested that CMS establish a policy for a materiality threshold at an individual ACO level instead of across all ACOs to recognize that although determinations may have an insignificant effect on the program as a whole, a negative impact could be financially devastating to an individual ACO. Many of these commenters suggested a lower materiality threshold for individual ACOs, such as one percent or two percent, although there were a few commenters that indicated five percent might be acceptable if the materiality threshold was applied at the individual ACO level. Some commenters requested that CMS consider adopting a tiered materiality threshold for ACOs of varying size, practice-mix, patient population, and overall level of sophistication. For example, according to this commenter, an error affecting a smaller or newer ACO or an ACO serving a high-need population should be subject to a lower materiality threshold. Some commenters believe it is important to maintain flexibility and that CMS should consider individual materiality thresholds for differing ACOs to help ACOs that are facing financial strain and duress.

Response: We appreciate the suggestions that commenters provided regarding issues related to the

materiality of a payment error and when CMS should reopen a payment determination for good cause. Based on a review of the comments, we believe that it would be appropriate to address issues related to the materiality of an error through subregulatory guidance rather than through regulations. We believe that both CMS and ACOs would benefit from gaining additional experience with issues related to reopenings of payment determinations in the Shared Savings Program before further considering whether additional regulations would be appropriate. However, we are concerned that it could be very complex and burdensome for CMS to tailor materiality considerations to the particular characteristics or circumstances of a given ACO, as suggested by some commenters. In considering when to reopen an error for good cause, we intend to strike a careful balance between important Medicare program integrity concerns that payments be made timely and accurately under the Shared Savings Program with our desire to minimize unnecessary operational burdens for ACOs and CMS, and to support the ACOs' ability to invest in additional improvements to increase quality and efficiency of care. To achieve this careful balance in objectives for reopenings to address CMS technical errors, we may consider whether the error satisfies a materiality threshold, such as 3 percent of the total amount of net shared savings and shared losses for all ACOs for the applicable performance year. As described in the 2016 proposed rule, we plan to provide additional information about how we may consider the materiality of an error in subregulatory guidance (see 81 FR 5856 through 5857). To illustrate, under such an approach, we could exercise our discretion to reopen the financial reconciliation for a performance year if we determined that a correction to address a CMS technical error would affect total net shared savings and shared losses (that is, the amount of shared savings after the amount of shared losses has been subtracted) for all ACOs for the affected performance year by 3 or more percent. We may consider a higher threshold, such as 5 percent, or a lower threshold, such as 1 or 2 percent. However, based on a review of guidance from the GAO for financial audits of federal entities, we believe that 3 percent could generally be a reasonable threshold for ''material effect.'' The GAO guidance was developed to assist auditors in assessing material effect for planning the audit scope for federal entities to ensure that financial statement audits achieve their intended outcomes of providing enhanced accountability over taxpayer-provided resources. This guidance has been used for a number of years by GAO financial auditors for performing financial statement audits of federal entities. (See the GAO Web site at *http://www.gao.gov/special.pubs/01765G/vol1_complete.pdf.*) Although ACOs are not federal entities, we believe it would be reasonable to consider the GAO guidance in determining when a technical error has a material effect across all ACOs, such that we should use our discretion to reopen for good cause. The Shared Savings Program is a relatively large federal program administered within HHS, including over 400 ACOs (as of January 1, 2016). Accordingly, we believe that the GAO guidance on federal entity audits, while not directly applicable, provides a relevant and appropriate resource in considering when errors in certain payment determinations under the Shared Savings Program are material and whether we should exercise our discretion to reopen for good cause.

Comment: Commenters did not directly address the PY1 payment determinations affected by the data source error described in the proposed rule. However, some commenters more broadly urged that CMS hold ACOs harmless for payment determination errors made by CMS. These commenters believe that ACOs ''should not be penalized for CMS errors'' because ACOs may have already used the affected funds to improve beneficiary care.

Response: Except as discussed in the proposed rule for the PY 1 data source error, we do not believe it would be appropriate to establish a finality policy to hold ACOs harmless for payment determination errors made by CMS. We acknowledge that from year to year, corrections could sometimes advantage individual ACOs and sometimes disadvantage individual ACOs. We anticipate that, over time, this approach would not likely have a biased effect on ACOs or Medicare expenditures since the impact of reopenings over time would be equally likely to increase/decrease net shared savings and losses. We also believe there would be program integrity concerns if we were to hold ACOs harmless for payment determination errors made by CMS.

Comment: A few commenters recommended that payment and recoupment activities associated with reopenings and revised initial payment determinations be administered as stand-alone activities rather than being combined with subsequent years' savings or losses. Their rationale is that ACOs are still evolving and their compositions are changing, sometimes dramatically, from year to year; therefore, recalculation of the financial reconciliation should impact the ACO participants from the corresponding performance year, and not the ACO participants in a subsequent performance year.

Response: We indicated in the proposal that we would consider ways to minimize program disruptions for ACOs that could result from one or more reopenings. Our intent is to reduce operational burdens, when feasible, that might result if an ACO were subject to one or more reopenings. The net effect on payments as a result of a reopening will not be different whether we perform the reopening independently or in conjunction with payment reconciliation for another performance year. In either case, we would provide ACOs with details regarding any necessary adjustments in their shared savings or shared losses resulting from reopened financial calculations for each performance year affected. We expect that ACOs would have sufficient information to be able to internally attribute any changes in shared savings/shared losses for a prior performance year as the ACO believes appropriate and consistent with the ACO's agreements with its ACO participants. Therefore, to the extent feasible, we will make corrections in a unified reopening (as opposed to multiple reopenings) to correct errors for a given performance year. In addition, we will consider other ways to reduce operational burdens for both ACOs and CMS that could result from making payment adjustments. For example, if we determine that a correction needs to be made to a prior performance year's results for good cause, we would seek to potentially adjust shared savings payments to the ACO or shared loss recoupments from the ACO for a subsequent performance year. To illustrate, if an ACO that generated shared savings for the second performance year of its agreement period owed CMS money based on a correction made to the payment determination for the prior performance year, we might be able to deduct the amount owed prior to making the current year shared savings payments (subject to the general requirement, discussed in the proposed rule, for ACOs to repay monies owed to CMS within 90 days of notification of the obligation). In either case, we expect to be able to provide ACOs with sufficient details regarding these corrections that they will be able to attribute the

additional payment or recoupment arising from the reopening internally and, as applicable, distribute additional funds to or collect amounts from the appropriate ACO participants from the prior PY.

FINAL ACTION: We are finalizing the administrative finality policy as proposed. Specifically, we are finalizing that if CMS determines that the amount of shared savings due to an ACO or the amount of shared losses owed by an ACO has been calculated in error, CMS may reopen the earlier payment determination and issue a revised initial determination: (1) At any time in the case of fraud or similar fault, as defined in § 405.902; or (2) not later than 4 years after the date of notification to the ACO of the initial determination of shared savings or shared losses for the relevant performance year under § 425.604(f), § 425.606(h) or § 425.610(h), for good cause. Good cause may be established when there is new and material evidence of an error or errors, that was not available or known at the time of the payment determination and may result in a different conclusion, or the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination. Good cause will not be established by a change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise. We will have sole discretion to determine whether good cause exists for reopening a payment determination. Also, good cause will not be established by a reconsideration, appeal, or other administrative or judicial review of any determinations precluded under § 425.800.

If we determine that the reopening criteria are met, we will recompute the financial results for all ACOs affected by the error or errors. We will not reopen and revise PY 1 payment determinations to address the data source error described previously. We will address issues regarding when an error is material such that it would be appropriate to exercise our discretion to reopen for good cause through subregulatory guidance.

We note that the current requirements for ACO repayment of shared losses after notification of the initial determination of shared losses will not be affected by any of the policies that we are adopting in this section of this final rule. As described under § 425.606(h)(3) (Track 2) and § 425.610(h)(3) (Track 3), if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification. These current requirements will continue to apply for repayment by ACOs for shared losses. For example, an ACO will not be able to delay recoupment of any payments required under § 425.606(h)(3) or § 425.610(h)(3) by notifying CMS of a possible error that could merit reopening. Instead, if we later determine that a correction should be made, we would subsequently combine, if feasible, the revised calculation of shared savings or shared losses for the affected performance year with the financial reconciliation for the most recent performance year. For example, we would add any amount owed to the ACO as a result of the reopening, to any shared savings payments for which the ACO is eligible for the most recent performance year. Finally, we had proposed to include these administrative finality provisions as a revision to § 425.314 (Audits and record retention) by removing (a)(4) and adding a new paragraph (e) to specify the circumstances under which we would reopen a payment determination under §§ 425.604(f), 425.606(h), 425.610(h), 425.804, or 425.806. However, we now believe these administrative finality provisions are a sufficiently distinct topic from ''audits and record retention'' that it would be clearer to instead incorporate these administrative finality provisions in a new, separate section at § 425.315 (Reopening Determinations of ACO Savings or Losses to Correct Financial Reconciliation Calculations). Accordingly, we are revising § 425.314 by removing (a)(4) and are adding a new § 425.315 to specify the circumstances under which we would reopen a payment determination under §§ 425.604(f), 425.606(h), 425.610(h), 425.804, or 425.806.

3. Conforming Change

As discussed earlier in the overview for this section, the determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, and the limit on the total amount of shared savings as well as the underlying financial calculations are excluded from administrative and judicial review under section 1899(g) of the Act. Accordingly, in the November 2011 final rule establishing the Shared Savings Program, we adopted the regulation at § 425.800 to preclude administrative and judicial review of the determination of whether an ACO is eligible for shared savings and the amount of shared savings under Track 1 and Track 2 (§ 425.800(a)(4)), and the limit on total amount of shared savings that may be earned under Track 1 and Track 2 (§ 425.800(a)(5)). In the June 2015 final rule, we amended the Shared Savings Program regulations by adding a new provision at § 425.610 to establish a new performance-based risk option (Track 3) that includes prospective beneficiary assignment and a higher sharing rate. However, in the June 2015 final rule we inadvertently did not also update § 425.800 to include references to determinations under § 425.610 (Track 3) in the list of determinations under this part for which there is no reconsideration, appeal, or other administrative or judicial review. Therefore, we proposed a conforming change to amend § 425.800 to add determinations under § 425.610 (Track 3) to the list of determinations under § 425.800(a)(4) and (a)(5) for which there is no reconsideration, appeal, or other administrative or judicial review.

Comment: We did not receive comments on this proposed conforming change.

Response: We will finalize this conforming change to the regulations to include determinations for Track 3 ACOs to the list of determinations for which there is no reconsideration, appeal, or other administrative or judicial review.

FINAL ACTION: We are amending § 425.800 to add determinations under § 425.610 (Track 3) to the list of determinations under § 425.800(a)(4) and (a)(5) for which there is no reconsideration, appeal, or other administrative or judicial review.

III. Collection of Information Requirements

As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make certain payment and policy changes to the Medicare Shared Savings Program established under section 1899 of the Act. The Shared Savings Program promotes accountability for a patient population, fosters the coordination of items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. These changes are focused on calculations for resetting the financial benchmark for an ACO's second or subsequent agreement period,

thereby fulfilling a goal communicated in the Shared Savings Program June 2015 final rule (80 FR 32692), and further discussed in the 2016 proposed rule, to take into account regional expenditures when resetting an ACO's financial benchmark for a second or subsequent agreement period.

B. Overall Impact

We examined the impacts 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 (January 18, 2011), 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) and the Congressional Review Act (5 U.S.C. 804(2)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). 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 have prepared a RIA, which to the best of our ability presents the costs and benefits of the rulemaking.

In keeping with our standard practice, the main analysis presented in this RIA compares the expected outcomes of the modifications finalized with this rulemaking to the expected outcomes under current regulations. We provide our analysis of the expected costs of the payment model under section 1899(i)(3) of the Act compared to the costs that would be incurred under the statutory payment model under section 1899(d) of the Act in section IV.E of this final rule.

C. Anticipated Effects

1. Effects on the Medicare Program

The Shared Savings Program is a voluntary program involving an innovative mix of financial incentives for demonstrating quality of care and efficiency gains within FFS Medicare. As a result, the changes to the Shared Savings Program adopted in this final rule could result in a range of possible outcomes. While evaluation of the program's overall impact to date is ongoing, the quality and financial results of the first 2 performance years are within the range originally projected for the program in the November 2011 final rule (see Table 8, 76 FR 67963). Also, at this point, we have seen no evidence of selective ACO participation that would systematically bias overall program performance as measured by ACO benchmarks.

In the June 2015 final rule, we established a policy for rebasing an ACO's financial benchmark for a second or subsequent agreement period by weighting each benchmark year equally and taking into account savings generated by the ACO in the previous agreement period. We also discussed potential future modifications to the rebasing methodology that would account for regional FFS expenditures and remove the policy of adding savings generated by the ACO in the previous agreement period. In the 2016 proposed rule, we proposed modifications to the program's regulations, focused on incorporating regional expenditures into ACOs' rebased historical benchmarks. In this final rule, we are adopting an alternative benchmarking approach for ACOs starting a second agreement period in 2017 and subsequent years. The rebasing methodology promulgated in the June 2015 rule will apply to ACOs that entered a second agreement period in 2016. The revised rebasing methodology promulgated in this final rule will apply to these ACOs starting in their third agreement period. Under the revised benchmarking methodology adopted in this final rule, an ACO's reset benchmark will be adjusted by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's rebased historical benchmark amount (described in section II.A.2.c of this final rule). Under the phased approach to using a higher percentage in calculating the adjustment for regional expenditures (described in section II.A.2.c.3 of this final rule): in the ACO's first agreement period in which the regional FFS adjustment is applied the percentage used in calculating the regional adjustment will be set as high as 35 percent; in the ACO's second agreement period in which the regional FFS adjustment is applied and subsequent agreement periods, the percentage will be set as high as 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. This approach will further limit the link between an ACO's performance in prior agreement periods and its benchmark in subsequent agreement periods by making the benchmark more reflective of costs in the ACO's regional service area. These changes are intended to strengthen the incentives for ACOs to invest in infrastructure and care redesign necessary to improve quality and efficiency and meet the goals of the Shared Savings Program. In response to comments, we are finalizing a modification that will moderate the phase-in of the regional FFS adjustment for ACOs that have higher costs than their region and for which the regional adjustment will reduce the ACO's benchmark. In such cases, the weight placed on the regional FFS adjustment will be reduced to 25 percent (down from 35 percent) in the first agreement period in which the regional FFS adjustment is applied, and 50 percent (down from 70 percent) in the second. By the third agreement period under the revised rebasing methodology, the weight placed on the regional FFS adjustment will be 70 percent for all ACOs, unless the Secretary determines a lower weight should be applied, as specified through future rulemaking.

Another key modification to the benchmark rebasing methodology involves refining certain calculations that currently rely on national FFS expenditures and corresponding trends so that they are instead determined according to county FFS trends observed in each ACO's unique assignment-weighted regional service area. Annual average per capita costs will be tabulated for assignable FFS beneficiaries in each county. For each ACO, a regional weighted average

expenditure will be found by applying ACO assigned-beneficiary weights to the average expenditures tabulated for each county. Changes in an ACO's regional service area average per capita expenditures (and relative risk reflected in associated HCC risk scores) will define a regional trend specific to each ACO's region. This regional trend will be utilized in two specific areas of the existing benchmark methodology to replace the: (1) National expenditure trend in calculations establishing the ACO's rebased historical benchmark; and (2) existing national ''flat dollar'' growth amount for updating the rebased historical benchmark for each performance year.

By replacing the national average FFS expenditure trend and ''flat dollar'' update with trends observed for county level FFS assignable beneficiaries in each ACO's unique assignment-weighted regional service area, benchmark calculations will be better structured to account for exogenous trend factors particular to each ACO's region and the pool of potentially-assignable beneficiaries therein (for example, higher trend due to a particularly acute flu season or an unusually large area wage index adjustment or change).

Although the policy will have mixed effects—increasing or decreasing benchmarks for ACOs in various circumstances—an overall increase in program savings will likely result from taking into account service-area trends in benchmark calculations. In some cases lower benchmarks will be produced, preventing shared savings payments to certain ACOs for whom national average trends and updates would have provided higher updated benchmarks. For other ACOs, such a policy will be more sensitive to regional circumstances outside of the ACO's control causing higher trends for the ACO's service area. In such cases, a higher benchmark could improve program cost savings in the long run by reducing the likelihood the ACO would choose to drop out of the program because a shared loss would otherwise have been assessed due to exogenous factors unrelated to the ACO's changes in care delivery.

In addition, applying the regional trend as a percentage (rather than ''flat dollar'') when updating the benchmark to a performance year basis is anticipated to further reduce program costs by improving the accuracy of updated benchmarks, particularly for ACOs that have historical benchmarks significantly below or above average. The November 2011 final rule discussed the risk that large nominal ''flat dollar'' growth updates could compound over an agreement period to excessively inflate benchmarks for ACOs with relatively low historical benchmark cost and could lead to predictable bias and resulting cost for selective participation in the program (76 FR 67964). Such risk has not materialized in program experience to date, largely due to the historically low national program trend used to update ACO benchmarks through the first 3 years of the program. However, the per capita trend for the Medicare FFS program is anticipated to be higher in future years associated with the period governed by this final rule in contrast to the relatively moderate growth in cost experienced over the first 3 years of the program's implementation.[3] The changes to the methodology for updating the benchmark included in this final rule will apply regional trends to update ACO benchmarks and therefore prevent the increased program cost the current update methodology risks by employing an average ''flat dollar'' update that compounds over the 3 years of an ACO's agreement period.

Program participation and ACO beneficiary assignment are not homogenously distributed geographically. ACOs tend to have service areas overlapping those of other ACOs in the same urban or suburban market(s). Therefore, to the extent that ACOs in these areas produce significant reductions in expenditures, a greater proportion of such savings will affect ACO-service-area trends than the average effect felt at the national program level, effectively reducing the average ACO's updated benchmark compared to what the use of a national trend alone would have produced. While such effect has the potential to reduce program costs by reducing net shared savings payments it could be seen as a disadvantage to participating organizations in ''ACO-heavy regions'' that manage to broadly increase efficiency at the overall regional market level.[4] However, on the whole, we anticipate this effect to be a reasonable trade-off that will not prevent an overall improvement in the incentive for ACOs to improve efficiency in care delivery in the context of periodic benchmark rebasing as a result of the policies adopted in this final rule. As described previously in this rule, we acknowledge the potential advantages of alternative approaches to determining benchmark updates, for example utilizing the national growth rate adjusted for regional price variation, and we anticipate exploring such approaches in future rulemaking.

Additionally, we anticipate significant program savings will result from ending the policy from the June 2015 rule under which savings generated in the previous agreement period are taken into account when resetting the benchmark in an ACO's second or subsequent agreement period. However, savings from this modification are not wholly retained by the program but are largely redistributed to ACOs that are measured to have demonstrated efficiency in a more standardized way, using a regional FFS adjustment to their benchmarks. As commenters on the 2016 proposed rule noted, roughly two-thirds of ACOs in the 2014 public use data released in conjunction with the 2016 proposed rule showed lower expenditures than their county-weighted FFS averages and would therefore likely benefit from the regional FFS adjustment.

Changes to the existing benchmark calculations described previously are expected to benefit program cost savings by producing rebased benchmarks with improved accuracy (for example, reflecting regional trends rather than national average trends and 'flat dollar' updates) and of somewhat lower per capita cost on average (due to removing the effect of the savings adjustment to the rebased benchmark and because regional trend calculations typically reflect a higher proportion of ACO assigned beneficiary experience than national average trend calculations). However, such savings are expected to be partly offset by increasing shared savings payments to ACOs benefiting from the adjustment to the rebased historical benchmark to reflect a portion of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's rebased historical benchmark amount. This trade-off reflects our intent to strengthen the reward for attainment of efficiency in an absolute sense, complementing the existing program's focus on rewarding improvement relative to an ACO's recent baseline.

[3] Traditional fee-for-service Medicare Part A and B annual per capita cost trend is expected to reach approximately 5 percent in 2019, as detailed in the 2017 Medicare Advantage Early Preview accessible at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/EarlyPreview2017GrowthRates.pdf.*

[4] Similarly, certain regions may be targeted for other care delivery reforms, for example certain Center for Medicare and Medicaid Innovation models. A downward bias on an ACO's benchmark could be felt to the extent that such activity reduces expenditures for beneficiaries in the ACO's region but not in a proportional way within the ACO's assigned population. Such scenarios are more likely when competing models are specifically targeted at beneficiaries not assigned to an ACO.

Making a regional adjustment to the ACO's rebased historical benchmark will strengthen an ACO's incentives to generate and maintain efficient care delivery over the long run by weakening the link between an ACO's prior performance and its future benchmark. This adjustment is expected to marginally increase program participation in agreement periods where risk (Track 2 or 3) is mandatory for an ACO since a significant portion of ACOs will have knowledge that a favorable baseline expenditure comparison to their FFS region will mitigate their risk of being assessed a shared loss in a subsequent agreement period. It is also expected to reduce the frequency with which ACOs in Track 2 or 3 drop out of the program during an agreement period because such ACOs will have somewhat greater certainty regarding the extent to which savings achieved in the prior agreement period will continue to be reflected in a rebased benchmark that incorporates a regional adjustment.

However, more predictable relationships, that is, an ACO's knowledge of its costs relative to FFS expenditures in its region, also create the risk of added cost to the Shared Savings Program by way of—(1) Increasing shared savings payments to ACOs exhibiting expenditures significantly below their region at baseline especially in cases where such differences are related to factors exogenous to efficiency in the delivery of care (where shared savings payments could be further inflated by increased selection of Track 3 over Track 2); (2) potentially losing participation from ACOs with expenditures high above their region at baseline—reducing the opportunity to impact beneficiary populations with the greatest potential for improvements in the cost and quality of care; [5] and (3) from structural shifts by ACOs in ways that would reduce assignment of relatively high cost beneficiaries and increase assignment of relatively healthy populations or shift the geography of their service area to similarly effect a more favorable benchmark adjustment. A primary uncertainty and significant potential concern is whether complex patients will continue to have their care successfully coordinated by ACO providers/suppliers under the revised benchmark methodology. If the regional adjustment results in unattainable benchmarks for ACOs serving at-risk and medically complex populations then the program would likely exhibit decreasing participation from providers serving populations where the greatest potential for savings through better care coordination and quality improvement would otherwise be present and therefore we would expect significantly lower savings for the program than currently anticipated.

In addition to the uncertainty with respect to the relationship of the potential offsetting effects noted previously, there remains broader uncertainty as to the number of ACOs that will participate in the program (especially under performance-based risk in Track 2 or Track 3), provider and supplier response to financial incentives offered by the program, interactions with other value based models and programs from CMS and other payers, and the ultimate effectiveness of the changes in care delivery that may result as ACOs work to improve the quality and efficiency of patient care. Certain ACOs that have achieved shared savings in their first agreement period may find that they receive significantly lower benchmarks under these revisions (especially in cases where regional expenditures are much lower than expenditures for the ACO's assigned beneficiary population). Other ACOs may seek to maximize sharing in savings by selecting Track 3 if they have assigned beneficiaries with significantly lower expenditures at baseline relative to their region. These uncertainties continue to complicate efforts to assess the financial impacts of the Shared Savings Program and result in a wide range of potential outcomes regarding the net impact of the changes included in this final rule on Medicare expenditures.

To best reflect these uncertainties, we continue to utilize a stochastic model that incorporates assumed probability distributions for each of the key variables that will affect the overall financial impact of the Shared Savings Program. A summary of assumptions and assumption ranges utilized in the model includes the following:

- Approximately 100, 100, and 200 ACOs will consider renewing in 2017, 2018, and 2019, respectively.
- ACOs will choose not to renew if—

++ Under the current policy: The ACO's gross loss in the prior performance year was 5 percent or greater; or

++ Under the policies included in this final rule: The ACO's gross loss is 3 percent or greater in the prior performance year after accounting for the expected effect of the revised rebasing methodology (for example, considering differences between the ACO's spending and that of its region) and adjusting for ACO participant changes that result in baseline cost reduction of 2 percent on average (see discussion elsewhere in this final rule).

In either scenario, the thresholds are calibrated to approximate the level of baseline loss an ACO would correlate to an expected shared loss from its rebased benchmark. The magnitude of the loss is roughly equal to the revenue ACO participating physicians may have gained from the 5 percent incentive payment under MACRA [6] that is potentially available to physicians and certain other practitioners in certain ACOs for participation in the Shared Savings Program. The policies included in this final rule are assumed to result in a lower tolerance for renewal after a prior agreement period loss because the regional adjustment to the rebased benchmark is expected to be more consistent from year to year whereas the current rebasing methodology would be expected to generate a higher benchmark reflecting to a greater degree the actual spending from the prior agreement period that led to the prior loss. However, ACOs that do renew under the policies included in this final rule are expected to be more likely to remain in the program for the entire agreement period because the benchmark adjustment improves the likelihood that favorable changes to the methodology for rebasing the benchmark that led the ACO to renew its agreement will continue to be evidenced in future performance years.

- Renewing ACO will choose higher risk in Track 3 if—

++ Under the current policies: The ACO's gross savings in prior performance year are 4 percent or greater; or

++ Under the policies included in this final rule: The ACO's prior performance year gross savings adjusted by regional expenditures are 2 percent or greater.

In either scenario, similar to the renewal assumption, policies included in the final rule offer greater certainty that adjusted prior performance will correlate to future performance and therefore the threshold for selecting

[5] Early program results indicate that ACOs with expenditures significantly above their risk-adjusted FFS regional average have produced greater than average reductions in expenditures than ACOs with low baseline expenditures relative to their region; however it is not yet evident that such early savings achieved for such relatively high cost populations are likely to grow to an extent that their expenditures would reach parity with their region.

[6] The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established new incentives to encourage physicians and certain other practitioners to participate in alternative payment models; pending final rulemaking, such incentive payments may equate to approximately 5 percent of physician fee schedule revenue to eligible clinicians participating in certain qualifying ACOs.

Track 3 is lower than what is assumed for the baseline scenario.

- Marginal gross savings will increase by between 0.0 percent to 1.0 percent for ACOs selecting higher performance-based risk in Track 3 and between 0.0 percent to 0.2 percent for all ACOs due to the adjusted rebasing methodology. These ranges were chosen to encompass a range of relative savings rates observed for performance-based risk accepted by ACOs participating in the Pioneer ACO Model relative to Shared Savings Program ACOs, the vast majority of which have elected to participate under the one-sided shared savings model (Track 1).
- ACOs experiencing a loss during the rebased agreement period are assumed to drop out prior to the second or third performance year if a shared loss from the prior performance year exceeds 2 percent. While Pioneer ACO Model experience would predict a lower tolerance for remaining in the program after a loss, 2 percent was chosen to approximate the incentive payment under MACRA that may be made available (pending final rulemaking) to physicians and certain other practitioners participating in ACOs in Track 2 and Track 3, which was not available to participants in Pioneer ACOs.
- ACOs will make adjustments to their ACO Participant Lists that reduce their cost relative to region by approximately 2 percent on average. This assumption is based on empirical analysis of 2015 ACO Participant List change requests and resulting impact on ACO baseline expenditures due to changes in assignment; the magnitude of bias is assumed to be greater for ACOs starting higher than their corresponding regional average expenditures and/or with a relatively small assigned beneficiary population and lower for ACOs starting below regional average expenditures and/or with a relatively large assigned beneficiary population.
- ACOs will achieve a mean quality score of 80 percent (based on analysis of Shared Savings Program ACO quality scores in 2013 and 2014).
- ACO savings will have an impact on regional expenditures and trends proportional to ACO assignment saturation of the FFS beneficiary population in the market.

Assumptions for ACO baseline costs, including variations in trends for ACOs and their relationship to their respective regions were determined by analyzing existing ACO expenditures and corresponding regional expenditures back to 2009, the first benchmark year used for the first wave of ACOs that entered the program in 2012. (Note, associated data for the 2012 through 2014 time period were released in conjunction with the 2016 proposed rule to assist commenters in modeling implications of the proposed policy changes.) The empirical time series data were randomly extrapolated to form baseline time series data through the end of the rebased agreement period by applying growth rates to ACOs and their regions by randomly sampling empirical growth rates for ACOs (and their respective regions) with similar characteristics in terms of size and relative cost to region.

Using a Monte Carlo simulation approach, the model randomly draws a set of extrapolated ACO baseline trends and specific values for each variable, reflecting the expected covariance among variables, and calculates the program's financial impact based on the specific set of assumptions. We repeated the process for a total of 1,000 random trials, tabulating the resulting individual cost or savings estimates to produce a distribution of potential outcomes that reflects the assumed probability distributions of the incorporated variables.

Table 4 details our estimate of the 3-year net impact of the policy changes included in this final rule on net FFS benefit claims costs, net shared savings payments to ACOs, and the resulting impact on net Federal cost. Projected impacts are detailed for the first 3 cohorts of ACOs that would be renewing agreements under these changes, renewing respectively for agreement periods starting in 2017, 2018, and 2019. During these agreement periods, a 35 percent weight would be placed on the benchmark expenditure adjustment for regional FFS expenditures (or a lower 25 percent weight in cases where the ACO's rebased costs are higher than its regional FFS average). In such agreement periods, total savings from these changes to the methodology for calculating and trending expenditures during the benchmark period in order to establish and update the benchmark, as well as anticipated savings from marginally increased program participation and improved incentives for creating efficiency, are expected to be greater than the increase in cost of net shared savings payments due to selective participation in response to adjustments that are predictably significant (either favorable or unfavorable) upon examination of how expenditures for the ACO's historically assigned beneficiary population compare to the expenditure level for the ACO's regional service area at baseline. For this reason the net Federal impact is projected to be a savings (that is, a negative change in net Federal cost) for the first 3 years for each renewing cohort, and correspondingly a $110 million net Federal savings for the first 3 calendar years of the projection window, 2017 through 2019. Such median impact on net Federal cost results from a projected increase in savings on net benefit claims costs of $410 million partially offset by a $300 million increase in net shared savings payments to ACOs. The last two rows of Table 4 enumerate the range of potential net Federal cost impacts our modeling projected, specifically the 10th percentile of simulation outcomes (a $240 million net Federal increase in cost) and the 90th percentile ($480 million net Federal savings). Overall, approximately two-thirds of trials resulted in combined net Federal savings over 2017 to 2019.

The estimate for this final rule reflects $10 million higher net Federal cost than the impact estimated for the 2016 proposed rule. As a result of finalizing a phase-in approach that reduces the weight for the regional FFS adjustment during an ACO's first and second agreement periods under the revised rebasing methodology in cases where it decreases the ACO's rebased benchmark, we estimate: (1) An increase in shared savings payments net of shared losses of $50 million over 2017 through 2019 compared to the corresponding estimate in the proposed rule, mainly because of increases to certain ACOs' rebased benchmarks; (2) a decrease in gross claims costs due to increased participation of $40 million relative to the corresponding estimate in the 2016 proposed rule.

TABLE 4—ESTIMATED 3-YEAR IMPACT OF CHANGES (INCLUDING A MAXIMUM 35 PERCENT WEIGHT USED IN DETERMINING REGIONAL ADJUSTMENT AMOUNT) ON NET BENEFIT COSTS, NET PAYMENTS TO ACOS, AND OVERALL NET FEDERAL COSTS CYS 2017 THROUGH 2019

[Impacts are Median Results Unless Otherwise Noted]

Calendar year	2017	2018	2019	3-Year total
Impact on Net Claims Costs ($Million):				
ACOs Renew 2017	−70	−70	−80	−220
ACOs Renew 2018	.....	−60	−70	−130
ACOs Renew 2019	.....	.....	−60	−60
All ACO Total	−70	−130	−210	−410
Impact on Net Shared Savings Pay ($Million):				
ACOs Renew 2017	50	40	40	130
ACOs Renew 2018	.....	40	40	80
ACOs Renew 2019	.....	.....	90	90
All ACO Total	50	80	170	300
Overall Impact on Net Federal Costs ($Million):				
ACOs Renew 2017	−20	−30	−40	−90
ACOs Renew 2018	.....	−20	−30	−50
ACOs Renew 2019	.....	.....	30	30
All ACO Total	−20	−50	−40	−110
Low (10th %-ile)	20	50	170	240
High (90th %-ile)	−70	−160	−250	−480

The stochastic model and resulting financial estimates were prepared by the CMS Office of the Actuary (OACT). The median result of $110 million increase in savings in net Federal cost is a reasonable ''point estimate'' of the impact of the changes included in this final rule on the Shared Savings Program during the period between 2017 through 2019. However, we emphasize the possibility of outcomes differing substantially from the median estimate, as illustrated by the estimate distribution. Accordingly, this RIA presents the costs and benefits of this final rule to the best of our ability. As further data emerge and are analyzed, we may improve the precision of future financial impact estimates.

To the extent that the Shared Savings Program will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums will also be correspondingly lower or higher. In addition, because MA payment rates depend on the level of spending within traditional FFS Medicare, savings or costs arising from the Shared Savings Program will result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

a. Effects of the Final Rule in Subsequent Agreement Periods

For an ACO's third agreement period (that is, the second rebased agreement period under the revised benchmarking methodology, for example the 3-year period covering 2020 through 2022 for ACOs renewing for a second agreement period in 2017) the weight on the adjustment to the benchmark for regional FFS expenditures will increase to 70 percent (except in cases where the ACO's rebased costs are higher than costs for its region in which case the weight will increase to 50 percent for the second rebased agreement period). Increasing the weight of the adjustment reduces the strength of the link between an ACO's effect on the cost of care for its assigned beneficiaries and the benchmark calculated for an ensuing agreement period. Weakening this link may increase the incentive for ACOs to make investments in care delivery reforms because resulting potential savings will be more likely to be rewarded over multiple agreement periods rather than being 'baked' back into the benchmark at the next rebasing. On the other hand, efficiency gains will need to be significantly greater than those currently achieved by the ACOs participating in the program to result in budget neutrality by sufficiently offsetting increased shared savings payments to ACOs favored by a regional adjustment with a 70 percent weight. As discussed previously, we are setting the maximum weight of the regional adjustment at 70 percent for ACOs with lower costs than their region in their second agreement period under the revised benchmarking methodology, and for all ACOs in their third and all subsequent agreement periods under this methodology, unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. This determination, which could be made in advance of the agreement period beginning January 1, 2020, may be based on an assessment of the effects of the regional adjustment (and other modifications to the program made under this rule) on the Shared Savings Program such as: The effects on net program costs; the extent of participation in the Shared Savings Program; and the efficiency and quality of care received by beneficiaries.

ACOs demonstrate a wide range of differences in expenditures relative to risk adjusted expenditure levels for their region (for the sample of roughly 200 ACOs that started in the program in 2012 or 2013 the percentage by which ACO per capita expenditures exceed or are exceeded by their respective risk-adjusted regional per capita expenditures varies with a standard deviation of approximately 10 percent). Transitioning to a 70 percent weight to calculate the regional adjustment effectively down-weights the savings generated by the changes we are making to the existing benchmark calculation, since an ACO's benchmark would have increased dependence on the regional FFS expenditures and correspondingly a decreasing dependence on the historical expenditures for the ACO. At the same

time, increasing the weight used to calculate the regional adjustment could result in selective participation and increases in shared savings payments to ACOs that have low beneficiary expenditures at baseline. If that were to happen, the overall anticipated cost of net shared savings payments would rise and outweigh the anticipated potential gains from additional care management and associated improvements in net benefit costs spurred by the improved incentives for efficiency generated by partially delinking ACO benchmarks from their own historical costs.

An element of the regional adjustment which becomes apparent when reviewing the accompanying data files and the performance of ACOs in 2013 and 2014 (for those roughly 200 ACOs that started in 2012 and 2013) is that ACOs that are above or below the regional service area expenditure amount used to adjust their rebased benchmark in 1 year tend to have a similar bias in the following year. Placing a 100 percent weight on the regional service area expenditure amount illustrates this. Of the 50 ACOs that were the furthest below their estimated regional service area expenditure level in 2013, all were at least 10 percent below and their average expenditures were roughly 15 percent below the expenditures for the region. In the subsequent year, 2014, none of these ACOs exceeded its regional service area expenditure level, and the average expenditure difference only moved by about 2 percentage points. Similar yet less glaring results occur in those ACOs above their regional service area expenditure level, with the 50 ACOs the furthest above their regional service area expenditure level having costs an average of approximately 10 percent above the regional service area expenditure level in 2013—an average difference for the group that only moved by about 2 percentage points the following year.

Of the approximately 150 ACOs that were more than 0.5 percent below their regional service area expenditure level, only about 10 percent were above their regional service area expenditure level in the following year. Again, ACOs above their regional service area expenditure level follow a similar pattern, though less drastic. Of the ACOs above their regional service area expenditure level by more than 0.5 percent, approximately 25 percent performed below their regional service area expenditure level in the following year. Notwithstanding the potential for behavioral changes, this illustrates that for a significant portion of existing ACOs, there is evidence of a bias when compared to their regional service area expenditure level and that bias is likely to be predictable over time. We have accounted for cost associated with program selection for ACOs favored by such bias and considered attrition in participation by ACOs disfavored by such bias. However, for some ACOs of the latter condition, it may take multiple years to sufficiently redesign their care delivery processes in order to generate savings substantial enough to offset high expenditures relative to their region at baseline. We note that this analysis is based on data from the first 2 years of program operations, and longer term effects may emerge to mitigate bias for certain ACOs with high expenditures at baseline.

Additionally, the passage of MACRA established new incentives to encourage providers to participate in alternative payment models. Paying for value and incentivizing better care coordination and integration is a top priority for us, and we have been implementing policies that encourage a shift towards paying for value instead of volume. MACRA provides additional tools to encourage care integration and value-based payment. Although implementation of MACRA is ongoing and many details are still to be finalized through rulemaking, the incentives created by MACRA could result in increased market pressure on providers to participate in ACOs. This may lower the risk of selective participation and potentially lead to higher expected net Federal savings.

Emerging data will be monitored in order to provide additional information for updating projections as part of the use of a higher percentage (70 percent) in calculating the regional adjustment amount for ACOs entering a third or subsequent agreement period. For example, if ACOs respond by generating new efficiencies in care beyond those that are anticipated, and/or potential selective participation responses are lower than expected, then a 70 percent weight could potentially be associated with revised expectations regarding net costs or net savings. However, it is also possible that gains in efficiency will fail to materialize and/or selective participation and other behavioral responses will increase cost beyond the level that is currently anticipated; in such scenario, we would consider further rulemaking as necessary to protect the Medicare Trust Funds (for example, in order to apply a lower percent weight in calculating the regional adjustment amount).

b. Further Considerations

This final rule introduces regional expenditure trends and a regional adjustment to the rebased historical benchmark that includes prospective HCC risk adjustment to ensure trending and the regional adjustment appropriately account for differences in risk between an ACO's assigned beneficiary population and its regional service area assignable beneficiary population. Current program experience supports the hypothesis that the current approach of applying conditional reliance on demographic risk ratios for a continuously-assigned subset of beneficiaries for purposes of adjusting the historical benchmark to a performance year basis provides a reasonable balance between accounting for changes in risk of the population and limiting the risk that coding intensity shifts would artificially inflate ACO benchmarks. This final rule retains this policy for adjusting the historical benchmark to a performance year basis.

However, for the changes involving the use of regional expenditure trends (to trend forward the benchmark years and to update the ACO's rebased historical benchmark) and the adjustment to the rebased benchmark for expenditures in the ACO's regional service area, we are not implementing any additional explicit policy for limiting coding intensity sensitivity at this time (beyond what is described in section II.A of this final rule), but rely on the difference between the average prospective HCC scores for the ACO's assigned beneficiary population and its regional service area assignable beneficiary population. Regional trend calculations for the rebased historical base years are expected to mitigate the risk of sensitivity to potential coding intensity efforts by ACO providers/suppliers for several reasons. The benchmark years for the new agreement period correspond to performance years from a prior agreement period where incentives for coding intensity changes were already actively limited by the continuously assigned demographic alternative calculation. In addition, coding intensity shifts that are uniform over a prior agreement period would not affect the trending of historical expenditures from the first 2 years to the third year of such period because such historical adjustments are only sensitive to risk score changes between the first 2 years and the third year of such baseline period. The CMS–HCC model has been updated for 2016 in ways that reduce its sensitivity to subjective coding levels for chronic conditions that are known to have historically

accounted for differences in coding levels for MA beneficiaries relative to FFS Medicare. Lastly, ACOs tend to neighbor each other in markets where any ACO coding intensity shifts would then likely drive similar market-wide effects (including effects from market spillover affecting diagnosis codes submitted for patients receiving care from ACO providers/suppliers but who are not ultimately assigned to an ACO) that would tend to net out any coding shifts in the calculation of risk scores relative to the ACO's region. This final consideration also offers a degree of reassurance that the calculation of the adjustment reflecting the difference between an ACO's expenditures relative to its region would be less likely to be materially biased by ACO coding intensity shifts.

We intend to carefully monitor emerging program data to assess whether the overall benchmark methodology as revised remains appropriately balanced between sensitivity to real changes in assigned population risk and protection from making shared savings payments due to potential coding intensity shifts. Of particular concern for close monitoring (and potential future rulemaking changes, if necessary) are the unique circumstances related to the use of a prospective beneficiary assignment methodology in Track 3 and the associated benchmark calculations for Track 3 ACOs. Prospective assignment creates an overlap between the claims considered for purposes of determining beneficiary assignment to the ACO and the period in which diagnosis submissions from claims are utilized for calculating a beneficiary's prospective HCC score for the year during which the beneficiary will be assigned to the ACO. A related area for monitoring is whether regional FFS expenditures tabulated at a county level for assignable beneficiaries determined using the assignment methodology used in Track 1 and Track 2 would provide an unbiased comparison to a beneficiary population assigned under the prospective assignment methodology for Track 3. For these reasons, as part of our monitoring we will consider the potential necessity to undertake rulemaking in order to make adjustments to regional calculations for Track 3 ACOs to avoid biasing the results.

2. Effects on Beneficiaries

As explained in more detail previously, we believe the changes included in this final rule will provide additional incentive for ACOs to improve care management efforts and maintain program participation. In addition, ACOs with low baseline expenditures relative to their region are more likely to transition to and sustain participation in a risk track (Tracks 2 or 3) in future agreement periods. Consequently, the changes in this final rule will also benefit beneficiaries through broader improvements in accountability and care coordination (such as through the use of the waiver of the 3-day stay SNF rule by Track 3 ACOs) than would occur under current regulations. Also, in this final rule we are finalizing a modified version of our proposal in order to provide a more gradual phase-in of the regional adjustment for ACOs with higher costs than their region. It is anticipated this modification will improve the ability of ACOs serving at-risk and medially complex populations to continue to participate and succeed in the program over the medium to long run.

Additionally, we intend to continue to analyze emerging program data to monitor for any potential unintended effect that the introduction of a regional adjustment to the ACO's rebased historical benchmark could potentially have on the incentive for ACOs to serve vulnerable populations (and for ACOs to maintain existing partnerships with providers and suppliers serving such populations). Further refinements that could be addressed in future rulemaking if monitoring ultimately revealed such problems could include reducing the percentage applied to the adjustment to the benchmark for regional expenditures, introducing additional adjustments (for example, enhancements or complements to the prospective CMS–HCC risk model) to control for exogenous factors impacting an ACO's costs relative to its region, or otherwise modifying the benchmark calculation to improve the balance between rewarding attainment and improvement in the efficiency and quality of care delivery for the full spectrum of beneficiaries enrolled in FFS Medicare.

3. Effects on Providers and Suppliers

We anticipate that including an adjustment to an ACO's historical benchmark reflecting a percentage of the difference between the ACO's regional service area average per capita expenditure amount and the ACO's rebased historical benchmark amount will provide an additional incentive for ACOs to make investments to improve care coordination. At the same time, this change in methodology also shifts the benchmark policy focus from rewarding improvement in trend relative to an ACO's original baseline to an incentive that places more weight on attainment of efficiency—how an ACO compares in absolute expenditures to its region. Certain ACOs that joined the program from a high expenditure baseline relative to their region and that showed savings under the first agreement period benchmark methodology will likely expect lower benchmarks and greater likelihood of shared losses under a methodology that includes at least a 25 percent weight on the regional expenditure adjustment. Additionally, certain ACOs that joined the program with relatively low expenditures relative to their region may now expect significant shared savings payments even if they failed to generate shared savings in their first agreement period under the existing benchmark methodology.

4. Effect on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most physician practices, hospitals, and other providers are small entities either by virtue of their nonprofit status or by qualifying as a small business under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards.* For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the Physician Fee Schedule.

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have developed our rules and regulations accordingly in order to minimize costs and administrative burden on such entities as well as to maximize their opportunity to participate. For example, networks of individual practices of ACO professionals are eligible to form an ACO. Also, the use of a MSR under Track 1, and, if elected by the ACO under Tracks 2 and 3, that varies by the size of the ACO's population that is calculated using a lower confidence

interval allows the MSRs (and, if applicable, MLRs) for smaller ACOs to be significantly lower than they would have been had CMS applied the higher confidence intervals used to derive MSRs (and MLRs) applicable to medium and large size ACOs. Further, eligible ACOs may remain under the one-sided model for a second agreement period to give them additional time to gain experience with the accountable care model before undertaking performance-based risk.

Small entities are both allowed and encouraged to participate in the Shared Savings Program, provided the ACO has a minimum of 5,000 assigned beneficiaries, thereby potentially realizing the economic benefits of receiving shared savings resulting from the utilization of enhanced and efficient systems of care and care coordination. Therefore, a solo, small physician practice or other small entity may realize economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible. We believe the policies included in this final rule, including facilitating the transition to performance-based risk (see section II.C of this final rule), may further encourage participation by small entities. For example, smaller entities (among others) that are risk averse but ready to transition to a performance-based risk track may elect the option that would defer by one year their entrance into a two-sided model. Once under a two-sided model, ACOs will have the opportunity for greater reward compared to participation under the one-sided model although they will be at risk for shared losses.

As detailed in this RIA, total median shared savings payments net of shared losses are expected to increase by $300 million over the 2017 to 2019 period as a result of changes that will increase benchmarks for certain ACOs participating in the Shared Savings Program and therefore increase the average small entity's shared savings revenue. However, the impact on any single small entity may depend on its relationship to costs calculated for the counties comprising its regional service area.

5. Effect on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 and has fewer than 100 beds. Although the Shared Savings Program is a voluntary program, this final rule will have a significant impact on the operations of a substantial number of small rural hospitals. We are changing our regulations such that benchmark trend calculations and adjustments for ACOs that include rural hospitals as ACO participants will reflect FFS costs and trends in the ACO's regional service area. Overall, we expect the average ACO to receive greater shared savings revenue under these changes ($300 million greater net sharing anticipated over 2017 through 2019). However, the impact on individual ACOs and their participating small rural hospitals may differ from the program average.

Comment: A commenter acknowledged that the impact on small entities and rural hospitals remains to be seen and suggested that CMS monitor the effects of the benchmarking changes to ensure that small entities and hospitals, particularly in rural and underserved areas, are not placed at a disadvantage.

Response: We appreciate the commenter's suggestion. This final rule describes a number of issues for monitoring and future consideration with respect to the changes being finalized to the methodology for resetting the ACO's benchmark, including: The approach to calculating regional FFS expenditures (in particular in relation to the methodology for defining the ACO's regional service area and use of assignable beneficiaries for determining county FFS expenditures), factors for consideration in relation to the weight applied in calculating the regional adjustment to the ACO's rebased historical benchmark, and the impact of coding initiatives on ACO benchmarks. This monitoring will include considerations relevant across the ACOs participating in the Shared Savings Program, which represent diverse interests by virtue of their ACO participant composition, patient populations, locations, and organizational structures, among other factors.

Comment: Although not discussing the specifics of data modeling, comments from stakeholders representing rural ACOs supported moving to the use of regional comparison data when resetting ACO benchmarks, indicating their belief that this approach creates a more meaningful comparison group and better reflects the health care environment in which the ACO operates.

Response: We appreciate commenters' feedback and also share commenters' beliefs that the revised rebasing methodology may benefit ACOs, including ACOs located in rural areas, by the increasing the weight on regional FFS expenditures in calculating the benchmark, and moving away from benchmarks based on the ACO's historical spending.

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This final rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $146 million in any 1 year. Furthermore, participation in this program is voluntary and is not mandated.

D. Alternatives Considered

As indicated in the June 2015 final rule (see 80 FR 32795 through 32796), and as discussed in the 2016 proposed rule (see 81 FR 5833 through 5834), we also considered an alternative method for establishing benchmarks for subsequent agreement periods that would incorporate regional trends. Under such method we would apply the regional trend to inflate an ACO's historical benchmark from the prior (that is, first) agreement period to represent expenditures expected for the most recent base year preceding the ACO's subsequent agreement period. This approach would therefore be delinked from an ACO's performance over the prior agreement period (except to the extent an ACO's assigned population impacts its wider regional trend)—improving the incentive for ACOs to invest in efforts to improve efficiency. In contrast to the methodology for calculating a regional adjustment established with this rule, it would also retain sensitivity to baseline costs demonstrated by beneficiaries assigned to the ACO in the prior agreement period, potentially mitigating concerns regarding certain types of program selection and possibly providing a more incremental transition for ACOs familiar with the existing benchmark methodology.

Specifically it was estimated that blending an ACO's rebased benchmark with its prior (first) historical benchmark inflated by a regional trend

would produce an overall budget neutral change in net program cost for the subsequent agreement period if the blending were accomplished via a 70 percent weight on an ACO's trended prior benchmark and a 30 percent weight on its rebased benchmark. While such blend would reasonably be expected to result in an improvement in program incentives for ACOs to generate new efficiencies in care delivery despite rebasing concerns, other considerations impacted the decision to ultimately set forth the different approach detailed in this final rule.

Primarily, program experience to date indicates that many ACOs make significant changes to their provider composition over the course of an agreement period. Attempting to lock-in a first historical benchmark that would be trended to form 70 percent of the historical benchmark for future agreement periods would invariably be complicated and in many cases biased by changes in provider composition made years after the ACO's first entry into the program. Such operational complications and potential biases would invariably grow in magnitude for subsequent agreement periods, necessitating modifications to future rebasing, for example by reducing the weight on the regionally-trended component of the benchmark or requiring the regionally trended component always to be sourced from the rebased benchmark from the prior agreement period—changes that would likely dampen the incentive for ACOs to make significant investments in redesigning care in efficient ways. Furthermore, the rebasing methodology adopted in this final rule has the comparative advantage of linking the regional adjustment to an ACO's historical expenditures to its region's contemporary standardized cost as opposed to the level of cost (and associated efficiency) that happened to be exhibited in an ACO's prior historical benchmark period. Therefore, it was determined that the approach we are adopting in this final rule generally offers a less complicated and more consistent and equitable mechanism for adjusting ACO rebased benchmarks to reflect regional expenditures over the long term.

E. Compliance With Requirements of Section 1899(i)(3)(B) of the Act

As previously discussed in this final rule, certain policies, including both existing policies and new policies adopted in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare FFS beneficiaries. Section 1899(i)(3)(B) requires that such other payment model must not result in additional program expenditures. Policies falling under the authority of section 1899(i)(3) of the Act include: Performance-based risk, refining the calculation of national expenditures used to update the historical benchmark to use the assignable subpopulation of total FFS enrollment, updating benchmarks with regional trends as opposed to national average absolute growth in per capita spending, and adjusting performance year expenditures to remove IME, DSH, and uncompensated care payments.

A comparison was constructed between the projected impact of the payment methodology that incorporates all changes and a hypothetical baseline payment methodology that excludes the elements described previously that require section 1899(i)(3) of the Act authority—most importantly performance based risk in Tracks 2 and 3 and updating benchmarks using regional trends. The hypothetical baseline was assumed to include adjustments allowable under section 1899(d)(1)(B)(ii) of the Act including the provision from the June 2015 final rule whereby an ACO's rebased benchmark might include an adjustment reflecting a portion of savings measured during the ACO's prior agreement period and the 35 percent weight used in calculating the regional adjustment to the ACO's rebased historical benchmark in this rule (or 25 percent weight should such regional adjustment be negative, as specified in this rule). The stochastic model and associated assumptions described previously in this section were adapted to reflect the agreement period spanning 2017 through 2019 for roughly 100 ACOs expected to renew in 2017. Such analysis estimated approximately $130 million greater average net program savings under the alternative payment model that includes all policies that require the authority of section 1899(i)(3) than would be expected under the hypothetical baseline in total over the 2017 to 2019 agreement period cycle.

Furthermore, approximately 79 percent of stochastic trials resulted in greater or equal net program savings. The alternative payment model, as adopted in this final rule, is projected to result in both greater savings on benefit costs and net payments to ACOs. Participation in performance-based risk under Track 2 and Track 3 is assumed to improve the incentive for ACOs to increase the efficiency of care for beneficiaries (similar to as assumed in the modeling of the impacts, described previously). Such added savings are partly offset by lower participation associated with the requirement to transition to performance-based risk. Correspondingly, net shared savings payments are also expected to be greater under the alternative payment model under section 1899(i)(3) of the Act than under the hypothetical baseline, mainly driven by the higher sharing rates and potentially lower minimum savings requirements in Track 2 and Track 3, but partly offset mainly by lower benchmarks resulting from ending the policy adopted in the June 2015 final rule of adding a portion of savings to the rebased benchmark, the use of more accurate regional benchmark updates, and new shared loss revenue.

Additionally, we projected a lower net federal savings of approximately $10 million would result from using the hypothetical baseline described previously, but without the adjustment to account for a portion of savings generated during the ACO's prior agreement period, which we eliminated from the hypothetical baseline's rebased benchmarks. We believe ending the adjustment for savings generated in the ACO's prior agreement period will enable us to place a greater weight on the amount of the regional adjustment in the future, while not over crediting or penalizing an ACO for its prior performance (discussed in section II.A.2.c of this final rule). This alternative hypothetical baseline more closely resembles the future hypothetical baseline that would be used in our analysis of the application of a higher weight in calculating the regional adjustment in subsequent agreement periods (for example, if we undertake future rulemaking further amending the methodology for rebasing and updating the benchmark, as discussed previously in this final rule).

Relative savings projected for the ACOs starting a second agreement period in 2017 participation cycle are reasonably assumed to be proportional for ACOs starting a second agreement period in 2018 and 2019 because the assumptions and parameters would be the same or similar. Accordingly, the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures is therefore satisfied for the period 2017 through 2019. As discussed elsewhere in this final rule, we will reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program

expenditures continues to be satisfied, taking into account, for example, increasing the weight placed on the regional adjustment to an ACO's rebased historical benchmark, which will increase to 70 percent for an ACO's second (or third for ACOs with higher costs than their region) and subsequent agreement periods under the revised rebasing methodology (unless the Secretary determines a lower weight should be applied, as specified through future rulemaking). In the event that we conclude that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

F. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866, in Table 5, we have prepared an accounting statement showing the change in net federal monetary transfers resulting from provisions of this final rule as compared to baseline.

TABLE 5—ACCOUNTING STATEMENT ESTIMATED IMPACTS

[CYs 2017–2019]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation (RIA, preamble, etc.)
Impact on Net Federal Cost From Finalized Changes to Medicare Shared Savings Program				
Annualized monetized: Discount rate: 7%	−36.2 million	76.6 million	−155.9 million	Table 4.
Annualized monetized: Discount rate: 3%	−36.5 million	78.5 million	−158.2 million.	
Notes: Amounts are expressed in 2016 dollars.	Negative values reflect reduction in federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.			

G. Publicly Available Data

In response to requests from ACOs and other stakeholders for data to allow for modeling of proposed changes to the benchmark rebasing methodology, CMS made new data files available through the Shared Savings Program's Web site, to coincide with the issuance of the 2016 proposed rule (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Statutes-Regulations-Guidance.html*). These files included: Average per capita county-level FFS spending and risk scores for 3 historical years; and ACO-specific data, on the total number of assigned beneficiaries residing in each county where at least 1 percent of the ACO's assigned beneficiaries reside, for 3 historical years. A listing of all publicly available Shared Savings Program ACO data and ACO performance data sources maintained by CMS is available through the Shared Savings Program Web site (see the guide titled ''Medicare Shared Savings Program Publicly available ACO data and ACO performance data sources maintained by CMS'' available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html*).

Comment: Some commenters modeled the proposed benchmarking changes using the publicly available data files released with the 2016 proposed rule, and other sources of Shared Savings Program performance data, and included remarks about their findings within their comment letters. For example, several comments reflect estimates that approximately two-fifths to two-thirds of ACOs will have their benchmarks upwardly adjusted as a result of the revised rebasing methodology. A commenter described its analysis as indicating some ACOs will experience significant and unexpected swings in their reset historical benchmarks (when comparing the benchmark values resulting from the current methodology versus the revised methodology). Another commenter explained its analysis showed relatively high-cost ACOs face increasing headwinds as their benchmarks converge with their region, whereas relatively low-cost ACOs would have more favorable benchmarks. Another commenter specified that the 35 percent weight used to calculate the regional adjustment for an ACO's first agreement period under the revised rebasing methodology would result in a benchmark reduction of about 2 percent for ACOs with spending one standard deviation above the regional mean, and noted this would be substantial relative to estimated savings.

Response: We appreciate commenters' careful attention to the details of the 2016 proposed rule, modeling of the proposed policies, and informative comments including their analyses. We note that the analyses provided by commenters pertaining to the key change to the methodology—institution of a regional FFS adjustment to the rebased benchmark—are generally in harmony with CMS' calculations in developing the rule and this impact analysis, providing reassurance that the data provided were a sufficient tool to allow the public to analyze the general impact of the new method for rebasing. We took into account commenters' observations regarding ACOs with high baseline costs for which a positive savings adjustment under the prior methodology will be replaced by a negative regional FFS adjustment. By reducing the weight applied to the regional FFS adjustment during the first two agreement periods under the revised rebasing methodology in cases where it lowers ACOs' benchmarks, this final rule will encourage continued participation by certain ACOs with significant potential to generate additional savings despite high baseline costs. We believe this change in policy from the proposed rule addresses concerns raised by commenters and illustrated in their analyses that the regional adjustment could disadvantage certain ACOs that have shown cost savings but may require longer than one agreement period to bring costs down toward the regional average in order to avoid a significant negative adjustment to their rebased benchmarks.

H. Conclusion

The analysis in this section, together with the remainder of this preamble, provides a regulatory impact analysis. As a result of this final rule, the median estimate of the financial impact of the

Shared Savings Program for CYs 2017 through 2019 is net federal savings of $110 million greater than what would have been saved if no changes were made. Although this is the best estimate of the financial impact of the Shared Savings Program during CYs 2017 through 2019, a relatively wide range of possible outcomes exists. While approximately two-thirds of the stochastic trials resulted in an increase in net program savings, the 10th and 90th percentiles of the estimated distribution show a net increase in costs of $240 million to net savings of $480 million, respectively.

Overall, our analysis projects that improvements in the accuracy of benchmark calculations, including through the introduction of a regional adjustment to the ACO's rebased historical benchmark, are expected to result in increased overall participation in the program. These changes are also expected to improve the incentive for ACOs to invest in effective care management efforts, increase the attractiveness of participation under performance-based risk in Track 2 or 3 for certain ACOs with lower beneficiary expenditures, and result in overall greater gains in savings on FFS benefit claims costs than the associated increase in expected shared savings payments to ACOs. We intend to monitor emerging results for effects on claims costs, changing participation (including risk for cost due to selective changes in participation), and unforeseen bias in benchmark adjustments due to diagnosis coding intensity shifts. Such monitoring will be used to inform future rulemaking, such as if the Secretary determines that a lower weight should be used in calculating the regional adjustment amount.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 425 as set forth below:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 1. The authority citation for part 425 is revised to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306, 1395hh, and 1395jjj).

■ 2. Amend § 425.20 by adding in alphabetical order definitions for ''ACO's regional service area'', ''Assignable beneficiary'', and ''BY'' to read as follows:

§ 425.20 Definitions.

* * * * *

ACO's regional service area means all counties where one or more beneficiaries assigned to the ACO reside.

* * * * *

Assignable beneficiary means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

* * * * *

BY stands for benchmark year.

* * * * *

■ 3. Amend § 425.200 as follows:

■ A. In paragraph (b)(2) introductory text by removing the phrase ''all subsequent years'' and adding in its place the phrase ''through 2016''.

■ B. By adding paragraph (b)(3).

■ C. By adding paragraph (e).

The additions read as follows:

§ 425.200 Participation agreement with CMS.

* * * * *

(b) * * *

(3) For 2017 and all subsequent years—

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years, except the term of an ACO's initial agreement period under Track 1 (as described under § 425.604) may be extended, at the ACO's option, for an additional year for a total of 4 performance years if the conditions specified in paragraph (e) of this section are met.

* * * * *

(e) *Optional fourth year.* (1) To qualify for a fourth performance year as described in paragraph (b)(3)(ii) of this section, the ACO must meet all of the following conditions:

(i) Is currently participating in its first agreement period under Track 1.

(ii) Has requested renewal of its participation agreement in accordance with § 425.224.

(iii) Has selected a two-sided model (as described under § 425.606 or § 425.610 of this part) in its renewal request.

(iv) Has requested an extension of its current agreement period and a 1-year deferral of the start of its second agreement period in a form and manner specified by CMS.

(v) CMS approves the ACO's renewal, extension, and deferral requests.

(2) An ACO that is approved for renewal, extension, and deferral that terminates its participation agreement before the start of the first performance year of the second agreement period is—

(i) Considered to have terminated its participation agreement for the second agreement period under § 425.220; and

(ii) Not eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

§ 425.314 [Amended]

■ 4. Amend § 425.314 by removing paragraph (a)(4).

■ 5. Add § 425.315 to read as follows:

§ 425.315 Reopening Determinations of ACO Shared Savings or Shared Losses to Correct Financial Reconciliation Calculations.

(a) *Reopenings.* (1) If CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS may reopen the initial determination or a final agency determination under subpart I of this part and issue a revised initial determination:

(i) At any time in the case of fraud or similar fault as defined in § 405.902; or

(ii) Not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year under § 425.604(f), § 425.606(h) or § 425.610(h), for good cause.

(2) Good cause may be established when—

(i) There is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion; or

(ii) The evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

(3) A change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under this section.

(4) CMS has sole discretion to determine whether good cause exists for reopening a payment determination under this section.

(b) [Reserved]

■ 6. Amend § 425.602 by:
■ A. Revising the section heading.
■ B. Revising paragraphs (a)(4), (5), and (8).
■ C. Adding paragraph (a)(9).
■ D. Revising paragraphs (b)(1) and (2).
■ E. Removing paragraph (c).

The revisions and additions read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period.

(a) * * *

(4) Truncation of expenditures:

(i) For agreement periods beginning before 2017—

(A) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year in order to minimize variation from catastrophically large claims; and

(B) For the 2017 performance year and any subsequent performance years in agreement periods beginning in 2014, 2015 and 2016, the benchmark is adjusted to reflect the use of assignable beneficiaries in determining the 99th percentile of Medicare fee-for-service expenditures for purposes of truncating expenditures for assigned beneficiaries during each benchmark year as specified in paragraph (a)(4)(ii) of this section.

(ii) For agreement periods beginning in 2017 and subsequent years, truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trending expenditures:

(i) For agreement periods beginning before 2017—

(A) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(B) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible Medicare and Medicaid beneficiaries.

(*4*) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(C) For the 2017 performance year and any subsequent performance years in agreement periods beginning in 2014, 2015 and 2016, the benchmark is adjusted to reflect the use of assignable beneficiaries to perform each of these calculations as specified in paragraph (a)(5)(ii) of this section.

(ii) For agreement periods beginning in 2017 and subsequent years—

(A) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year, and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(B) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible Medicare and Medicaid beneficiaries.

(*4*) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

* * * * *

(8) The benchmark is adjusted to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the most recent certified ACO participant list for the relevant performance year.

(9) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix 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) * * *

(1) For performance years before 2017, CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

(i) CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary.

(ii) To update the benchmark, CMS makes expenditure calculations for separate categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) For the 2017 performance year and subsequent performance years, CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is calculated.

(i) CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is being calculated using data from CMS' Office of the Actuary.

(ii) To update the benchmark, CMS makes expenditure calculations for separate categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

■ 7. Add § 425.603 to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period.

(a) An ACO's benchmark is reset at the start of each subsequent agreement period.

(b) For second agreement periods beginning in 2016, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with § 425.602(a) and (b) with the following modifications:

(1) Rather than weighting each year of the benchmark using the percentages provided at § 425.602(a)(7), each benchmark year is weighted equally.

(2) An additional adjustment is made to account for the average per capita amount of savings generated during the ACO's previous agreement period. The adjustment is limited to the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period.

(c) For second or subsequent agreement periods beginning in 2017 and subsequent years, CMS establishes the rebased historical benchmark by determining the per capita Parts A and B fee-for-service expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years before the agreement period using the certified ACO participant list submitted before the start of the agreement period as required under § 425.118. CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using regional growth rates based on expenditures for the ACO's regional service area as determined under paragraphs (e) and (f) of this section, making separate expenditure calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(6) Restates BY1 and BY2 trended and risk-adjusted expenditures in BY3 proportions of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each benchmark year equally.

(8) The ACO's benchmark will be adjusted in accordance with § 425.118(b) for the addition and removal of ACO participants or ACO providers/suppliers during the term of the agreement period. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the most recent certified ACO participant list for the relevant performance year.

(ii) Redetermines the regional adjustment amount under paragraph (c)(9) of this section, according to the ACO's assigned beneficiaries for BY3 resulting from the most recent certified ACO participant list for the relevant performance year.

(9) Adjusts the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. CMS does all of the following:

(i) Calculates an average per capita amount of expenditures for the ACO's regional service area as follows:

(A) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(B) Determines the ACO's regional expenditures as specified under paragraphs (e) and (f) of this section for BY3.

(C) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area identified for the 12-month calendar year that corresponds to BY3.

(ii) Calculates the adjustment as follows:

(A) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (c)(9)(i) of this section and the average per capita amount of the ACO's rebased historical benchmark determined under paragraphs (c)(1) through)(8) of this section, for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible Medicare and Medicaid beneficiaries.

(*4*) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) Applies a percentage, determined as follows:

(*1*) The first time an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment as follows:

(*i*) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area;

(*ii*) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(*2*) The second time that an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment to the historical benchmark as follows:

(*i*) Using 70 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, unless the Secretary determines a lower weight should be applied, if the ACO is determined to have lower spending than the ACO's regional service area;

(*ii*) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(*3*) The third or subsequent time that an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment to the historical benchmark using 70 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark, unless the Secretary determines a lower weight should be applied.

(*4*) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(*i*) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark for each population of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(9)(ii)(A) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) for benchmark year 3 of the rebased historical benchmark.

(*ii*) Sums the amounts determined in paragraph (c)(9)(ii)(B)(*4*)(*i*) of this section across the populations of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries).

(*iii*) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(*iv*) If CMS adjusts the ACO's benchmark for the addition or removal of ACO participants or ACO providers/suppliers during the term of the agreement period as specified in paragraph (c)(8) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage used in calculating the adjustment in paragraphs (c)(9)(ii)(B)(*1*) and (*2*) of this section.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix 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).

(d) For second or subsequent agreement periods beginning in 2017 and subsequent years, CMS updates the rebased historical benchmark under paragraph (c) of this section, annually for each year of the agreement period by the growth in risk adjusted regional per beneficiary FFS spending for the ACO's regional service area by doing all of the following:

(1) Determining the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population used to determine financial reconciliation for the relevant performance year.

(2) Determining growth rates based on expenditures for counties in the ACO's regional service area calculated under paragraphs (e) and (f) of this section, for the performance year compared to BY3 for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Updating the benchmark by making separate calculations for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(e) For second or subsequent agreement periods beginning in 2017 and subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county, where assignable beneficiaries are identified for the 12-month calendar year corresponding to the relevant benchmark or performance year.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective CMS–HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(f) For second or subsequent agreement periods beginning in 2017 and subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by—

(1) Weighting the risk-adjusted county-level fee-for-service expenditures determined under paragraph (e) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Aggregating the values determined under paragraph (f)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area; and

(3) Weighting the aggregate expenditure values determined for each population of beneficiaries (according to Medicare enrollment type) under paragraph (f)(2) of this section by a weight reflecting the proportion of the ACO's overall beneficiary population in the applicable Medicare enrollment type for the relevant benchmark or performance year.

■ 8. Amend § 425.604 as follows:

■ A. In paragraphs (a)(1) and (a)(2)(i) and (ii) by removing the phrase ''adjust for changes'' and adding in its place the

phrase ''adjust the benchmark for changes''.

■ B. In paragraph (a)(3) introductory text by removing the phrase ''In adjusting for health status'' and adding in its place the phrase ''In adjusting the benchmark for health status''.

■ C. Redesignating paragraph (a)(4) as paragraph (a)(4)(i).

■ D. In newly redesignated paragraph (a)(4)(i) by removing the phrase ''To minimize variation'' and adding in its place the phrase ''For performance years before 2017 to minimize variation''.

■ E. Adding paragraph (a)(4)(ii).

The addition reads as follows:

§ 425.604 Calculation of savings under the one-sided model.

(a) * * *

(4) * * *

(ii) For the 2017 performance year and subsequent performance years, to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

* * * * *

■ 9. Amend § 425.606 as follows:

■ A. In paragraphs (a)(1) and (a)(2)(i) and (ii) by removing the phrase ''adjust for changes'' and adding in its place the phrase ''adjust the benchmark for changes''.

■ B. In paragraph (a)(3) introductory text by removing the phrase ''In adjusting for health status'' and adding in its place the phrase ''In adjusting the benchmark for health status''.

■ C. Redesignating paragraph (a)(4) as paragraph (a)(4)(i).

■ D. In newly redesignated paragraph (a)(4)(i) by removing the phrase ''To minimize variation'' and adding in its place the phrase ''For performance years before 2017 to minimize variation''.

■ E. Adding paragraph (a)(4)(ii).

The addition reads as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

(a) * * *

(4) * * *

(ii) For the 2017 performance year and subsequent performance years, to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

* * * * *

■ 10. Amend § 425.610 as follows:

■ A. In paragraphs (a)(1) and (a)(2)(i) and (ii) by removing the phrase ''adjust for changes'' and adding in its place the phrase ''adjust the benchmark for changes''.

■ B. In paragraph (a)(3) introductory text by removing the phrase ''In adjusting for health status'' and adding in its place the phrase ''In adjusting the benchmark for health status''.

■ C. Redesignating paragraph (a)(4) as paragraph (a)(4)(i).

■ D. In newly redesignated paragraph (a)(4)(i) by removing the phrase ''To minimize variation'' and adding in its place the phrase ''For performance years before 2017 to minimize variation''.

■ E. Adding paragraph (a)(4)(ii).

The addition reads as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

(a) * * *

(4) * * *

(ii) For the 2017 performance year and subsequent performance years, to minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

* * * * *

§ 425.800 [Amended]

■ 11. Amend § 425.800 as follows:

■ A. In paragraph (a)(4) by—

■ i. Removing the phrase ''The determination of whether'' and adding in its place the phrase ''The initial determination or revised initial determination of whether''.

■ ii. Removing the phrase ''including the determination'' and adding in its place the phrase ''including the initial determination or revised initial determination''.

■ iii. Removing the cross-reference ''§ 425.602, § 425.604, and § 425.606'' and adding in its place the cross-reference ''§§ 425.602, 425.604, 425.606, and 425.610''.

■ B. In paragraph (a)(5) by removing the cross-reference ''§ 425.604 and 425.606'' and adding in its place ''§§ 425.604, 425.606, and 425.610''.

Dated: May 27, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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Secretary, Department of Health and Human Services.

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