

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 409, 410, 414, 424, and 484****[CMS–1730–F, CMS–1744–IFC, and CMS–5531–IFC]****RIN 0938–AU06, 0938–AU31, and 0938–AU32****Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule updates the home health prospective payment system (HH PPS) payment rates and wage index for calendar year (CY) 2021. This final rule also implements the changes to the home health regulations regarding the use of telecommunications technology in providing services under the Medicare home health benefit as described in the “Medicare and Medicaid Programs, Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” interim final rule with comment period (March 2020 COVID–19 IFC). In addition, this rule implements the permanent home infusion therapy services benefit and supplier enrollment requirements for CY 2021 and finalizes conforming regulations text changes excluding home infusion therapy services from coverage under the Medicare home health benefit. This rule also finalizes a policy to align the Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program (HH QRP) during the COVID–19 PHE and also finalizes a policy for granting exceptions to the New Measures data reporting requirements during the COVID–19 PHE, as described in the “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality

Reporting Program” interim final rule with comment period (May 2020 COVID–19 IFC).

DATES: These regulations are effective on January 1, 2021.**FOR FURTHER INFORMATION CONTACT:**

Brian Slater (410) 786–5229, for home health and home infusion therapy payment inquiries.

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov*.

For general information about home infusion payment, send your inquiry via email to: *HomeInfusionPolicy@cms.hhs.gov*.

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to *HHQRPquestions@cms.hhs.gov*.

Mary Rossi-Coajou, (410) 786–6051, for condition of participation (CoP) OASIS requirements.

For information about the Home Health Value Based Model, send your inquiry via email to *HHVBPquestions@cms.hhs.gov*.

Joseph Schultz, (410) 786–2656, for information about home infusion therapy supplier enrollment requirements.

SUPPLEMENTARY INFORMATION: Wage index addenda will be available only through the CMS Coding and Billing Information website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.

I. Executive Summary**A. Purpose****1. Home Health Prospective Payment System (HH PPS)**

This final rule updates the payment rates for home health agencies (HHAs) for calendar year (CY) 2021, as required under section 1895(b) of the Social Security Act (the Act). This rule sets forth the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2021; the CY 2021 fixed-dollar loss ratio (FDL); and the loss-sharing ratio for outlier payments (as required by section 1895(b)(5)(A) of the Act). Additionally, this rule adopts the revised Office of Management and Budget (OMB) statistical area delineations as described in the September 14, 2018 OMB Bulletin No. 18–04¹ for the labor market delineations used in the home health wage index, effective beginning in CY

¹ On March 6, 2020, OMB issued the most recent OMB Bulletin No. 20–01.

2021. This rule finalizes a cap on wage index decreases in excess of 5 percent and adopts the OMB statistical areas and the 5-percent cap on wage index decreases under the statutory discretion afforded to the Secretary under sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act. Lastly, this rule finalizes the changes to § 409.43(a) as set forth in the interim final rule with comment period that appeared in the April 6, 2020 **Federal Register** titled “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” (PHE) (March 2020 COVID–19 IFC), to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system (85 FR 19230).

2. Home Health Quality Reporting Program (HH QRP)

We did not propose any changes for the HH QRP and therefore are not finalizing any policies in this final rule.

3. Changes to the Conditions of Participation (CoPs) OASIS Requirements

This final rule removes an obsolete provision that requires new HHAs that do not yet have a CMS certification number to conduct test OASIS data transmissions to the CMS data system as part of the initial certification process.

4. Reporting Under the Home Health Value Based Purchasing (HHVBP) Model During the COVID–19 PHE

This rule finalizes a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP as well as a policy for granting exceptions to the New Measures data reporting requirements during the COVID–19 PHE, as described in the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** titled “Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (85 FR 27553) (May 2020 COVID–19 IFC).

5. Home Infusion Therapy Services

This final rule summarizes the home infusion therapy policies codified in the CY 2020 HH PPS final rule with comment period (84 FR 60615), as required by section 1834(u) of the Act. This rule also finalizes the exclusion of

home infusion therapy services from coverage under the Medicare home health benefit as required by section 5012(c)(3) of the 21st Century Cures Act.

6. Enrollment Requirements for Qualified Home Infusion Therapy Suppliers

This final rule establishes Medicare provider enrollment policies for qualified home infusion therapy suppliers.

B. Summary of the Provisions of This Rule

In section III.A of this rule, we set the LUPA thresholds and the case-mix weights for CY 2021 equal to the CY 2020 LUPA thresholds and case-mix weights established for the first year of the Patient-Driven Groupings Model (PDGM). The PDGM is a new case-mix adjustment methodology used to adjust payments for home health periods of care beginning on or after January 1, 2020. The PDGM relies more heavily on clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the Bipartisan Budget Act of 2018 (BBA of 2018).

Section III.B. of this rule adopts the OMB statistical area delineations outlined in a September 14, 2018, OMB bulletin No. 18–04. This rule also finalizes the transition with a 1-year cap on wage index decreases in excess of 5 percent, consistent with the policy

finalized for other Medicare payment systems. This rule adopts the OMB statistical areas and the 5 percent cap on wage index decreases under the statutory discretion afforded to the Secretary under sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act.

In section III.C. of this rule, we update the home health wage index, the CY 2021 national, standardized 30-day period of care payment amounts and the CY 2021 national per-visit payment amounts by the home health payment update percentage. The home health payment update percentage for CY 2021 is 2.0 percent. Section III.D. of this rule describes the rural add-on payments as required by section 50208(a)(1)(D) of the BBA of 2018 for home health episodes or periods ending during CYs 2019 through 2022. Section III.E. of this rule maintains the fixed-dollar loss ratio at 0.56, as finalized for CY 2020, in order to ensure that outlier payments as a percentage of total payments is closer to, but no more than, 2.5 percent, as required by section 1895(b)(5)(A) of the Act.

Section III.F. of this rule finalizes the changes to § 409.43(a) as implemented in the March, 2020 COVID–19 IFC, to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, in accordance with section 1895(e)(1)(A) of the Act.

Section III.G. of this rule, finalizes conforming regulation text changes at §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 regarding allowed practitioner certification as a condition for payment for home health services.

Section IV.A and B. of this final rule discuss the HH QRP and changes to the Conditions of Participation (CoPs) OASIS requirements.

Section IV.C. of this final rule discusses final policies on reporting under the HHVBP Model during the COVID–19 PHE.

In sections V.A.1. and V.A.2. of this rule, we discuss the background and overview of the home infusion therapy services benefit, as well as review the payment policies we finalized in the CY 2020 HH PPS final rule with comment period for the CY 2021 implementation (84 FR 60628). Sections V.A.3. and V.A.4. describe the payment categories and payment amounts for home infusion therapy services for CY 2021, as well as payment adjustments for CY 2021 home infusion therapy services. In section V.A.5. of this rule, we finalize technical regulations text changes to exclude home infusion therapy services from coverage under the Medicare home health benefit, as required by section 5012(c)(3) of the 21st Century Cures Act, which amended section 1861(m) of the Act. In section V.B. of this rule, we discuss the home infusion therapy supplier enrollment requirements.

C. Summary of Costs, Transfers, and Benefits

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TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2021 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated \$390 million (1.9 percent) in increased payments to HHAs in CY 2021.	To ensure home health payments are consistent with statutory payment authority for CY 2021.
HH QRP	No proposals were made. Therefore, there are no costs or savings associated with this provision.		
OASIS	There are no costs associated with this provision.		Simplifies the submission process. HHAs are no longer limited to two users for submission of assessment data since VPN and CMSNet are no longer required.
Reporting Under the HHVBP Model During the COVID-19 PHE	We do not anticipate a change to Medicare expenditures as a result of this policy. However, we expect reduced burden on providers.	The overall economic impact of the HHVBP Model for CYs 2018 through 2022 is an estimated \$378 million in total savings to Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	Aligning HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE and implementing a policy for granting exceptions to the New Measures data reporting requirements during the COVID-19 PHE helps to provide HHAs with flexibility to respond to the COVID-19 PHE.
CY 2021 Payments for Home Infusion Therapy Services		The overall economic impact of updating the payment rates for home infusion therapy services, based on the proposed Physician Fee Schedule amounts for CY 2021, is a 0.7 percent decrease (\$384,800) in payments to eligible home infusion therapy suppliers in CY 2021.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2021.
Home Infusion Therapy Supplier Enrollment	The estimated average annual burden associated with home infusion therapy supplier enrollment over the 3-year OMB approval period is 583 hours at a cost of \$28,583.	We estimate a total application fee cost to enrollees of \$364,800 (or 600 x \$608) in the first year, \$31,050 (or 50 x \$621) in the second year, and \$31,700 (or 50 x \$634) in the third year. This constitutes an average annual figure over the first 3 years of this requirement of \$142,517.	Enrollment ensures that home infusion therapy suppliers meet all applicable requirements.

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D. Issuance of the Proposed Rulemaking and Correction

In the CY 2021 HH PPS proposed rule that appeared in the June 30, 2020 **Federal Register** (85 FR 39408), we proposed changes to the payment rates, factors, and other payment and policy-

related changes to programs associated with under the HH PPS for CY 2021 and home infusion therapy services benefit for CY 2021. In addition, we set forth proposed changes to the reporting of OASIS requirements and requirements for home infusion therapy suppliers.

We note that Office of the Federal Register issued a correction to the

comment period closing date for the CY 2021 HH PPS proposed rule in the July 20, 2020 **Federal Register** (85 FR 43805). The correct closing date for public comments was August 24, 2020.

We note that in response to the CY 2021 HH PPS proposed rule, we received approximately 162 timely pieces of correspondence from the

public, including from home health agencies, national and state provider associations, patient and other advocacy organizations, nurses, and other healthcare professionals. In the following sections, we summarize the proposed provisions and the public comments, and provide the responses to comments.

II. Overview of the Home Health Prospective Payment System (HH PPS)

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system. Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled “Prospective Payment for Home Health Services.” Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act required that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act required the following: (1) The computation of a standard prospective payment amount that includes all costs for home health services covered and paid for on a reasonable cost basis, and that such amounts be initially based on the most recent audited cost report data available to the Secretary (as of the effective date of the 2000 final rule); and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act requires the standard prospective payment amounts be annually updated by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and

geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of area wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act. Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care

quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2.0 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) amended section 421(a) of the MMA to extend the 3 percent rural add-on payment for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) through January 1, 2018. In addition, section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that CY 2018 home health payments be updated by a 1.0 percent market basket increase. Section 50208(a)(1) of the BBA of 2018 again extended the 3.0 percent rural add-on through the end of 2018. In addition, this section of the BBA of 2018 made some important changes to the rural add-on for CYs 2019 through 2022.

Section 51001(a)(1)(B) of the BBA of 2018 amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service, furnished that end during the 12-month period beginning January 1, 2020, in a

budget neutral manner, such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as

determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases, based on retrospective behavior, to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. And finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

B. Current System for Payment of Home Health Services Beginning in CY 2020 and Subsequent Years

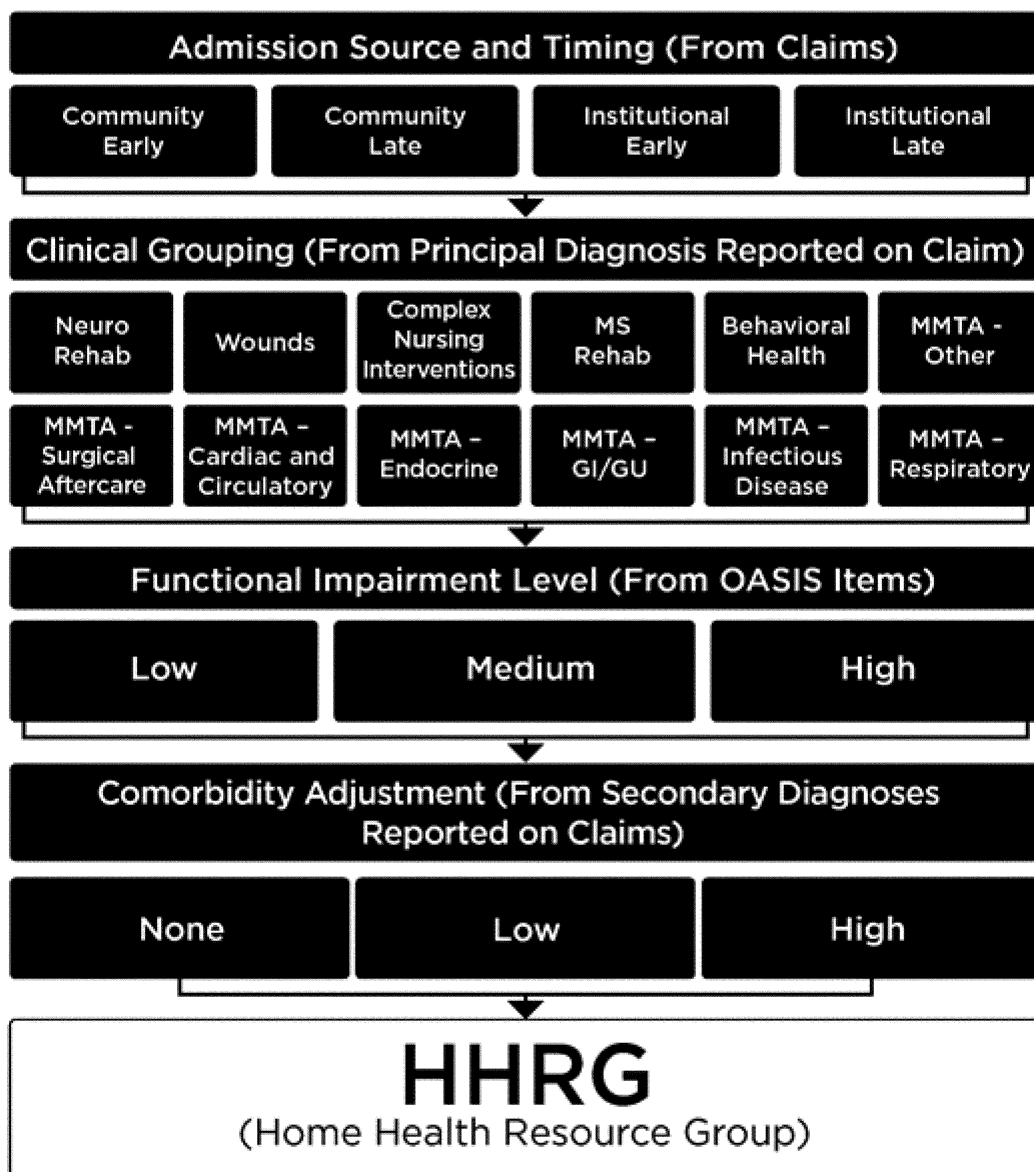
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for the applicable case-mix and wage index in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is now part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount and is not

included in the national, standardized 30-day period payment amount.

To better align payment with patient care needs and ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) assessment instrument. These 432 HHRGs represent the different payment groups based on five main case-mix variables under the PDGM, as shown in Figure 1, and subsequently described in more detail throughout this section. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this new case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories listed in this section of this final rule (admission source, timing clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. Below is a description of each of the case-mix variables under the PDGM.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



1. Timing

Thirty-day periods of care are classified as “early” or “late” depending on when they occur within a sequence of 30-day periods. The first 30-day period of care is classified as early and all subsequent 30-day periods of care in the sequence (second or later) are classified as late. A 30-day period is not considered early unless there is a gap of more than 60 days between the end of one period of care and the start of another. Information regarding the timing of a 30-day period of care comes from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is “early” or “late”. While the PDGM case-mix adjustment is applied to each 30-

day period of care, other home health requirements continue on a 60-day basis. Specifically, certifications and recertifications continue on a 60-day basis and the comprehensive assessment must still be completed within 5 days of the start of care date and completed no less frequently than during the last 5 days of every 60 days beginning with the start of care date, as currently required by § 484.55, “Condition of participation: Comprehensive assessment of patients.”

2. Admission Source

Each 30-day period of care is classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to home health. Thirty-day

periods of care for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long-term care hospital (LTCH) stays within 14-days prior to a home health admission are designated as institutional admissions.

The institutional admission source category also includes patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted (that is, the “admission date” and “from

date” for the subsequent 30-day period of care do not match), as we acknowledge that HHAs have discretion as to whether they discharge the patient due to a hospitalization and then readmit the patient after hospital discharge. However, we do not categorize post-acute care stays, meaning SNF, IRF, LTCH, or IPF stays, that occur during a previous 30-day period of care and within 14 days of a subsequent, contiguous 30-day period of care as institutional (that is, the “admission date” and “from date” for the subsequent 30-day period of care do not match), as HHAs should discharge the patient if the patient required post-acute care in a different setting, or inpatient psychiatric care, and then readmit the patient, if necessary, after discharge from such setting. All other 30-day periods of care would be designated as community admissions.

Information from the Medicare claims processing system determines the appropriate admission source for final claim payment. The OASIS assessment is not utilized in evaluating for admission source information. Obtaining this information from the Medicare claims processing system, rather than as reported on the OASIS, is

a more accurate way to determine admission source information as HHAs may be unaware of an acute or post-acute care stay prior to home health admission. While HHAs can report an occurrence code on submitted claims to indicate the admission source, obtaining this information from the Medicare claims processing system allows CMS the opportunity and flexibility to verify the source of the admission and correct any improper payments as deemed appropriate. When the Medicare claims processing system receives a Medicare home health claim, the systems check for the presence of a Medicare acute or post-acute care claim for an institutional stay. If such an institutional claim is found, and the institutional claim occurred within 14 days of the home health admission, our systems trigger an automatic adjustment to the corresponding home health claim to the appropriate institutional category. Similarly, when the Medicare claims processing system receives a Medicare acute or post-acute care claim for an institutional stay, the systems will check for the presence of a home health claim with a community admission source payment group. If such home

health claim is found, and the institutional stay occurred within 14 days prior to the home health admission, our systems trigger an automatic adjustment of the home health claim to the appropriate institutional category. This process may occur any time within the 12-month timely filing period for the acute or post-acute claim. For the purpose of a Request for Anticipated Payment (RAP), only the final claim will be adjusted to reflect the admission source. More information regarding the admission source reporting requirements for RAP and claims submission, including the use of admission source occurrence codes, can be found in the Medicare Claims Processing Manual, chapter 10.²

3. Clinical Groupings

Each 30-day period of care is grouped into one of 12 clinical groups that describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on home health claims. The 12 clinical groups are listed and described in Table 2.

TABLE 2: CLINICAL GROUPS FOR CASE-MIX ADJUSTMENT

Clinical Groups	The Primary Reason for the Home Health Encounter is to Provide:
Musculoskeletal Rehabilitation	Therapy (physical, occupational or speech) for a musculoskeletal condition
Neuro/Stroke Rehabilitation	Therapy (physical, occupational or speech) for a neurological condition or stroke
Wounds – Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care	Assessment, treatment & evaluation of a surgical wound(s); assessment, treatment & evaluation of non-surgical wounds, ulcers, burns, and other lesions
Behavioral Health Care	Assessment, treatment & evaluation of psychiatric and substance abuse conditions
Complex Nursing Interventions	Assessment, treatment & evaluation of complex medical & surgical conditions including IV, TPN, enteral nutrition, ventilator, and ostomies
Medication Management, Teaching and Assessment (MMTA)	
MMTA –Surgical Aftercare	Assessment, evaluation, teaching, and medication management for surgical aftercare
MMTA – Cardiac/Circulatory	Assessment, evaluation, teaching, and medication management for cardiac or other circulatory related conditions
MMTA – Endocrine	Assessment, evaluation, teaching, and medication management for endocrine related conditions
MMTA – GI/GU	Assessment, evaluation, teaching, and medication management for gastrointestinal or genitourinary related conditions
MMTA – Infectious Disease/Neoplasms/Blood-forming Diseases	Assessment, evaluation, teaching, and medication management for conditions related to infectious diseases, neoplasms, and blood-forming diseases
MMTA –Respiratory	Assessment, evaluation, teaching, and medication management for respiratory related conditions
MMTA – Other	Assessment, evaluation, teaching, and medication management for a variety of medical and surgical conditions not classified in one of the previously listed groups

If a home health claim is submitted with a principal diagnosis that is not assigned to a clinical group (for

example, because the diagnosis code is vague, ill-defined, unspecified, or is subject to certain ICD–10–CM coding

conventions), the claim is returned to the provider for more definitive coding. While these clinical groups represent

² Medicare Claims Processing Manual Chapter 10—Home Health Agency Billing. <https://>

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf.

the primary reason for home health services during a 30-day period of care, this does not mean that they represent the only reason for home health services. Home health remains a multidisciplinary benefit and payment is bundled to cover all necessary home health services identified on the individualized home health plan of care. Therefore, regardless of the clinical group assignment, HHAs are required, in accordance with the home health CoPs at § 484.60(a)(2), to ensure that the individualized home health plan of care addresses all care needs, including the disciplines to provide such care. Under the PDGM, the clinical group is just one variable in the overall case-mix adjustment for a home health period of care. Moreover, it is possible for the principal diagnosis to change between the first and second 30-day period of care and the claim for the second 30-day period of care would reflect the new principal diagnosis. HHAs would not change the claim for the first 30-day period.

4. Functional Impairment Level

Each 30-day period of care will be placed into one of three functional impairment levels, low, medium, or high, based on responses to certain OASIS functional items associated with grooming, bathing, dressing, ambulating, transferring, and risk for hospitalization. The specific OASIS items that are used for the functional impairment level are found in Table 7 in the CY 2020 HH PPS final rule with comment period (84 FR 60490). Responses to these OASIS items are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, “Overview of the Home Health Groupings Model”, which is posted on our HHA web page.³ The sum of these points’ results in a functional impairment level score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. The functional impairment level will remain the same for the first and second 30-day periods of care unless there has been a significant change in condition which warranted an

“other follow-up” assessment prior to the second 30-day period of care. For each 30-day period of care, the Medicare claims processing system will look for the most recent OASIS assessment based on the claims “from date.”

5. Comorbidity Adjustment

Thirty-day periods will receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the secondary diagnoses have at least as high as the median resource use and represent more than 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.

- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to if they were reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.

- *No comorbidity adjustment:* A 30-day period of care will receive no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment. A 30-day period of care can have a low comorbidity adjustment or a high comorbidity adjustment, but not both. A 30-day period of care can receive only one low comorbidity adjustment regardless of the number of secondary diagnoses reported on the home health claim that fell into one of the individual comorbidity subgroups or one high comorbidity adjustment regardless of the number of comorbidity group interactions, as applicable. The low comorbidity adjustment amount will be the same across the subgroups and the high comorbidity adjustment will be the same across the subgroup interactions.

III. Payment Under the Home Health Prospective Payment System (HH PPS)

A. CY 2021 PDGM Low-Utilization Payment Adjustment (LUPA) Thresholds and PDGM Case-Mix Weights

1. CY 2021 PDGM LUPA Thresholds

Under the HH PPS, low utilization payment adjustments (LUPAs) are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. The approach to calculating the LUPA thresholds under the PDGM changed to account for the 30-day unit of payment. Therefore, in order to target the same percentage of LUPA periods as under the previous 153-group case-mix system (that is, approximately 7–8 percent of 30-day periods would be LUPAs), in the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized that the LUPA thresholds would be set at the 10th percentile of visits or 2 visits, whichever is higher, for each payment group. This means that the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care will be paid the full 30-day period case-mix adjusted payment amount. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the CY 2021 per-visit payment amounts as described in section III.C.3.c. of this final rule. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or less visits, payment is made using the per-visit payment amounts.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group would be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, CY 2020 was the first year of the new case-mix adjustment methodology and 30-day unit of payment and at this time we do not have sufficient CY 2020 data in which to make any changes to the LUPA thresholds for CY 2021. We believe that making any changes to the LUPA thresholds for CY 2021 based off 2019 utilization using the 153-group model would result in little change in the LUPA thresholds from CY 2020 to CY 2021 and would result in additional burden to HHAs and software vendors in revising their internal billing software

³ Overview of the Home Health Groupings Model. November 18, 2016. <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

to reflect only minor changes. Therefore, we proposed to maintain the LUPA thresholds finalized and shown in Table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. We will repost the LUPA thresholds (along with the case-mix weights) that will be used for CY 2021 on the HHA Center and PDGM web pages.

2. CY 2021 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called HHRGs. We also finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56515) our policy to annually recalibrate the PDGM case-mix weights using a fixed effects model using the most recent, complete utilization data available at the time of annual rulemaking. However, as noted previously, we do not have sufficient CY 2020 data from the first year of the new case-mix methodology and because the 2019 data utilize the old 153-case-mix methodology and 60-day episodes of payment, such data are not appropriate for use to simulate 30-day periods under the PDGM in order to recalibrate the case-mix weights for CY 2021. Therefore, we proposed to maintain the PDGM case-mix weights finalized and shown in Table 16 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes.

We will repost the case-mix weights for CY 2021 on the HHA Center and PDGM web pages. As mentioned previously in this section, we believe this approach for CY 2021 is more accurate, given the limited utilization data for CY 2020; and that the approach will be less burdensome for HHAs and software vendors, who continue to familiarize themselves with this new case-mix methodology.

B. Home Health Wage Index Changes

1. Implementation of New Labor Market Delineations

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On

April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued, OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combines Statistical Areas, and guidance on uses of the delineation in these areas. A copy of the September 2018 bulletin is available at: <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>. We note that on March 6, 2020 OMB issued OMB Bulletin No. 20–01 (available at <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>). Bulletin No. 18–04 states it “provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published in the June 28, 2010, **Federal Register** (75 FR 37246 through 37252), and Census Bureau data.”

While the revisions OMB published on September 14, 2018, are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2006, the September 14, 2018 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart. We believe it is important for the home health wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the September 2018 OMB delineations would increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We have reviewed our findings and impacts relating to the new OMB delineations, and have concluded that there is no compelling reason to further delay implementation. We proposed to implement the new OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04 for the home health wage index effective beginning in CY 2021. As noted previously, the March 6, 2020 OMB Bulletin No. 20–01 was not available in time for development of the proposed rule. We will include any updates from OMB

Bulletin No. 20–01 in any changes that would be adopted in future rulemaking.

(a) Micropolitan Statistical Areas

As discussed in the CY 2006 HH PPS proposed rule (70 FR 40788) and final rule (70 FR 68132), CMS considered how to use the Micropolitan statistical area definitions in the calculation of the wage index. OMB defines a “Micropolitan Statistical Area” as a “CBSA” associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as “rural” and include them in the calculation of each state’s home health rural wage index (see 70 FR 40788 and 70 FR 68132). Thus, the HH PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in non-Metropolitan Statistical Areas (MSA).

Based upon the 2010 Decennial Census data, a number of urban counties have switched status and have joined or became Micropolitan Areas, and some counties that once were part of a Micropolitan Area, have become urban. Overall, there are fewer Micropolitan Areas (542) under the new OMB delineations based on the 2010 Census than existed under the latest data from the 2000 Census (581). We believe that the best course of action would be to continue the policy established in the CY 2006 HH PPS final rule and include Micropolitan Areas in each state’s rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000 to 49,999). Therefore, in conjunction with our proposal to implement the new OMB labor market delineations beginning in CY 2021 and consistent with the treatment of Micropolitan Areas under the IPPS, we proposed to continue to treat Micropolitan Areas as “rural” and to include Micropolitan Areas in the calculation of each state’s rural wage index.

(b) Urban Counties Becoming Rural

Under the new OMB delineations (based upon the 2010 decennial Census data), a total of 34 counties (and county equivalents) that are currently considered urban are considered rural beginning in CY 2021. Table 3 lists the 34 counties that are changing to rural

status with the implementation of the new OMB delineations.

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TABLE 3: COUNTIES CHANGING TO RURAL STATUS

County Name	State	CBSA	CBSA Name
BAKER	GA	10500	Albany, GA
NEWTON	TX	13140	Beaumont-Port Arthur, TX
GOLDEN VALLEY	MT	13740	Billings, MT
WALKER	AL	13820	Birmingham-Hoover, AL
SIOUX	ND	13900	Bismarck, ND
FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
DE WITT	IL	14010	Bloomington, IL
FORD	IL	16580	Champaign-Urbana, IL
BUCKINGHAM	VA	16820	Charlottesville, VA
ARANSAS	TX	18580	Corpus Christi, TX
MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
LE FLORE	OK	22900	Fort Smith, AR-OK
WELLS	IN	23060	Fort Wayne, IN
HOOD	TX	23104	Fort Worth-Arlington, TX
SOMERVELL	TX	23104	Fort Worth-Arlington, TX
HAMILTON	NE	24260	Grand Island, NE
BARRY	MI	24340	Grand Rapids-Wyoming, MI
KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI
VAN BUREN	MI	28020	Kalamazoo-Portage, MI
SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
BENTON	MS	32820	Memphis, TN-MS-AR
SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
GULF	FL	37460	Panama City, FL
CUSTER	SD	39660	Rapid City, SD
CAROLINE	VA	40060	Richmond, VA
WEBSTER	LA	43340	Shreveport-Bossier City, LA
PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
UNION	SC	43900	Spartanburg, SC
PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA
COLUMBIA	WA	47460	Walla Walla, WA
PULASKI	GA	47580	Warner Robins, GA
KINGMAN	KS	48620	Wichita, KS

(c) Rural Counties Becoming Urban
Under the new OMB delineations (based upon the 2010 decennial Census

data), a total of 47 counties (and county equivalents) that are currently designated rural and are considered urban beginning in CY 2021. Table 4

lists the 47 counties that are changing to urban status.

TABLE 4: COUNTIES CHANGING TO URBAN STATUS

County Name	State	CBSA	CBSA Name
GREENE	AL	46220	Tuscaloosa, AL
WASHINGTON	AL	33660	Mobile, AL
FRANKLIN	AR	22900	Fort Smith, AR-OK
LEVY	FL	23540	Gainesville, FL
STEWART	GA	17980	Columbus, GA-AL
TALBOT	GA	17980	Columbus, GA-AL
POWER	ID	38540	Pocatello, ID
FULTON	IL	37900	Peoria, IL
JOHNSON	IL	16060	Carbondale-Marion, IL
FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
PARKE	IN	45460	Terre Haute, IN
WARREN	IN	29200	Lafayette-West Lafayette, IN
BOONE	IA	11180	Ames, IA
JASPER	IA	19780	Des Moines-West Des Moines, IA
GEARY	KS	31740	Manhattan, KS
CARTER	KY	26580	Huntington-Ashland, WV-KY-OH
ASSUMPTION	LA	12940	Baton Rouge, LA
MOREHOUSE	LA	33740	Monroe, LA
FRANKLIN	MA	44140	Springfield, MA
IONIA	MI	24340	Grand Rapids-Kentwood, MI
SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
LAKE	MN	20260	Duluth, MN-WI
COVINGTON	MS	25620	Hattiesburg, MS
HOLMES	MS	27140	Jackson, MS
STONE	MS	25060	Gulfport-Biloxi, MS
COOPER	MO	17860	Columbia, MO
HOWARD	MO	17860	Columbia, MO
STILLWATER	MT	13740	Billings, MT
ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
GRANVILLE	NC	20500	Durham-Chapel Hill, NC
HARNETT	NC	22180	Fayetteville, NC
OTTAWA	OH	45780	Toledo, OH
CLARENDON	SC	44940	Sumter, SC
GIBSON	TN	27180	Jackson, TN
STEWART	TN	17300	Clarksville, TN-KY
HARRISON	TX	30980	Longview, TX
STERLING	TX	41660	San Angelo, TX
KING AND QUEEN	VA	40060	Richmond, VA
MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
JACKSON	WV	16620	Charleston, WV
MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
LINCOLN	WI	48140	Wausau-Weston, WI
ADJUNTAS	PR	38660	Ponce, PR
LAS MARIAS	PR	32420	Mayagüez, PR

(d) Urban Counties Moving to a Different Urban CBSA

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties are shifting from one urban CBSA to another urban CBSA upon implementation of the new OMB delineations (Table 5). In other

cases, applying the new OMB delineations involves a change only in CBSA name or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) experiences both a change to its number and its name, and becomes CBSA 19430 (Dayton-Kettering, OH), while all of its

three constituent counties remain the same. In other cases, only the name of the CBSA is modified, and none of the currently assigned counties are reassigned to a different urban CBSA. We are not discussing these changes in this section because they are inconsequential changes with respect to the home health wage index.

TABLE 5: COUNTIES CHANGING NAME AND/ OR CBSA NUMBER

Proposed CBSA Code	Proposed CBSA Title	Current CBSA Code	Current CBSA Title
10540	Albany-Lebanon, OR	10540	Albany, OR
11500	Anniston-Oxford, AL	11500	Anniston-Oxford-Jacksonville, AL
12060	Atlanta-Sandy Springs-Alpharetta, GA	12060	Atlanta-Sandy Springs-Roswell, GA
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock, TX
13460	Bend, OR	13460	Bend-Redmond, OR
13980	Blacksburg-Christiansburg, VA	13980	Blacksburg-Christiansburg-Radford, VA
14740	Bremerton-Silverdale-Port Orchard, WA	14740	Bremerton-Silverdale, WA
15380	Buffalo-Cheektowaga, NY	15380	Buffalo-Cheektowaga-Niagara Falls, NY
19430	Dayton-Kettering, OH	19380	Dayton, OH
24340	Grand Rapids-Kentwood, MI	24340	Grand Rapids-Wyoming, MI
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Mauldin, SC
25060	Gulfport-Biloxi, MS	25060	Gulfport-Biloxi-Pascagoula, MS
25540	Hartford-East Hartford-Middletown, CT	25540	Hartford-West Hartford-East Hartford, CT
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Beaufort, SC
28700	Kingsport-Bristol, TN-VA	28700	Kingsport-Bristol-Bristol, TN-VA
31860	Mankato, MN	31860	Mankato-North Mankato, MN
33340	Milwaukee-Waukesha, WI	33340	Milwaukee-Waukesha-West Allis, WI
34940	Naples-Marco Island, FL	34940	Naples-Immokalee-Marco Island, FL
35660	Niles, MI	35660	Niles-Benton Harbor, MI
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Hayward-Berkeley, CA
36500	Olympia-Lacey-Tumwater, WA	36500	Olympia-Tumwater, WA
38060	Phoenix-Mesa-Chandler, AZ	38060	Phoenix-Mesa-Scottsdale, AZ
39150	Prescott Valley-Prescott, AZ	39140	Prescott, AZ
23224	Frederick-Gaithersburg-Rockville, MD	43524	Silver Spring-Frederick-Rockville, MD
44420	Staunton, VA	44420	Staunton-Waynesboro, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
45940	Trenton-Princeton, NJ	45940	Trenton, NJ
46700	Vallejo, CA	46700	Vallejo-Fairfield, CA
47300	Visalia, CA	47300	Visalia-Porterville, CA
48140	Wausau-Weston, WI	48140	Wausau, WI
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL

However, in other cases, under the new OMB delineations, counties shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. In another type of change, some

CBSAs have counties that split off to become part of or to form entirely new labor market areas. Finally, in some cases, a CBSA loses counties to another existing CBSA after implementing the

new OMB delineations. Table 6 lists the urban counties moving from one urban CBSA to a newly or modified CBSA under the new OMB delineations.

TABLE 6: COUNTIES CHANGING TO A DIFFERENT CBSA

Previous CBSA	New CBSA	County	State
16974	16984	COOK	IL
16974	16984	DU PAGE	IL
16974	16984	GRUNDY	IL
16974	20994	KENDALL	IL
16974	16984	MC HENRY	IL
16974	16984	WILL	IL
20524	39100	DUTCHESS	NY
20524	35614	PUTNAM	NY
26580	16620	LINCOLN	WV
28940	34100	GRAINGER	TN
35084	35154	SOMERSET	NJ
35614	35154	MIDDLESEX	NJ
35614	35154	MONMOUTH	NJ
35614	35154	OCEAN	NJ
35614	39100	ORANGE	NY
38660	49500	GUANICA	PR
38660	49500	GUAYANILLA	PR
38660	49500	PENUELAS	PR
38660	49500	YAUCO	PR

BILLING CODE 4120-01-C**2. Transition Period**

As discussed previously, overall, we believe that adopting the revised OMB delineations for CY 2021 results in HH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some home health agencies would experience decreases in their area wage index values as a result of our proposal. We also realize that many home health agencies would have higher area wage index values under the new OMB delineations.

To mitigate the potential impacts of proposed policies on home health agencies, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget neutral transition policies to help mitigate negative impacts on home health agencies following the adoption of the new CBSA delineations based on the 2010 decennial census data in the CY 2015 home health final rule (79 FR 66032). Specifically, we implemented a 1-year 50/50 blended wage to the new OMB delineations. We applied a

blended wage index for 1 year (CY 2015) for all geographic areas that would consist of a 50/50 blend of the wage index values using OMB's old area delineations and the wage index values using OMB's new area delineations. That is, for each county, a blended wage index was calculated equal to 50 percent of the CY 2015 wage index using the old labor market area delineation and 50 percent of the CY 2015 wage index using the new labor market area delineation, which resulted in an average of the two values. While we believed that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels, we also recognized that adopting such changes may cause some short-term instability in home health payments. Similar instability may result from the proposed wage policies herein, in particular for home health agencies that would be negatively impacted by the proposed adoption of the updates to the OMB delineations. We proposed a transition policy to help mitigate any significant negative impacts that home health agencies may experience due to our proposal to adopt the revised OMB delineations.

Specifically, for CY 2021 as a transition, we proposed to apply a 5 percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior calendar year. This transition allows the effects of the adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)). We believe a 5 percent cap on the overall decrease in a geographic area's wage index value, regardless of the circumstance causing the decline, is an appropriate transition for CY 2021 as it provides predictability in payment levels from CY 2020 to the upcoming CY 2021 and additional transparency because it is administratively simpler than our prior 1-year 50/50 blended wage index approach. Consistent with the policy finalized under the IPPS and finalized in other Medicare settings, we believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in a geographic area's wage index value for CY 2021 that could result from the adoption of the new OMB delineations.

We believe a 1-year 5 percent cap provides home health agencies sufficient time to plan appropriately for CY 2022 and subsequent years. Because we believe that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels we proposed to include a cap on the overall decrease in a geographic area's wage index value.

While there are some minimal impacts on certain HHAs as a result of the 5 percent cap as shown in the regulatory impact analysis of this final rule, overall, the impact between the CY 2021 wage index using the old OMB delineations and the CY 2021 wage index using the new OMB delineations would be 0.0 percent due to the wage index budget neutrality factor, which ensures that wage index updates and revisions are implemented in a budget-neutral manner.

We received several comments on the FY 2021 home health wage index proposals from various stakeholders including home health agencies, national industry associations and MedPAC. A summary of these comments and our responses to those comments are as follows:

Comment: Commenters generally supported the adoption of the revised OMB delineations from the September 14, 2018 Bulletin No. 18-04 and the proposed transition methodology that would apply a 5 percent cap on decreases to a geographic area's wage index value relative to the wage index value from the prior calendar year.

Response: We appreciate the commenters' support of the adoption of the new OMB delineations and a 5 percent cap on wage index decreases for CY 2021 as an appropriate transition policy.

Comment: A few commenters recommended that CMS reconsider the implementation of the revised OMB delineations. A few commenters stated their concerns regarding potential wage index decreases in the newly created New Brunswick-Lakewood, NJ CBSA. A commenter suggested the redefinition of the New York-Jersey City-White Plains, NY-NJ CBSA will cause major Medicare reimbursement reductions across many hospitals and other providers, including Home Health Agencies, in New York and New Jersey.

Response: We appreciate the concerns sent in by the commenters regarding the impact of implementing the New Brunswick-Lakewood, NJ CBSA designation on their specific counties. While we understand the commenters' concern regarding the potential financial impact, we believe that

implementing the revised OMB delineations will create more accurate representations of labor market areas nationally and result in home health wage index values being more representative of the actual costs of labor in a given area. Although this comment only addressed the negative impact on the commenter's geographic area, we believe it is important to note that there are many geographic locations and home health providers that will experience positive impacts upon implementation of the revised CBSA designations. We recognize there are areas that will experience a decrease in their wage index. As such, in the CY 2021 HH PPS proposed rule, we proposed a transition in order to mitigate the resulting short-term instability and negative impacts on certain providers and to provide time for providers to adjust to their new labor market delineations. We continue to believe that the 1-year 5 percent cap transition policy provides an adequate safeguard against any significant payment reductions in CY 2021 while improving the accuracy of the payment adjustment for differences in area wage levels. Therefore, we believe that it is appropriate to implement the new OMB delineations without further delay.

Comment: Several commenters stated that they were interested in gaining a deeper understanding of the impact of the 5 percent cap transition policy compared to the 50/50 blend transition that we have used in the past. These commenters recommended that CMS develop and make public an impact analysis of applying the previous transition approach in implementing new wage areas in the wage index where a 50/50 blend of old and new indexes was used. A commenter also suggested that for CY 2021, both the 50/50 blend transition and the 5 percent cap on reductions should be used for this transition.

Response: We thank the commenters for their recommendations. We continue to believe that the 5 percent cap on wage index decreases is the best transition approach for CY 2021. We note that the use of a 50/50 blended wage index transition or a combination of the 50/50 blend and the 5 percent cap would be more administratively burdensome as it would affect a larger number of CBSAs and rural areas as a transition wage index value for such areas would need to be used. Likewise, the 5 percent cap on wage index decreases will help effectively mitigate any significant decreases in wage index values for CY 2021 for those HHAs in CBSAs where there would be decreases in the wage index due to the adoption

of the new OMB delineations. Finally, we believe that it is important to remain consistent with the other Medicare payment systems such as Hospice, SNF, IRF and IPF where the 5 percent cap transition was finalized for FY 2021 to ensure consistency and parity in the wage index methodology used by Medicare.

Comment: A few commenters, including MedPAC, suggested alternatives to the 5 percent cap transition policy. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index so that no provider would have its wage index value increase or decrease by more than 5 percent for CY 2021. A commenter suggested that wage index decreases should be capped at 3 percent instead of 5 percent. Finally, several commenters recommended that CMS consider implementing a 5 percent cap, similar to that which we proposed for CY 2021, for years beyond the implementation of the revised OMB delineations.

Response: We appreciate MedPAC's suggestion that the cap on wage index changes of more than 5 percent should be applied to increases in the wage index. However, as we discussed in the proposed rule, the purpose of the proposed transition policy is to help mitigate the significant negative impacts of certain wage index changes.

Additionally, we believe that the 5 percent cap on wage index decreases is an adequate safeguard against any significant payment reductions and do not believe that capping wage index decreases at 3 percent instead of 5 percent is appropriate. We believe that 5 percent is a reasonable level for the cap rather than 3 percent because it would more effectively mitigate any significant decreases in a home health agency's wage index for CY 2021, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, a 5 percent cap on wage index decreases in CY 2021 provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face in CY 2022, after the transition period has ended. Finally, with regards to the comments recommending that CMS consider implementing this type of transition in future years, we believe that this would be counter to the purpose of the wage index, which is used to adjust payments to account for local differences in area wage levels. While we believe that a transition is necessary to help mitigate the negative

impact from the revised OMB delineations in the first year of implementation, this transition must be balanced against the importance of ensuring accurate payments.

Final Decision: We are finalizing our proposal to adopt the revised OMB delineations from the September 14, 2018 OMB Bulletin 18-04 and apply a 1-year 5 percent cap on wage index decreases as proposed, meaning the counties impacted will receive a 5 percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior calendar year for CY 2021 effective January 1, 2021.

Due to the way that the transition wage index is calculated, some Core Based Statistical Areas (CBSAs) and statewide rural areas will have more than one wage index value associated with that CBSA or rural area. For example, some counties that change OMB designations will have a wage index value that is different than the wage index value associated with the CBSA or rural area they are moving to because of the transition. However, each county will have only one wage index value. For counties that correspond to a different transition wage index value, the CBSA number will not be able to be used for CY 2021 claims. In these cases, a number other than the CBSA number will be needed to identify the appropriate wage index value for claims for home health care provided in CY 2021. These numbers are five digits in length and begin with "50". These special 50xxx codes are shown in the last column of the CY 2021 home health wage index file. For counties located in CBSAs and rural areas that do not correspond to a different transition wage index value, the CBSA number will still be used. More information regarding the counties that will receive the transition wage index will be provided in the Home Health Payment Update Change Request (CR) located at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2020-Transmittals>.

The final wage index applicable to CY 2021 can be found on the CMS website at: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>. The final HH PPS wage index for CY 2021 will be effective January 1, 2021 through December 31, 2021.

The wage index file posted on the CMS website provides a crosswalk between each state and county and its corresponding wage index along with the previous CBSA number, the new CBSA number or alternate identification number, and the new CBSA name.

C. CY 2021 Home Health Payment Rate Updates

1. CY 2021 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2021 be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. In the CY 2019 HH PPS final rule with comment period (83 FR 56425), we finalized a policy rebasing the home health market basket to reflect 2016 Medicare cost report (MCR) data, the latest available and complete data on the actual structure of HHA costs. As such, based on the rebased 2016-based home health market basket, we finalized our policy that the labor-related share will be 76.1 percent and the non-labor-related share is 23.9 percent. A detailed description of how we rebased the HHA market basket is available in the CY 2019 HH PPS final rule with comment period (83 FR 56425 through 56436).

Section 1895(b)(3)(B) of the Act requires that in CY 2015 and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted April 16, 2015)), and CY 2020 (under section 53110 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115-123, enacted February 9, 2018)), the market basket percentage under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the "MFP adjustment"). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please visit <http://www.bls.gov/mfp>, to obtain the BLS historical published MFP data.

Consistent with our historical practice and our proposal, we estimate the market basket increase and the MFP adjustment based on IHS Global Inc.'s (IGI) forecast using the most recent available data. In the CY 2021 HH PPS proposed rule (85 FR 39421), we proposed to establish a home health payment update percentage for CY 2021

of 2.7 percent, based on the best available data at that time (that is, the estimated HHA market basket percentage increase of 3.1 percent, less the MFP adjustment of 0.4 percentage point). Consistent with our historical practice, we also proposed to use a more recent estimate of the home health market basket update and the MFP adjustment, if appropriate, to determine the home health payment update percentage for CY 2021 in the final rule.

For this final rule based on IGI's third-quarter 2020 forecast (with historical data through second-quarter 2020), the home health market basket percentage increase for CY 2021 is, as specified at section 1895(b)(3)(B)(iii) of the Act, 2.3 percent. We note that the first quarter 2020 forecast used for the proposed home health market basket percentage increase was developed prior to the economic impacts of the COVID-19 PHE. This lower update (2.3 percent) for CY 2021, relative to the proposed rule (3.1 percent), is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery. Compensation costs account for 76 percent of the 2016-based HHA market basket and other labor-related costs account for an additional 12 percent of the 2016-based HHA market basket.

The CY 2021 home health market basket percentage increase of 2.3 percent is then reduced by a MFP adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148). Based on the more recent data available for this final rule, the current estimate of the 10-year moving average growth of MFP for CY 2021 is 0.3 percentage points. This MFP is based on the most recent forecast of the macroeconomic outlook from IGI at the time of rulemaking (released September 2020) in order to reflect more current historical economic data. IGI produces monthly macroeconomic forecasts, which include projections of all of the economic series used to derive MFP. In contrast, IGI only produces forecasts of the more detailed price proxies used in the HHA market basket on a quarterly basis. Therefore, IGI's third quarter 2020 forecast is the most recent forecast of the HHA market basket percentage increase.

We note that it has typically been our practice to base the projection of the market basket price proxies and MFP in the final rule on the third quarter IGI forecast. For this final rule, we are using

the IGI September 2020 macroeconomic forecast for MFP because it is a more recent forecast, and it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID-19 PHE. However, we also note that the 10-year moving average of MFP based on the third quarter 2020 forecast is also 0.3 percentage points.

Therefore, the final CY 2021 home health payment update percentage for CY 2021 is 2.0 percent (HHA market basket percentage increase of 2.3 percent less 0.3 percentage points MFP adjustment). Section 1895(b)(3)(B)(v) of the Act requires that the home health payment update percentage be decreased by 2.0 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2021, the home health payment update percentage would be 0.0 percent (2.0 percent minus 2.0 percentage points).

Comment: Nearly all commenters supported the proposed 2.7 percent increase for a market basket update. Several commenters stated concerns regarding additional costs of personal protective equipment (PPE) and other infection control measures due to the COVID-19 PHE, and recommended CMS to include a PPE cost add-on to the 2020 30-day period payment and per visit payment rates. Additionally, a few commenters requested to use the proposed 2.7 percent increase as a floor and urged CMS to not make any downward adjustments to the market basket in the final rule. Finally, a commenter recommended the same approach to the MFP adjustment as used in other rulemaking this year to more accurately capture the impacts of the COVID-19 PHE on economic productivity.

Response: CMS thanks the commenters for their comments on the market basket percentage and appreciates their concerns regarding additional costs, such as PPE, due to the COVID-19 PHE. However, we do not yet have the claims and cost report data to conduct the analysis needed for a possible add-on payment to account for any increased costs for PPE. Historically, payments under the HH PPS have been higher than costs, and in its March 2020 Report to Congress, MedPAC estimates HHAs to have projected average Medicare margins of 17 percent in 2020.⁴ Therefore, it is

anticipated that HHAs have sufficient payment to account for the costs of PPE. However, we can examine overall costs once we have complete claims and cost report data for CY 2020.

Consistent with our proposal and prior HHA PPS final rules, as well as other FY 2021 Medicare PPS final rules, we believe it is appropriate to determine the home health payment update percentage for CY 2021 for the final rule based on the most recent forecast (at the time of rulemaking) of the HHA market basket percentage increase and MFP adjustment.

Final Decision: After consideration of public comments, CMS is finalizing the home health payment update percentage for CY 2021 based on the most recent forecast of the HHA market basket percentage increase and MFP adjustment at the time of rulemaking. Based on IGI's third-quarter 2020 forecast (with historical data through second-quarter 2020) of the HHA market basket percentage increase and IGI's September 2020 macroeconomic forecast of MFP, the home health payment update percentage for CY 2021 will be 2.0 percent (2.3 percent HHA market basket percentage increase less 0.3 percentage point MFP adjustment) for HHAs that submit the required quality data and 0.0 percent (2.0 percent minus 2.0 percentage points) for HHAs that do not submit quality data as required by the Secretary.

2. CY 2021 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home health payments. We proposed to continue this practice for CY 2021, as we continue to believe that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. As discussed previously, we proposed to use the FY 2021 pre-floor, pre-reclassified hospital wage index with the September 2018 OMB delineations as the CY 2021 wage adjustment to the labor portion of the HH PPS rates. For CY 2021, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017 (FY 2017 cost report data). We apply the

appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2021 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we proposed to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we proposed to continue to use the most recent wage index previously available for that area. The most recent wage index previously available for rural Puerto Rico is 0.4047. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2021, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). The CY 2021 new delineations wage index value for Hinesville, GA is 0.8388.

On February 28, 2013, OMB issued Bulletin No. 13-01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted OMB's area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17-01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2021 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8668. Bulletin No. 17-01 is available at <https://www.whitehouse.gov/sites/>

⁴ Home Health Services, Chapter 9. MedPAC. March 2020. http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch9_sec.pdf.

[whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf](https://www.whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf).⁵

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at <https://www.whitehouse.gov/wpcontent/uploads/2018/09/Bulletin-18-04.pdf>.

As discussed previously the most recent OMB Bulletin (No. 20–01) was published on March 6, 2020 and is available at <https://www.whitehouse.gov/wpcontent/uploads/2020/03/Bulletin-20-01.pdf>. This bulletin was not available in time for development of the CY 2021 proposed rule, however we will include any updates from OMB Bulletin No. 20–01 in future rulemaking.

A summary of the general comments on the home health wage index and our responses to those comments are as follows:

Comment: Many commenters recommended more far-reaching revisions and reforms to the wage index methodology used under Medicare fee-for-service. A few commenters recommended a home health specific wage index. MedPAC recommended that Congress repeal the existing hospital wage index and instead implement a market-level wage index for use across the inpatient prospective payment system and other prospective payment systems, including certain post-acute care providers. A commenter recommended a home health floor similar to the floor used in hospice. Finally, a few commenters recommended that the home health wage index utilize geographic reclassification and a rural floor like the hospital wage index.

Response: While we thank the commenters for their recommendations, these comments are outside the scope of the proposed rule. Any changes to the way we adjust home health payments to account for geographic wage differences, beyond the wage index proposals

discussed in the CY 2021 HH PPS proposed rule, would have to go through notice and comment rulemaking. While CMS and other stakeholders have explored potential alternatives to using OMB’s statistical area definitions, no consensus has been achieved regarding how best to implement a replacement system. We believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for home health payments. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital’s geographic classification. The reclassification provision found in section 1886(d)(10) of the Act is specific to IPPS hospitals only. Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that state. This is the rural floor provision and it is only specific to IPPS hospitals. Additionally, the application of the hospice floor is specific to hospices and does not apply to HHAs. The hospice floor was developed through a negotiated rulemaking advisory committee, under the process established by the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648). Committee members included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; consumer groups; and a government representative. The Committee reached consensus on a methodology that resulted in the hospice wage index. Because the reclassification provision and the hospital rural floor applies only to hospitals, and the hospice floor applies only to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the home health payment rates. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and Hospice).

Final Decision: After considering the comments received in response to the proposed rule and for the reasons discussed previously, we are finalizing our proposal to use the FY 2021 pre-floor, pre-reclassified hospital wage index data as the basis for the CY 2021 HH PPS wage index. The final CY 2021

wage index is available on the CMS website at: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>.

3. CY 2021 Annual Payment Update

(a) Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020. As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2019 HH PPS final rule with comment period (83 FR 56435), we finalized rebasing the home health market basket to reflect 2016 MCR data, the latest available and most complete data on the actual structure of HHA costs. We also finalized a revision to the labor-related share to reflect the 2016-based home health market basket compensation (Wages and Salaries plus Benefits) cost weight. We finalized that for CY 2019 and subsequent years, the labor-related share would be 76.1 percent and the non-labor-related share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period rates for CY 2021:

- Multiply the national, standardized 30-day period rate by the patient’s applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period rate, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225

⁵ “Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas”. OMB Bulletin No. 17–01. August 15, 2017. <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.

sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(c), for an HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health payment update, minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A partial payment adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

(b) CY 2021 National, Standardized 30-Day period Payment Amount

Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, requires us to analyze data for CYs 2020 through 2026, after

implementation of the 30-day unit of payment and new PDGM case-mix adjustment methodology, to annually determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. In the CY 2021 HH PPS proposed rule, we stated that we would continue to monitor the impact of these changes on patient outcomes and Medicare expenditures, but that we believed it would be premature to release any information related to these issues based on the amount of data currently available and in light of the COVID-19 PHE. Therefore, for CY 2021, we did not propose to make any additional changes to the national, standardized 30-day period payment rate other than the routine rate updates outlined in the proposed rule. We stated that in future rulemaking, we plan to determine whether any changes need to be made to the national, standardized 30-day period payment rate based on the analysis of the actual versus assumed behavior change.

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget-neutral manner. To determine the CY 2021 national, standardized 30-day period payment rate, we apply a wage index budget neutrality factor and the home health payment update percentage discussed in section III.C.2. of this final rule.

To calculate the wage index budget neutrality factor, we simulated total

payments, using CY 2019 Medicare claims data for episodes ending on or before December 31, 2019 for which we had a linked OASIS assessment, for non-LUPA 30-day periods using the CY 2021 wage index and compared it to our simulation of total payments for non-LUPA 30-day periods using the CY 2020 wage index. By dividing the total payments for non-LUPA 30-day periods using the CY 2021 wage index by the total payments for non-LUPA 30-day periods using the CY 2020 wage index, we obtain a wage index budget neutrality factor of 0.9999. We apply the wage index budget neutrality factor of 0.9999 to the calculation of the CY 2021 national, standardized 30-day period payment rate.

We note that in past years, a case-mix budget neutrality factor was annually applied to the HH PPS base rates to account for the change between the previous year's case-mix weights and the newly recalibrated case-mix weights. Since CY 2020 was the first year of PDGM, we did not propose to recalibrate the PDGM case-mix weights and; therefore, a case-mix budget neutrality factor is not needed. However, in future years under the PDGM, we would apply a case-mix budget neutrality factor with the annual payment update in order to account for the change between the previous year's PDGM case-mix weights and the new recalibrated PDGM case-mix weights.

Next, we update the 30-day payment rate by the CY 2021 home health payment update percentage of 2.0 percent. The CY 2021 national, standardized 30-day period payment rate is calculated in Table 7.

TABLE 7: CY 2021 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2020 30-day Budget Neutral (BN) Standard Amount	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update	CY 2021 National, Standardized 30-Day Period Payment
\$1,864.03	X 0.9999	X 1.020	\$1,901.12

The CY 2021 national, standardized 30-day period payment rate for an HHA that does not submit the required

quality data is updated by the CY 2021 home health payment update of 2.0

percent minus 2 percentage points and is shown in Table 8.

TABLE 8: CY 2021 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2020 National, Standardized 30-Day Budget Neutral (BN) Period Payment	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update Minus 2 Percentage Points	CY 2021 National, Standardized 30-Day Period Payment
\$1,864.03	X 0.9999	X 1.000	\$1,863.84

Comments regarding the update to the CY 2021 national, standardized 30-day period payment amount are summarized in this section of this final rule. In addition, although we did not propose any changes the national, standardized 30-day period payment rate for CY 2021, except for the statutorily-required routine payment rate update, we received numerous comments regarding the behavior assumptions adjustment and these are summarized in this section of this final rule.

Comment: Commenters generally supported the home health payment updates for CY 2021. MedPAC stated that it recognizes that the public health emergency has had an effect on the home health benefit and will continue to monitor its effects, but still felt that many HHAs have been able to mitigate the negative impacts of the public health emergency through various mechanisms, including accessing funds through the Payroll Protection Program. MedPAC reiterated its recommendation from its March 2020 report to the Congress to reduce home health payments by 7 percent in CY 2021.

Response: Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2021 be increased by a factor equal to the applicable home health market basket percentage increase reduced by the MFP adjustment, and as such, we have no statutory or regulatory discretion in this matter.

Comment: Several commenters recommended that CMS reduce or eliminate the 4.36 percent behavior assumption reduction, finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60511–60519), to the national, standardized 30-day period payment rate for the remainder of CY 2020 and for CY 2021 rate setting. Commenters stated that the effects of the COVID–19 PHE, in tandem with a new home health payment system, has brought about changes in patient mix, decreased utilization of home health services, and changing demands from patients in need of care. These commenters stated that the impact on

payment to home health agencies would make it highly unlikely that Medicare home health spending in CY 2020 would be budget neutral in comparison to the level of spending that would have occurred if the PDGM and the change to a 30-day unit of payment had not been implemented.

Response: We thank the commenters for their recommendations and while we did not propose any changes for CY 2021 relating to the behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period (84 FR 56461), or to the 4.36 percent behavior assumption reduction, finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60519), we want to respond with what CMS is required to do by law. Under section 1895(b)(3)(A)(iv) of the Act, we were required to calculate a 30-day payment amount for CY 2020 in a budget-neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 would be equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment. Section 1895(b)(3)(A)(iv) of the Act also required that in calculating a 30-day payment amount in a budget-neutral manner the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors established under 1895(b)(4)(B) of the Act. We were also required to calculate a budget-neutral 30-day payment amount before the provisions of section 1895(b)(3)(B) of the Act were applied; that is, before the home health applicable percentage increase, the adjustment if quality data are not reported, and the productivity adjustment.

In the CY 2020 HH PPS final rule with comment period, we stated that applying the previously finalized clinical group and comorbidity coding assumptions, and the LUPA threshold assumption, as required by section

1895(b)(3)(A)(iv) of the Act, would result in the need to decrease the CY 2020 30-day payment amount by 8.389 percent to maintain budget neutrality. However, commenters stated that CMS overestimated the magnitude of the behavior changes that would occur as HHAs transitioned to a new case-mix methodology and a change to a 30-day unit of payment. Commenters stated that behavior change would not occur 100 percent of the time for all 30-day periods of care. Therefore, in response to comments as to the frequency of the assumed behaviors during the first year of the transition to a new unit of payment and case-mix adjustment methodology, we finalized to apply the three behavior change assumptions, as finalized in the CY 2019 HH PPS final rule with comment period, to only half of the 30-day periods for purposes of calculating the CY 2020 30-day payment rate. As such, in the CY 2020 HH PPS final rule with comment period, we finalized a ×4.36 percent behavior assumption adjustment in order to calculate the 30-day payment rate in a budget-neutral manner for CY 2020 (84 FR 60511–60519).

Additionally, section 1895(b)(3)(D) of the Act requires the Secretary to analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology under the PDGM, to annually determine the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures and, at a time and manner determined appropriate by the Secretary, make permanent and temporary adjustments to the 30-day payment amounts. This means that if CMS underestimates the reductions to the 30-day payment amount necessary to offset behavior changes and maintain budget neutrality, larger adjustments to the 30-day payment amount would be required in the future to ensure budget neutrality. Likewise, if CMS overestimates the reductions, we are required to make the appropriate payment adjustments accordingly. In the CY 2019 HH PPS final rule with

comment period (83 FR 56459), we stated that any adjustment to the payment amount resulting from differences between assumed versus actual behavior changes would not be related to increases in the number of beneficiaries utilizing Medicare home health services. The same would hold true for any decreases in the number of beneficiaries utilizing Medicare home health services. That is to say, the law required that CMS calculate the 30-day payment amount for CY 2020 to ensure that the aggregate expenditures during CY 2020 under the new case-mix methodology and 30-day unit of payment would be the same as if the 153-group model was still in place in CY 2020. Therefore, any future payment adjustment required by section 1895(b)(3)(D) of the Act, must be based on the difference in aggregate payments between the assumed versus actual behavior change and not because of utilization changes resulting from the COVID-19 PHE. However, CMS issued several IFCs, as described throughout this final rule, to provide flexibilities to ensure that HHAs could provide care to Medicare beneficiaries in the least burdensome manner during the COVID-19 PHE. These flexibilities include:

- Allowing HHAs to provide more services to beneficiaries using telecommunications technology within the 30-day period of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care;
- Allowing the face-to-face encounter for home health to be conducted via telehealth (i.e., 2-way audio-video telecommunications technology);
- Extending the 5-day completion requirement for the comprehensive assessment to 30 days;
- Waiving the 30-day OASIS submission requirement (though HHAs must submit OASIS data prior to submitting their final claim in order to receive Medicare payment);

- Waiving the requirements in 42 CFR 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered; and
- Changing the home health regulations to include physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services.

These flexibilities were provided to help mitigate commenters' concerns about the provision of home health services during the COVID-19 PHE. Moreover, as we stated in the CY 2021 HH PPS proposed rule, we believed it would be premature to propose any changes to the CY 2021 payment rate based on the data available at the time of CY 2021 rulemaking and in light of the ongoing COVID-19 PHE. Finally, any changes to the national, standardized 30-day period payment rates to account for differences in assumed versus actual behavior change are required to go through notice and comment rulemaking, as required by 1895(b)(3)(D)(ii) and (iii) of the Act.

Comment: Several commenters stated that the first eight months of the PDGM cannot be understood as an accurate representation of the new payment model given the public health emergency. These commenters stated that the short and long-term effects are not yet fully known and therefore, there should be no changes to the payment system for CY 2021.

Response: We thank commenters for their recommendation and we did not propose any changes to the home health prospective payment system, other than the routine payment updates, for CY 2021.

(c) CY 2021 National Per-Visit Rates for 30-Day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to

compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2021 national per-visit rates, we started with the CY 2020 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA 30-day periods of care using the CY 2021 wage index and comparing it to simulated total payments for LUPA 30-day periods using the CY 2020 wage index. By dividing the total payments for LUPA 30-day periods using the CY 2021 wage index by the total payments for LUPA 30-day periods using the CY 2020 wage index, we obtained a wage index budget neutrality factor of 0.9997. Lastly, the per-visit rates for each discipline are updated by the CY 2021 home health payment update percentage of 2.0 percent. The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments.

The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for 30-day periods that occur as the only 30-day period or the initial period in a sequence of adjacent 30-day periods. The CY 2021 national per-visit rates for HHAs that submit the required quality data are shown in Table 9.

TABLE 9: CY 2021 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2020 Per-Visit Payment	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update	CY 2021 Per-Visit Payment
Home Health Aide	\$67.78	X 0.9997	X 1.020	\$69.11
Medical Social Services	\$239.92	X 0.9997	X 1.020	\$244.64
Occupational Therapy	\$164.74	X 0.9997	X 1.020	\$167.98
Physical Therapy	\$163.61	X 0.9997	X 1.020	\$166.83
Skilled Nursing	\$149.68	X 0.9997	X 1.020	\$152.63
Speech-Language Pathology	\$177.84	X 0.9997	X 1.020	\$181.34

The CY 2021 per-visit payment rates for HHAs that do not submit the required quality data are updated by the

CY 2020 home health payment update percentage of 2.0 percent minus 2.0

percentage points and are shown in Table 10.

TABLE 10: CY 2021 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2020 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2021 HH Payment Update Minus 2 Percentage Points	CY 2021 Per-Visit Rates
Home Health Aide	\$67.78	X 0.9997	X 1.000	\$67.76
Medical Social Services	\$239.92	X 0.9997	X 1.000	\$239.85
Occupational Therapy	\$164.74	X 0.9997	X 1.000	\$164.69
Physical Therapy	\$163.61	X 0.9997	X 1.000	\$163.56
Skilled Nursing	\$149.68	X 0.9997	X 1.000	\$149.64
Speech- Language Pathology	\$177.84	X 0.9997	X 1.000	\$177.79

In the CY 2021 HH PPS proposed rule (85 FR 39424), we reminded stakeholders of the policies finalized in the CY 2020 HH PPS final rule with comment (84 FR 60544) with regards to the submission of Requests for Anticipated Payment (RAPs) for CY 2021 and the implementation of a new one-time Notice of Admission (NOA) process starting in CY 2022. In that final rule, we finalized the reduction in upfront payment made in response to a RAP to zero percent for all 30-day periods of care beginning on or after January 1, 2021 (84 FR 60544). For CY 2021, all HHAs (both existing and newly-enrolled HHAs) will submit a RAP at the beginning of each 30-day period to establish the home health period of care in the common working file and also to trigger the consolidated billing edits. With the removal of the upfront RAP payment for CY 2021, we relaxed the required information for submitting the RAP for CY 2021 and stated that the information required for submitting a NOA for CYs 2022 and subsequent years would mirror that of the RAP in CY 2021. Starting in CY 2022, HHAs will submit a one-time NOA that establishes the home health period of care and covers all contiguous 30-day periods of care until the individual is discharged from Medicare home health services. In addition, for both the submission of the RAP in CY 2021 and the one-time NOA for CYs 2022 and subsequent years, we finalized a payment reduction if the HHA does not submit the RAP for CY 2021 or NOA for CYs 2022 and subsequent years within 5 calendar days from the start of care. That is, if an HHA fails to submit

a timely RAP for CY 2021 or fails to submit a timely NOA for CYs 2022 and subsequent years, the reduction in payment amount would be equal to a one-thirtieth reduction to the wage and case-mix adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the RAP or NOA. In other words, the one-thirtieth reduction would be to the 30-day period adjusted payment amount, including any outlier payment, that the HHA otherwise would have received absent any reduction. For LUPA 30-day periods of care in which an HHA fails to submit a timely RAP or NOA, no LUPA payments would be made for days that fall within the period of care prior to the submission of the RAP or NOA. We stated that these days would be a provider liability, the payment reduction could not exceed the total payment of the claim, and that the provider may not bill the beneficiary for these days. For more in-depth information regarding the finalized policies associated with RAPs and the new one-time NOA process, we refer readers to the CY 2020 HH PPS final rule with comment (84 FR 60544).

Though we did not solicit comments on the previously finalized split percentage payment approach for CY 2021 or the NOA process for CY 2022, we did receive several comments on various components of the finalized policy. While most of the comments were out of scope of the proposed rule because we did not propose to make any changes, we did receive a few technical comments regarding the implementation of the finalized policy, which are

summarized in this section of this final rule.

Comment: A commenter requested clarification on the methodology used to calculate the non-timely submission payment reduction. This commenter asked whether the reduction begins on day 1 or day 6. Another commenter recommended an alternative to the non-timely submission payment reduction. This commenter recommended that no RAP/NOA be considered late until day 6 of the 30-day period. The commenter suggested making the reduction one 25th for each day that it is late beyond day 5 (days 6–30).

Response: For purposes of determining if a “no-pay” RAP is timely-filed, the “no-pay” RAP must be submitted within 5 calendar days after the start of each 30-day period of care. For example, if the start of care for the first 30-day period is January 1, 2021, the “no-pay” RAP would be considered timely-filed if it is submitted on or before January 6, 2021.

Example:
 1/1/2021 = Day 0 (start of the first 30-day period of care)
 1/6/2021 = Day 5 (A “no-pay” RAP submitted on or before this date would be considered “timely-filed”.)
 1/7/2021 and after = Day 6 and beyond (A “no-pay” RAP submitted on and after this date will trigger the penalty.)

In the event that the “no-pay” RAP is not timely-filed, the penalty is calculated from the first day of that 30-day period (in the example, the penalty calculation would begin with the start of care date of January 1, 2021, counting as the first day of the penalty) until the date of the submission of the “no-pay”

RAP. As finalized in the CY 2020 HH PPS final rule with comment period, Medicare does not pay for those days of home health services based on the “from date” on the claim to the date of filing of the RAP. Therefore, in CY 2021, the wage and case-mix adjusted 30-day payment amount is reduced by 1/30th for each day from the home health based on the “from date” on the claim until the date of filing of the RAP. For example, if an HHA submits their “no-pay” RAP one day late (with a submission 6 days after the start of care), the result would be a 20 percent reduction to the 30-day payment amount. Additionally, the finalized policy states that no LUPA payments are made that fall within the late period; the payment reduction cannot exceed the total payment of the claim; the non-covered days are a provider liability; and the provider must not bill the beneficiary for the non-covered days. And finally, in the CY 2020 HH PPS final rule with comment period (84 FR 60546), we stated that the “no-pay” RAP submission in CY 2021 and the NOA process beginning in CY 2022 would be similar to the hospice Notice of Election (NOE) process and where the penalty is calculated beginning with the start of care date. Therefore, we do not believe that the penalty calculation should begin on day 6 as the commenters recommended.

Comment: A few commenters provided several scenarios in which the HHA believed that the patient was covered under Medicare Advantage or another payer only to find out that the patient was actually covered under traditional Medicare and this could create a situation in which the RAP submission would be submitted after the timely-filing requirement. A commenter stated that agencies struggle with ascertaining beneficiary eligibility against inaccurate information in the Common Working File (CWF) as there can be significant lag time between a beneficiary’s enrollment/disenrollment date and CWF update and that several days can pass before the plan provides any eligibility and/or authorization information on the beneficiary. Therefore, the commenter is concerned that agencies could be at risk for missing the 5-day window while seeking to confirm a beneficiary’s insurance coverage. These commenters asked if there would be claim payment penalties for the periods that are being updated and re-billed to reflect the retroactive enrollment in Original Medicare.

Response: In the CY 2020 HH PPS final rule with comment period, we finalized exceptions to the timely filing consequences of the RAP requirements

at § 484.205(g)(4). Specifically, we finalized that CMS may waive the consequences of failure to submit a timely-filed RAP if it is determined that a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence. As finalized in the CY 2020 HH PPS final rule with comment period and as set forth in regulation at § 484.205(g)(4), an exceptional circumstance may be due to, but is not limited to the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency’s ability to operate.
- A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.
- A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to be beyond the control of the home health agency.

If an HHA believes that there is a circumstance that may qualify for an exception, the home health agency must fully document and furnish any requested documentation to CMS for a determination of exception. The scenarios provided by commenters may fall into one of the established timely filing exceptions.

(d) Low-Utilization Payment Adjustment (LUPA) Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, we stated that the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occurred as the only episode or as an initial episode in a sequence of adjacent episodes were adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount.

In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only 30-day period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. For example, using the finalized CY 2021 per-visit payment rates for those HHAs that submit the required quality data, for LUPA periods that occur as the only period or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit would be \$281.62 (1.8451 multiplied by \$152.63), subject to area wage adjustment. We did not receive any comments on the LUPA add-on factors.

Final Decision: After considering the comments received in response to the proposed CY 2021 annual payment update and for the reasons discussed previously, we are finalizing the CY 2021 national, standardized 30-day payment rates, the per-visit payment rates and the home health payment update percentage of 2.0 percent for CY 2021 as proposed. We are not making any changes to the policies previously finalized in the CY 2020 HH PPS final rule regarding the behavior assumptions adjustment. In accordance with section 1895(b)(3)(D) of the Act, we will analyze data for CYs 2020 through 2026, after implementation of the 30-day unit of payment and new case-mix adjustment methodology under the PDGM, to annually determine the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures and, at a time and manner determined appropriate by the Secretary, make permanent and temporary adjustments to the 30-day payment amounts. Any future changes to the national, standardized 30-day period payment rates to account for differences in assumed versus actual behavior change, as a result of the implementation of the 30-day unit of payment and the case-mix adjustment methodology under the PDGM, are required to go through notice and comment rulemaking as required by 1895(b)(3)(D)(ii) and (iii) of the Act. We are not making any changes to the split-percentage payment policy finalized in the CY 2020 HH PPS final rule. That is,

for CY 2021, all HHAs will submit a “no-pay” RAP at the beginning of each 30-day period to allow the beneficiary to be claimed in the CWF and also to trigger the consolidated billing edits.

D. Rural Add-On Payments for CY 2021 and CY 2022

1. Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) required, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent. Section 5201 of the Deficit Reduction Act of 2003 (DRA) (Pub. L. 108–171) amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under

section 1895 of the Act for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the BBA of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019.

2. Rural Add-On Payments for CYs 2019 through CY 2022

Section 50208(a)(1)(D) of the BBA of 2018 added a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes or visits ending during CYs 2019 through 2022. It also mandated implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provided varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories: (1) Rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under Part A of Medicare or enrolled for benefits under Part B of Medicare only, but not enrolled in a Medicare Advantage plan under Part C of Medicare (the “High utilization” category); (2) rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not

included in the “High utilization” category (the “Low population density” category); and (3) rural counties and equivalent areas not in either the “High utilization” or “Low population density” categories (the “All other” category).

In the CY 2019 HH PPS final rule with comment period (83 FR 56443), CMS finalized policies for the rural add-on payments for CY 2019 through CY 2022, in accordance with section 50208 of the BBA of 2018. The CY 2019 HH PPS proposed rule (83 FR 32373) described the provisions of the rural add-on payments, the methodology for applying the new payments, and outlined how we categorized rural counties (or equivalent areas) based on claims data, the Medicare Beneficiary Summary File and Census data. The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this rule at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html>. In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) state and county codes, and their designation into one of the three rural add-on categories is available for download.

The HH PRICER module, located within CMS’ claims processing system, will increase the CY 2021 30-day base payment rates, described in section III.C.3.b. of this final rule, by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2019 through CY 2022 rural add-on percentages outlined in law are shown in Table 11.

TABLE 11: HH PPS RURAL ADD-ON PERCENTAGES, CYs 2019-2022

Category	CY 2019	CY 2020	CY 2021	CY 2022
High utilization	1.5%	0.5%	None	None
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	None

Though we did not make any proposals regarding the rural add-on percentages in the CY 2021 HH PPS proposed rule, we did receive some comments as summarized in this section of this final rule.

Comment: While commenters understood the rural add-on payments decrease has been mandated by the BBA

of 2018, many expressed continued concern and frustration of the reduction in support for access to rural beneficiaries. Several requested for stakeholders and CMS to work together with Congress to establish legislation to extend the 3 percent rural add-on payment. A few commenters recommended to continue monitoring

utilization during the post-implementation period and to extend or modify the rural add-on as necessary. Some commenters had specific concerns about HHAs serving patients that reside in counties in the rural add-on high utilization category and such category losing its rural add-on payment in CY 2021. A commenter had concerns

regarding the change in the OMB delineations and how the new CBSA re-designation would affect any rural add-on payments. Specifically, the commenter asked if a rural add-on payment would be paid in CY 2021 if an HHA changed from an urban to a rural CBSA and whether the rural add-on payment would no longer be paid if an HHA changed from a rural to an urban CBSA in CY 2021 based on the new OMB delineations. A few commenters expressed support for the proposed rural add-on payment for CY 2021 and the methodology used to implement Section 50208 of the BBA of 2018, but recommended that CMS work with both stakeholders and Congress on long-term solutions for rural safeguards, given the cost and population health differences in rural America. Finally, a commenter recommended that, with the sunset of the rural add-on payment, CMS should include telehealth or virtual visits as a billable visit to help offset the financial burden of rural HHAs.

Response: We thank commenters for their recommendations. We understand commenter concerns about the phase-out of rural add-on payments and potential effects on rural HHAs. However, because the current rural add-on policy is statutory, we have no regulatory discretion to modify or extend it. However, CMS will continue to monitor patient access to home health services and the costs associated with providing home health care in rural versus urban areas. In response to the comment regarding the new OMB delineations and the potential effect on the rural add-on payment, section 50208(a)(1)(D) of the BBA of 2018 (revising section 421 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)) states that the designation for the rural add-on payment shall be made a single time and shall apply for the duration of the period to which the subsection applies. That is to say, that each county had a one-time designation as described CY 2019 HH PPS final rule with comment period (83 FR 56443) and the rural add-on payment is made based on that designation regardless of any change in CBSA status based on the new OMB delineations. In response to comments regarding the inclusion of telehealth services as billable visits, we refer readers to section III.F. of this final rule for a summary of comments and our responses on the use of telecommunications technology under the Medicare home health benefit.

Final Decision: Policies for the provision of rural add-on payments for CY 2019 through CY 2022 were

finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56443), in accordance with section 50208 of the BBA of 2018. The data used to categorize each county or equivalent area are available in the downloads section associated with the publication of this rule at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html>. In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) state and county codes, and their designation into one of the three rural add-on categories is available for download.

E. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or partial episode payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were

reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10-percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the

amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

We will publish the cost-per-unit amounts for CY 2021 in the rate update change request, which is issued after the publication of the CY 2021 HH PPS final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per unit rates used to estimate an episode's cost will be updated by the home health payment update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost of an episode of care (81 FR 76727). We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of the PDGM beginning in CY 2020 and that we will calculate payment for high-cost outliers based upon 30-day periods of care.

2. Fixed Dollar Loss (FDL) Ratio for CY 2021

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of periods that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of

the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio, which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount. In the CY 2020 HH PPS final rule with comment period, given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we finalized a FDL ratio of 0.56 for 30-day periods of care in CY 2020. For CY 2021, we proposed to maintain the same fixed-dollar loss ratio finalized for CY 2020.

Comment: A commenter remarked on the proposed FDL ratio of 0.63 that was in the CY 2021 HH PPS proposed rule and stated that the FDL ratio that was finalized for CY 2020 was 0.56. This commenter requested clarification as to this discrepancy and asked that CMS clearly state in the final rule the correct FDL ratio for CY 2021.

Response: We apologize for the typographical error in the CY 2021 HH PPS proposed rule regarding the FDL ratio for CY 2021. This commenter is correct, and as noted previously, the FDL ratio for CY 2021 will be 0.56.

Comment: A commenter supports the methodology used in the outlier provision and the per unit basis is appropriate to account for utilization and accompanying resources allocations by HHAs.

Response: We thank the commenter for their support.

Comment: A few commenters recommended to end the outlier provision entirely and reinstate the 5 percent withheld into regular reimbursements.

Response: Section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. We believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care.

Final Decision: We are finalizing the fixed-dollar loss ratio of 0.56 for CY 2021 to ensure that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS.

F. The Use of Telecommunications Technology Under the Medicare Home Health Benefit

In the CY 2021 HH PPS proposed rule (85 FR 39427), we discussed the plan of care requirements at § 409.43(a), revised on an interim basis, as outlined in the March 2020 COVID-19 IFC (85 FR 19230). For the purposes of Medicare payment during the COVID-19 PHE, this revision requires the plan of care to include any provision of remote patient monitoring or other services furnished via a telecommunications system and must describe how the use of such technology is tied to the patient-specific needs as identified in the comprehensive assessment and will help to achieve the goals outlined on the plan of care. The amended plan of care requirements at § 409.43(a) also state that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, in accordance with section 1895(e)(1)(A) of the Act. We stated that we believed that this change will help to increase access to technologies, such as telemedicine and remote patient monitoring, during the COVID-19 PHE (85 FR 19250).

Additionally, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136) included section 3707 related to encouraging use of telecommunications systems for home health services furnished during the COVID-19 PHE. Specifically, section 3707 of the CARES Act requires, with respect to home health services furnished during the COVID-19 PHE, that the Secretary consider ways to encourage the use of telecommunications systems, including for remote patient monitoring as described in § 409.46(e) and other communications or monitoring services, consistent with the plan of care for the individual, including by clarifying guidance and conducting outreach, as appropriate. In the CY 2021 HH PPS proposed rule (85 FR 39427), we stated that we believe that the policies finalized on an interim basis meet the requirements of section 3707 of the CARES Act.

We also discussed hearing from stakeholders about the various applications of technologies that are currently in use by HHAs in the delivery of appropriate home health services outside of the COVID-19 PHE (85 FR 39427). We stated that although section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-person home

health services ordered as part of a plan of care, we understand that there are ways in which technology can be further utilized to improve patient care, better leverage advanced practice clinicians, and improve outcomes while potentially making the provision of home health care more efficient.

For these reasons, we proposed to finalize the amendment to § 409.43(a) as set out in the March 2020 COVID-19 IFC (85 FR 19230) beyond the period of the COVID-19 PHE. We also proposed to allow HHAs to continue to report the costs of telehealth/telemedicine as allowable administrative costs on line 5 of the home health agency cost report. We proposed to modify the instructions regarding this line on the cost report to reflect a broader use of telecommunications technology. Specifically, we proposed to amend § 409.46(e) to include not only remote patient monitoring, but other communication or monitoring services, consistent with the plan of care for the individual.

We also reminded stakeholders that access to telecommunications technology must be accessible, including for patients with disabilities. Section 504 of the Rehabilitation Act, section 1557 of the Patient Protection and Affordable Care Act (ACA), and the Americans with Disabilities Act (ADA) protect qualified individuals with disabilities from discrimination on the basis of disability in the provision of benefits and services. Concerns related to potential discrimination issues under section 504, section 1557 of the ACA, and Title II of the ADA⁶ should be referred to the Office of Civil Rights for further review. Likewise, we reminded HHAs that the home health CoPs at § 484.50(f)(1) require that information be provided to persons with disabilities in plain language and in a manner that is accessible and timely, including accessible websites and the provision of auxiliary aids and services at no cost to the individual in accordance with the ADA, section 1557 of the ACA, and section 504 of the Rehabilitation Act. This means that the HHA must meet these requirements to ensure access to and use of telecommunications as required by law. Appendix B of the State Operations Manual (regarding home health services) provides detailed examples of “auxiliary aids and services”.⁷

⁶ Discrimination on the Basis of Disability. <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>.

⁷ State Operations Manual Appendix B—Guidance to Surveyors: Home Health Agencies, Tab G490. <https://www.cms.gov/Regulations-and->

We also reiterated the expectation that services provided by telecommunications technology are services that could also be provided through an in-person visit. We stated that if there is a service that cannot be provided through telecommunications technology (for example, wound care which requires in-person, hands-on care), the HHA must make an in-person visit to furnish such services (85 FR 39428). We also stated that an HHA couldn't discriminate against any individual who is unable (including because of other forms of discrimination), or unwilling to receive home health services provided via telecommunications technology. In those circumstances, the HHA must provide such services through in-person visits. Section 1861(m) of the Act defines “home health services” to mean the furnishing of items and services *on a visiting basis in an individual's home* (emphasis added).

We received comments on the March 2020 COVID-19 IFC (85 FR 19230) regarding the interim amendment to § 409.43(a), allowing the use of telecommunications technology to be included as part of the home health plan of care as long as the use of such technology does not substitute for in-person visits ordered on the plan of care during the COVID-19 PHE, as well as comments on our proposal in the CY 2021 HH PPS proposed rule to finalize the amendment to § 409.43(a) in the March 2020 COVID-19 IFC (85 FR 19247). We also received comments on our proposal in the CY 2021 HH PPS proposed rule to amend the language at § 409.46(e), allowing a broader use of telecommunications technology to be reported as an allowable administrative cost on the home health agency cost report. A summary of the comments and our responses are as follows:

Comment: Commenters overwhelmingly supported CMS' acknowledgment that telecommunications technology has a place in home health for public health emergencies and beyond. Many commenters supported the amendment to § 409.43(a), allowing the use of telecommunications technology to be included as part of the home health plan of care during both the COVID-19 PHE, as well as beyond this time period, under the Medicare home health benefit. Commenters also supported amending the language at § 409.46(e) allowing a broader use of telecommunications technology to be reported as allowable administrative

Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf.

costs on the home health cost report. Specifically, a commenter stated that in rural areas, “telehealth services help to increase access to home health services that patients may otherwise forego due to challenges they face accessing care.” This commenter stated that home health delivery through telecommunications technologies may help alleviate some of these access challenges and will provide greater flexibility for both patients and home health providers. Another commenter noted that these changes would ensure patient access to the latest technology and give home health agencies the confidence that they can continue to use telecommunications technology as part of patient care beyond the COVID-19 PHE. This commenter noted that allowing services via telecommunications technology is especially useful for certain vulnerable subsets of Medicare patients, such as cancer patients who may be immunocompromised, by helping to reduce unnecessary exposure to all illnesses, not just COVID-19. A few commenters noted that the decision to provide services via telecommunications technology should be based on the individual's needs as identified during the comprehensive assessment, making the proposal to incorporate these services into the plan of care essential. This may be especially important for individuals with dementia whose services may be more appropriately delivered solely through in-person care.

Response: We thank commenters for their support.

Comment: A few commenters noted that, while helpful for many home health patients, especially those with chronic conditions, CMS should put safeguards in place to ensure that in-person visits are not being replaced by telecommunications technology and that in-person visits remain at adequate levels. They reiterated the importance of ensuring patient choice for those patients that are appropriate candidates for remote patient monitoring or other services furnished via telecommunications technology. Additionally, a commenter noted that the policy changes might provide incentive for patient selection, causing agencies to favor patients who benefit from these services and avoid those who do not benefit. These commenters suggested that CMS monitor and analyze the effects of these policy changes on beneficiary care and program costs prior to extending them beyond the COVID-19 PHE. A commenter stated that monitoring might be difficult because there is no requirement for HHAs to report on

claims or patient assessments when an episode includes the provision of services via telecommunications technology. This commenter also stated that a new category of broadly defined services could also reduce the accuracy of home health agency cost reports, potentially resulting in erroneous reporting and distorting the financial information that CMS uses to set and analyze payment weights, and suggested that CMS indicate how, in the absence of patient-level reporting, the agency plans to assess the impact of “other services provided via telecommunications” and ensure access to and quality of care while maintaining program integrity.

Response: We appreciate the commenters’ concerns regarding how these changes will affect the delivery of home health care beyond the period of the COVID-19 PHE. We agree with the importance of ensuring that any services furnished via telecommunications technology and/or remote patient monitoring do not replace in-person visits as ordered on the plan of care as this is prohibited by statute. However, we believe that the use of telecommunications technology in furnishing services in the home has the potential to improve efficiencies, expand the reach of healthcare providers, allow more specialized care in the home, and allow HHAs to see more patients or to communicate with patients more often. We expect physicians and allowed practitioners to only order services to be furnished via telecommunications technology, including remote patient monitoring, when it is in the best interest of each individual patient and after it has been determined that the patient would benefit from services furnished in this manner, as in-person care in the patient’s home is the hallmark of the home health benefit. We proposed that the use of the technology must be related to the skilled services being furnished in order to optimize the services furnished during the home visit and included on the plan of care, along with a description of how the use of such technology is tied to the patient-specific needs as identified in the comprehensive assessment and how it will help to achieve the goals outlined on the plan of care. Implementing this as a condition for payment is a patient safeguard to ensure that HHAs are carefully evaluating not only whether a patient is an appropriate candidate for services furnished via telecommunications technology, but also that once implemented into the patient’s care, it is benefitting the

patient. We plan to monitor and analyze the cost report data and, as with all allowable administrative costs, we expect HHAs to be diligent and accurate in their reporting of these costs. We will also consider potential options regarding collecting data on the use of telecommunications technology on home health claims in order to expand monitoring efforts and evaluation.

Comment: Several commenters expressed concern about the proposed plan of care requirement, stating that without some flexibility in this requirement, HHAs may be at risk for unreasonable claim denials. Commenters suggested that CMS should permit documentation throughout the medical record to be used to support the use of telecommunications technology, and limit the plan of care requirement to the physician’s order that permits the HHA to use the telecommunications technology.

Response: In accordance with the home health CoPs at § 484.60 the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This includes the types of services, supplies, and equipment required to meet these needs. Requiring that services furnished through telecommunications technology be incorporated into the plan of care, rather than simply requiring a physician’s or allowed practitioner’s order, acknowledges that each plan of care is unique to the individual. It is not our intent to simply promote the use of telecommunications technology without ensuring that furnishing the service in this way is beneficial to the individual patient.

We believe it is essential to ensure that each patient is evaluated during the comprehensive assessment and care planning process for appropriateness of the use of services furnished via telecommunications technology. The patient care plan would then identify and distinguish goals and expected outcomes, outline nursing observations and interventions needed for documentation, and include instructions the patient or caregiver may require. These tailored objectives are exceptionally important when furnishing services in a manner that may be new or unfamiliar to patients and family members and help to provide consistency among caregivers; however, we do understand that this

information may be documented more extensively throughout the medical record, along with more detail regarding how the patient is benefitting from the technology. We maintain that the provision of remote patient monitoring or other services furnished via a telecommunications system must be on the plan of care and such services must be tied to the patient-specific needs as identified in the comprehensive assessment; however, in response to comments from the public, we are not requiring as part of the plan of care, a description of how the use of such technology will help to achieve the goals outlined on the plan of care. Instead, we would expect information regarding how such services will help to achieve the goals outlined on the plan of care to be in the medical record documentation for the patient.

Comment: Several commenters stated that because these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, the new flexibilities will be of little benefit to HHAs and Medicare beneficiaries. These commenters requested that CMS work with Congress to amend Social Security Act section 1895(e)(1)(A) to allow payment for services furnished via a telecommunications system when those services substitute for in-person home health services ordered as part of a plan of care. Other commenters requested that Medicare reimburse the HHA for telehealth services that are included in the plan of care on the physician fee schedule or at the current low utilization payment adjustment rates per discipline of service, or explore ways to reimburse telehealth furnished by home health agencies in a way that supplements in-person visits, recognizing the statutory impediment. Commenters suggested that CMS develop a model for claims reporting and payment for home health visits provided by telecommunications systems. Additionally, a few commenters stated that CMS should permit telecommunication technologies to include audio only (telephonic) technology beyond the period of the COVID-19 PHE.

Response: By law, services furnished via a telecommunications system cannot be considered a home health visit for purposes of eligibility or payment; however, we disagree that this means these services will offer little benefit to HHAs and beneficiaries for the reasons discussed in previously in this section of this final rule. As stated previously, we believe utilizing telecommunications technology to furnish home health

services has the potential to improve efficiencies, expand the reach of healthcare providers, allow more specialized care in the home, and allow HHAs to see more patients or to communicate with patients more often. We will consider potential options for collecting data regarding the use of telecommunications technology on home health claims. We believe that using any available form of telecommunications technology or audio-only technology (*i.e.*, telephone calls), for certain home health services is imperative during the period of the COVID-19 PHE, and did not propose to restrict its usage beyond this timeframe. Therefore, we are clarifying in the regulations that audio-only technology may continue to be utilized to furnish skilled home health services (though audio-only telephone calls are not considered a visit for purposes of eligibility or payment and cannot replace in-person visits as ordered on the plan of care) after the expiration of the PHE. Like telecommunications technology, if audio-only services are ordered by the physician or allowed practitioner to furnish a skilled service, this must be included on the plan of care. The home health agency and patient's physician/practitioner must determine whether such audio-only technology can meet the patient's needs. Unlike telecommunications technology, audio-only technology (that is, telephones) is reported as a "general" expense and would not be reported on line 5 of the home health cost report as an allowed administrative expense for telecommunications technology.

Comment: A commenter recommended that CMS consider applying a PHE policy that was established for skilled nursing facilities to the Part A home health benefit, which would allow services provided on the premises, though not necessarily in the same room as the patient, to be considered in-person services.

Response: It is unclear how the skilled nursing facility policy finalized during the COVID-19 PHE would translate to the home health benefit beyond the PHE. It does not seem cost effective to furnish a home visit at the patient's house conducted via a telecommunications system, when the use of telecommunications technology cannot be considered a visit for purposes of payment or eligibility, as outlined in statute at section 1895(e) of the Act. However, we do appreciate the commenter exploring ways in which these services could be utilized to limit potential exposure to COVID-19.

Final Decision: We are finalizing the proposal to require that any provision of

remote patient monitoring or other services furnished via a telecommunications system or audio-only technology must be included on the plan of care and cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of eligibility or payment. We will still require that the use of such telecommunications technology or audio-only technology be tied to the patient-specific needs as identified in the comprehensive assessment, but we will not require as part of the plan of care, a description of how such technology will help to achieve the goals outlined on the plan of care. We expect to see documentation of how such services will be used to help achieve the goals outlined on the plan of care throughout the medical record when such technology is used. We are also finalizing the regulation text changes allowing a broader use of telecommunications technology to be considered allowable administrative costs on the home health cost report.

G. Care Planning for Medicare Home Health Services

Section 3708 of the CARES Act, amended section 1861(aa)(5) of the Act, allowing the Secretary regulatory discretion regarding the requirements for nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs). That is, NPs, CNSs, and PAs (as those terms are defined in section 1861(aa) of the Act), would be able to practice at the top of their state licensure to certify eligibility for home health services, as well as establish and periodically review the home health plan of care. In accordance with section 1861(aa)(5) of the Act, NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs such services. HHAs or other practitioners should check with the relevant state licensing authority websites to ensure that practitioners are working within their scope of practice and prescriptive authority.

As stated in the May 2020 COVID-19 IFC, we amended the regulations at parts 409, 424, and 484 to define an NP, a CNS, and a PA (as such qualifications are defined at §§ 410.74 through 410.76) as an "allowed practitioner" (85 FR 27572). This means that in addition to a physician, as defined at section 1861(r) of the Act, an "allowed practitioner" may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit.

Additionally, we amended the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed non-physician practitioner (NPP), as set forth in § 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. These regulation changes were not time limited to the period of the COVID-19 PHE.

We inadvertently did not update §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 in the regulations when implementing the requirements set forth in the CARES Act in the May 2020 COVID-19 IFC regarding the "allowed practitioners" who can certify and establish home health services. Therefore, in this final rule we are finalizing conforming regulation text changes at §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 regarding allowed practitioner certification as a condition for payment for home health services. Although these changes were not proposed in the CY 2021 HH PPS proposed rule, we are adopting the changes here under a "good cause" waiver of proposed rulemaking, as described in section VI of this final rule. The specific changes we are making in the regulations are simply conforming regulations text changes to an already implemented policy required by section 3708 of the CARES Act, and do not reflect any additional substantive changes. Therefore, we find that undertaking further notice and comment procedures to incorporate these changes into this final rule is unnecessary and contrary to the public interest. We received a few comments on the regulation changes finalized in the May 2020 COVID-19 IFC.

Comment: Commenters gave their overall support for PAs and advanced practice registered nurses (APRNs) to order, certify, and recertify home health services. A commenter requested that CMS review and modify the language and definition of PAs and APRNs for home health services, specifically suggesting that CMS defer to state rules that govern the practice of NPs and CNSs with respect to collaboration with the physician and remove references to "working in collaboration with the physician" in the NP and CNS definitions.

Response: We amended the regulations at parts 409, 424, and 484 to define an NP, a CNS, and a PA as such

qualifications are defined at §§ 410.74 through 410.76. These sections specify that the services performed by these entities are only covered if the entity performs the services in accordance with state law and state scope of practice rules for PAs, NPs, and CNSs in the state in which such practitioner's professional services are furnished. Section 1861(aa)(5) of the Act allows the Secretary regulatory discretion regarding the requirements for NPs, CNSs, and PAs, and as such, we believe that we should align, for Medicare home health purposes, the definitions for such practitioners with the existing definitions in regulation at §§ 410.74 through 410.76, for consistency across the Medicare program and to ensure that Medicare home health beneficiaries are afforded the same standard of care. Therefore, we are not revising the definitions at this time. As stated in the May 2020 COVID-19 IFC, HHAs or other practitioners should check with the relevant state licensing authority websites to ensure that practitioners are working within their scope of practice and prescriptive authority.

IV. Other Home Health Related Provisions

A. Home Health Quality Reporting Program (HH QRP)

1. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time,

specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the following:

- CY 2007 HH PPS final rule (71 FR 65888 through 65891).
- CY 2008 HH PPS final rule (72 FR 49861 through 49864).
- CY 2009 HH PPS update notice (73 FR 65356).
- CY 2010 HH PPS final rule (74 FR 58096 through 58098).
- CY 2011 HH PPS final rule (75 FR 70400 through 70407).
- CY 2012 HH PPS final rule (76 FR 68574).

- CY 2013 HH PPS final rule (77 FR 67092).
- CY 2014 HH PPS final rule (78 FR 72297).
- CY 2015 HH PPS final rule (79 FR 66073 through 66074).
- CY 2016 HH PPS final rule (80 FR 68690 through 68695).
- CY 2017 HH PPS final rule (81 FR 76752).
- CY 2018 HH PPS final rule (82 FR 51711 through 51712).
- CY 2019 HH PPS final rule with comment period (83 FR 56547).
- CY 2020 HH PPS final rule with comment period (84 FR 60554).

2. General Considerations Used for the Selection of Quality Measures for the HH QRP

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule with comment (83 FR 56548 through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

3. Quality Measures Currently Adopted for the CY 2022 HH QRP

The HH QRP currently includes 20 measures for the CY 2022 program year.⁸

⁸ The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

TABLE 12: MEASURES CURRENTLY ADOPTED FOR THE CY 2022 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (NQF #0526).
TOH - Provider	Transfer of Health Information to Provider-Post-Acute Care
TOH - Patient	Transfer of Health Information to Patient-Post-Acute Care
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (NQF #3477)
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
HHCAHPS-based	
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (NQF #0517) <ul style="list-style-type: none"> - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

There were no proposals or updates for the Home Health Quality Reporting Program (HH QRP). We received several comments on the HH QRP.

Comment: Several commenters provided feedback on the Home Health Quality Reporting Program. A commenter recommended that CMS expedite development of new measures to address pain management after the recent removal of the Improvement in Pain Interfering with Activity quality measure from the HH QRP. Another commenter suggested the need to develop measures to address

maintenance of functional status for patients who may not improve. A number of commenters expressed support for CMS's waivers related to quality reporting for quarters affected by the COVID-19 PHE. These commenters also suggested that CMS continue monitoring the effects of the public health epidemic on home health agencies' performance on all quality measures during the PHE. A commenter suggested adding new measures to the HH QRP to address advanced care planning and timely referral to hospice care. Another commenter noted support

for the continued inclusion of the Influenza Immunization Received for the Current Flu Season quality measure and suggested the addition of the new composite adult immunizations measure being tested by the National Committee on Quality Assurance.

Response: We appreciate these suggestions. These comments are outside the scope of the CY HH PPS 2021 proposed rule but we will consider them, as applicable, in future rulemaking.

We recognize the importance of pain management as part of home health. We

would like to note that in the CY 2020 Home Health PPS final rule with comment period (84 FR 60592 through 60594), CMS finalized the Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities) data elements as standardized patient assessment data elements. This will allow HHAs to continue to collect information on patient pain that could support care planning, quality improvement, and potential quality measurement, including risk adjustment. HHAs must begin collecting data on the Pain Interference (Pain Effect on Sleep, Pain Interference With Therapy Activities, and Pain Interference With Day-to-Day Activities) SPADE on January 1st of the year that is at least one full calendar year after the end of the COVID-19 PHE (85 FR 27595 through 27596). In addition, the HHS Roadmap⁹ emphasizes non-pharmacological options for managing pain as critical in the efforts to reduce over-reliance on and misuse of opioids.

We appreciate the suggestions and we will continue to monitor the performance of home health agencies on quality measures and will consider the issues raised by commenters in future measure development efforts.

B. Change to the Conditions of Participation (CoPs) OASIS Requirements

Section 484.45(c)(2) of the home health agency conditions of participation (CoPs) requires that new home health agencies must successfully transmit test data to the Quality Improvement & Evaluation System (QIES) or CMS OASIS contractor as part of the initial process for becoming a Medicare-participating home health agency. The previous data submission system limited HHAs to only two users who had permission to access the system, and required the use of a virtual private network (VPN) to access CMSNet. New HHAs do not yet have a CMS Certification Number (CCN). Therefore, they used a fake or test CCN in order to transmit test data to the Quality Improvement & Evaluation System Assessment Submission & Processing (QIES ASAP) System or CMS OASIS contractor.

CMS recently enhanced the system that HHAs use to submit OASIS data to be more user friendly. The new CMS data submission system, internet

Quality Improvement & Evaluation System (iQIES), is now internet-based. Therefore, HHAs are no longer limited to two users for submission of assessment data since VPN and CMSNet are no longer required. These factors make the data submission process simpler. In addition, the new iQIES data submission system requires users to include a valid CCN with their iQIES user role request that will allow them to submit their OASIS assessment data to CMS; the new data system no longer supports the use of test or fake CCNs, making it impossible for new HHAs that do not yet have a CCN to submit test data.

The transition to the new data submission system, the simpler data submission process and the inability to use test or fake CCNs has rendered the requirement at § 484.45(c)(2) obsolete. Therefore, we proposed to remove the requirement at § 484.45(c)(2). HHAs must be able to submit assessments in order for the claims match process to occur and relay the data needed for payment under the PDGM system. This link to the payment process gives HHAs strong incentive to ensure that they can successfully submit their OASIS assessments in the absence of this regulatory requirement.

We received two timely public comments on our proposed change to remove the OASIS requirement at § 484.45(c)(2). Commenters included an industry association and an accreditation organization. Overall, the commenters were supportive of the removal of the provisions related to test transmission of OASIS data by a new HHA, because the provision is now obsolete due to changes in our data submission system. Summaries of the comments received and our responses are as follows.

Comment: The commenters supported CMS's proposal to remove the provisions related to test transmission of OASIS data by a new HHA at § 484.45(c)(2). Commenters agreed that as a result of the implementation of the internet Quality Improvement & Evaluation System (iQIES), they support removing the requirement at § 484.45(c)(2) in accordance with improved online connectivity for reporting OASIS data.

Response: We appreciate the unanimous support in deleting the OASIS requirement at § 484.45(c)(2). Therefore, we are finalizing the removal of this requirement at § 484.45(c)(2) for HHAs to successfully transmit test data to the QIES ASAP System or CMS OASIS contractor.

C. Finalization of the Provisions of the May 2020 Interim Final Rule With Comment Period Relating to the Home Health Value-Based Purchasing Model (HHVBP)

1. Background

In the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** (May 2020 COVID-19 IFC) (85 FR 27553 through 27554), we implemented a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP as well as a policy for granting exceptions to the New Measures data reporting requirements during the COVID-19 PHE. The comment period for that rule closed on July 7, 2020. In this section, we summarize these provisions of the May 2020 COVID-19 IFC, summarize and respond to the comments we received, and finalize these policies.

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process. All Medicare certified HHAs providing services in Arizona, Florida, Iowa, Nebraska, North Carolina, Tennessee, Maryland, Massachusetts, and Washington are required to compete in the Model. The HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act based on the competing HHAs' performance on applicable measures. The maximum payment adjustment percentage increases incrementally over the course of the HHVBP Model in the following manner, upward or downward: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY), which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS), completed Home Health Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys, and select claims data elements; and (2) three New

⁹ CMS Roadmap, Strategy to Fight the Opioid Crisis. June 2020. <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf>.

Measures for which points are achieved for reporting data.

2. Reporting Under the HHVBP Model for CY 2020 During the COVID-19 PHE

In the May 2020 COVID-19 IFC, we established a policy to align the HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE. We also established a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for COVID-19. Specifically, during the COVID-19 PHE, to the extent that the data that participating HHAs in the nine HHVBP Model states are required to report are the same data that those HHAs are also required to report for the HH QRP, HHAs are required to report those data for the HHVBP Model in the same time, form and manner that HHAs are required to report those data for the HH QRP. As such, if CMS grants an exception or extension that either exempts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model. In addition, we adopted a policy to allow exceptions or extensions to New Measure reporting for HHAs participating in the HHVBP Model during the PHE for COVID-19.

In the May 2020 COVID-19 IFC, we explained that the HHVBP Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including HHCAPPS survey data. The other HHVBP measures are calculated using OASIS data, which are still required to be reported during the PHE; however, we have given providers additional time to submit OASIS data (<https://www.cms.gov/files/document/covid-home-health-agencies.pdf>); claims-based data extracted from Medicare fee-for-service (FFS) claims; and New Measure data. To assist HHAs while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff, we adopted a policy for the HHVBP Model to align the HHVBP data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE. For the same reason, we also established a policy for granting exceptions to New Measure reporting requirements for HHAs participating in the HHVBP Model during the COVID-19 PHE.

We explained that under this policy, to the extent CMS has granted an

exception to the HH QRP (for 2019 Q4 and 2020 Qs 1 and 2 as noted in the May 2020 COVID-19 IFC and below in this section), or may grant any future exceptions or extensions under this same program for other CY 2020 reporting periods, HHAs in the nine HHVBP Model states do not need to separately report these measures for purposes of the HHVBP Model, and those same exceptions apply to the submission of those same data for the HHVBP Model. In accordance with this policy, we stated that if CMS grants an exception or extension under the HH QRP that either exempts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model.

In response to the COVID-19 PHE, on March 27, 2020, we issued public guidance (<https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>) exempting HHAs from the requirement to report any HH QRP data for the following quarters:

- October 1, 2019–December 31, 2019 (Q4 2019).
- January 1, 2020–March 31, 2020 (Q1 2020).
- April 1, 2020–June 30, 2020 (Q2 2020).

Under our policy to align HHVBP data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE, HHAs in the nine HHVBP Model states are not required to separately report measure data for these quarters for purposes of the HHVBP Model. We noted that with regard to the exception from the requirement to report Q4 2019 HH QRP data, we do not anticipate any issues in calculating the TPSs based on CY 2019 data under the HHVBP Model because HHAs were able to submit these Q4 2019 data on a rolling basis prior to the COVID-19 PHE.

In addition, to ensure that HHAs are able to focus on patient care in lieu of data submission during the COVID-19 PHE, we established a policy to allow us to grant exceptions to New Measure reporting for HHAs participating in the HHVBP Model during the COVID-19 PHE. We also specified that we were codifying these changes at § 484.315(b). In accordance with this policy, we granted an exception to all HHAs participating in the HHVBP Model for the following New Measure reporting requirements:

- April 2020 New Measures submission period (data collection period October 1, 2019–March 31, 2020).

- July 2020 New Measures submission period (data collection period April 1, 2020–June 30, 2020).

We noted in the May 2020 COVID-19 IFC that although the data collection period for the April 2020 New Measures submission period began in 2019, the data collected during this period are used for the calculation of the TPSs based on CY 2020, not CY 2019, data. We further noted that HHAs may optionally submit part or all of these data by the applicable submission deadlines. We stated that if we make the determination to grant an exception to New Measure data reporting for periods beyond the April and July 2020 submission periods, for example if the PHE for COVID-19 extends beyond the New Measure submission periods we had listed in the IFC, we would communicate this decision through routine communication channels to the HHAs participating in the HHVBP Model, including but not limited to issuing memos, emails and posting on the HHVBP Connect site (<https://app.innovation.cms.gov/HHVBPConnect>).

We acknowledged that the exceptions to the HH QRP reporting requirements, as well as the modified submission deadlines for OASIS data and our exceptions for the New Measures reporting requirements, may impact the calculation of performance under the HHVBP Model for PY 2020. We also noted that while we are able to extract the claims-based data from submitted Medicare FFS claims, we may need to assess the appropriateness of using the claims data submitted for the period of the PHE for COVID-19 for purposes of performance calculations under the HHVBP Model. We further explained that we are evaluating possible changes to our payment methodologies for CY 2022 in light of this more limited data, such as whether we would be able to calculate payment adjustments for participating HHAs for CY 2022, including those that continue to report data during CY 2020, if the overall data is not sufficient, as well as whether we may consider a different weighting methodology given that we may have sufficient data for some measures and not others. Further, we are also evaluating possible changes to our public reporting of CY 2020 performance year data. We stated that we intend to address any such changes to our payment methodologies for CY 2022 or public reporting of data in future rulemaking.

The following is a summary of public comments received and our responses:

Comment: Several commenters supported the policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for COVID-19.

Response: We thank the commenters for their support.

Comment: Several commenters inquired about CMS's utilization of data from the last performance year of the Model (CY 2020). Commenters suggested that we examine how the PHE has affected operations and relative performance and how that might impact 2020 performance calculations for the HHVBP Model. Several commenters requested that we not use any performance data from CY 2020 and terminate or suspend the model early. Another commenter requested that we extend reporting exceptions for Quarters 3 and 4 of CY 2020, stating that this would continue to provide regulatory relief for quality reporting programs across Medicare Fee-for-Service payment systems.

Response: We thank the commenters for their comments. As we discussed in the May 2020 COVID-19 IFC, we acknowledge that the exceptions to the reporting requirements and modified submission deadlines may impact the calculation of performance under the HHVBP Model, and also that we may need to assess the appropriateness of using certain data submitted for the period of the PHE for purposes of performance calculations. CMS will continue to examine these issues as it reviews the data collected during CY 2020. We intend to address possible changes to our CY 2022 payment methodologies through rulemaking in the CY 2022 HH PPS proposed rule. With respect to the request to extend the reporting exceptions for additional quarters, we note that we did not grant any further exceptions under the HH QRP beyond Q2 of 2020 (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Spotlight-and-Announcements>). As previously described, our policy is to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for COVID-19. For this same reason, we also did not grant further exceptions to HHVBP Model New Measure data submission periods beyond the July 2020 submission period.

Final Decision: After consideration of the comments received, we are finalizing without modification the

policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE, as described in the May 2020 COVID-19 IFC. We are also finalizing without modification the policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the COVID-19 PHE, including the codification of these changes at § 484.315(b), as described in the May 2020 COVID-19 IFC.

V. Home Infusion Therapy

A. Medicare Coverage of Home Infusion Therapy Services

1. Background and Overview

(a) Background

Section 5012 of the 21st Century Cures Act ("the Cures Act") (Pub. L. 114-255), which amended sections 1834(u), 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education not otherwise covered under the durable medical equipment benefit, remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier. This benefit will ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries.

Section 50401 of the BBA of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. This temporary payment covers the cost of most of the same items and services, as defined in section 1861(iii)(2)(A) and (B) of the Act, related to the administration of home infusion drugs. The temporary transitional payment began on January 1, 2019 and will end the day before the full implementation of the home infusion therapy services benefit on January 1, 2021, as required by section 5012 of the 21st Century Cures Act.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized the implementation of temporary transitional payments for

home infusion therapy services to begin on January 1, 2019. In addition, we implemented the establishment of regulatory authority for the oversight of national accrediting organizations (AOs) that accredit home infusion therapy suppliers, and their CMS-approved home infusion therapy accreditation programs.

(b) Overview of Infusion Therapy

Infusion drugs can be administered in multiple health care settings, including inpatient hospitals, skilled nursing facilities (SNFs), hospital outpatient departments (HOPDs), physicians' offices, and in the home. Traditional fee-for-service (FFS) Medicare provides coverage for infusion drugs, equipment, supplies, and administration services. However, Medicare coverage requirements and payment vary for each of these settings. Infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, SNFs, HOPDs, and physicians' offices.

Under the various Part A prospective payment systems, Medicare payment for the drugs, equipment, supplies, and services are bundled, meaning a single payment is made based on expected costs for clinically-defined episodes of care. For example, if a beneficiary is receiving an infusion drug during an inpatient hospital stay, the Part A payment for the drug, supplies, equipment, and drug administration is included in the diagnosis-related group (DRG) payment to the hospital under the Medicare inpatient prospective payment system. Beneficiaries are liable for the Medicare inpatient hospital deductible and no coinsurance for the first 60 days. Similarly, if a beneficiary is receiving an infusion drug while in a SNF under a Part A stay, the payment for the drug, supplies, equipment, and drug administration are included in the SNF prospective payment system payment. After 20 days of SNF care, there is a daily beneficiary cost-sharing amount through day 100 when the beneficiary becomes responsible for all costs for each day after day 100 of the benefit period.

Under Medicare Part B, certain items and services are paid separately while other items and services may be packaged into a single payment together. For example, in an HOPD and in a physician's office, the drug is paid separately, generally at the average sales price (ASP) plus 6 percent (77 FR 68210). Medicare also makes a separate payment to the physician or hospital outpatient departments (HOPD) for administering the drug. The separate payment for infusion drug

administration in an HOPD and in a physician's office generally includes a base payment amount for the first hour and a payment add-on that is a different amount for each additional hour of administration. The beneficiary is responsible for the 20 percent coinsurance under Medicare Part B.

Medicare FFS covers outpatient infusion drugs under Part B, "incident to" a physician's service, provided the drugs are not usually self-administered by the patient. Drugs that are "not usually self-administered," are defined in our manual according to how the Medicare population as a whole uses the drug, not how an individual patient or physician may choose to use a particular drug. For the purpose of this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. The term "by the patient" means Medicare beneficiaries as a collective whole. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is generally excluded from Part B coverage. This determination is made on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.¹⁰ The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.¹¹

Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home. Certain drugs can be infused in the home, but the nature of the home setting presents different challenges than the settings previously described. Generally, the components needed to perform home infusion include the drug (for example, antivirals, immune globulin, equipment (for example, a pump), and supplies (for example, tubing and catheters). Likewise, nursing services are usually necessary to train and educate the patient and caregivers on the safe administration of infusion drugs in the home. Visiting nurses often play a large role in home infusion. These nurses typically train the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to assess the infusion site and provide dressing changes. Depending on patient acuity or the

complexity of the drug administration, certain infusions may require more training and education, especially those that require special handling or pre- or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.

With regard to payment under traditional Medicare, most home infusion drugs are generally covered under Part B or Part D. Certain infusion pumps, supplies (including home infusion drugs and the services required to furnish the drug, (that is, preparation and dispensing), and nursing are covered in some circumstances through the Part B durable medical equipment (DME) benefit, the Medicare home health benefit, or some combination of these benefits. In accordance with section 50401 of the BBA of 2018, beginning on January 1, 2019, for CYs 2019 and 2020, Medicare implemented temporary transitional payments for home infusion therapy services furnished in coordination with the furnishing of transitional home infusion drugs. This payment, for home infusion therapy services, is only made if a beneficiary is furnished certain drugs and biologicals administered through an item of covered DME, and payable only to suppliers enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies (including the drug). With regard to the coverage of the home infusion drugs, Medicare Part B covers a limited number of home infusion drugs through the DME benefit if: (1) the drug is necessary for the effective use of an external infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and (2) the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury.

Only certain types of infusion pumps are covered under the DME benefit. In order for the infusion pump to be covered under the DME benefit, it must be appropriate for use in the home (§ 414.202). The Medicare National Coverage Determinations Manual, chapter 1, part 4, section 280.14 describes the types of infusion pumps that are covered under the DME benefit.¹² For DME external infusion pumps, Medicare Part B covers the

infusion drugs and other supplies and services necessary for the effective use of the pump. Through the Local Coverage Determination (LCD) for External Infusion Pumps (L33794), the DME Medicare administrative contractors (MACs) specify the details of which infusion drugs are covered with these pumps. Examples of covered Part B DME infusion drugs include, among others, certain IV drugs for heart failure and pulmonary arterial hypertension, immune globulin for primary immune deficiency (PID), insulin, antifungals, antivirals, and chemotherapy, in limited circumstances.

(c) Home Infusion Therapy Legislation

(1). 21st Century Cures Act

Effective January 1, 2021, section 5012 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) created a separate Medicare Part B benefit category under section 1861(s)(2)(GG) of the Act for coverage of home infusion therapy services needed for the safe and effective administration of certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is an item of DME. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the Part B DME benefit. Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: The professional services, including nursing services, furnished in accordance with the plan, training and education (not otherwise paid for as DME), remote monitoring, and other monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Section 1861(iii)(3)(B) of the Act defines the patient's home to mean a place of residence used as the home of an individual as defined for purposes of section 1861(n) of the Act. As outlined in section 1861(iii)(1) of the Act, to be eligible to receive home infusion therapy services under the home infusion therapy services benefit, the patient must be under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant), and the patient must be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. The plan of care must be periodically reviewed by the physician in coordination with the

¹⁰ Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services", section 50.2—Determining Self-Administration of Drug or Biological. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

¹¹ Self-Administered Drug (SAD) Exclusion List Report. www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.

¹² National Coverage Determinations Manual. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.html>.

furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act). Section 1861(iii)(3)(C) of the Act defines a “home infusion drug” under the home infusion therapy services benefit as a drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the patient’s home, through a pump that is an item of DME as defined under section 1861(n) of the Act. This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list.

Section 1861(iii)(3)(D)(i) of the Act defines a “qualified home infusion therapy supplier” as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. The provision specifies that qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an organization designated by the Secretary; and meet other such requirements as the Secretary deems appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage (MA) plans under Part C and in the private sector. The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements.

Section 1834(u)(1) of the Act requires the Secretary to implement a payment system under which, beginning January 1, 2021, a single payment is made to a qualified home infusion therapy supplier for the items and services (professional services, including nursing services; training and education; remote monitoring, and other monitoring services). The single payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type. In addition, the single payment amount is required to be adjusted to reflect geographic wage index and other costs that may vary by region, patient acuity, and complexity of drug administration. The single payment may be adjusted to reflect outlier situations, and other factors as deemed appropriate by the Secretary, which are required to be done in a budget-neutral manner. Section 1834(u)(2) of the Act specifies certain items that “the Secretary may consider” in developing the home infusion

therapy payment system: “the costs of furnishing infusion therapy in the home, consult[ation] with home infusion therapy suppliers, . . . payment amounts for similar items and services under this part and Part A, and . . . payment amounts established by Medicare Advantage plans under Part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy)”. Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made, beginning January 1, 2022, by increasing the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Under section 1834(u)(1)(A)(iii) of the Act, the single payment amount for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician’s office. This statutory provision limits the single payment amount so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Section 1834(u)(4) of the Act also allows the Secretary discretion, as appropriate, to consider prior authorization requirements for home infusion therapy services. Finally, section 5012(c)(3) of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the HH PPS beginning on January 1, 2021.

(2). Bipartisan Budget Act of 2018

Section 50401 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs, beginning January 1, 2019. This payment covers the same items and services as defined in section 1861(iii)(2)(A) and (B) of the Act, furnished in coordination with the furnishing of transitional home infusion drugs. Section 1834(u)(7)(A)(iii) of the Act defines the term “transitional home infusion drug” using the same definition as “home infusion drug”

under section 1861(iii)(3)(C) of the Act, which is a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME as defined under section 1861(n) of the Act. The definition of “home infusion drug” excludes “a self-administered drug or biological on a self-administered drug exclusion list” but the definition of “transitional home infusion drug” notes that this exclusion shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of 1834(u)(7)(C) of the Act. Section 1834(u)(7)(C) of the Act sets out the Healthcare Common Procedure Coding System (HCPCS) codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794),¹³ as the drugs covered during the temporary transitional period. In addition, section 1834(u)(7)(C) of the Act states that the Secretary shall assign to an appropriate payment category drugs which are covered under the DME LCD for External Infusion Pumps (L33794)¹⁴ and billed under HCPCS codes J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified), or billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug.

Section 1834(u)(7)(E)(i) of the Act states that payment to an eligible home infusion supplier or qualified home infusion therapy supplier for an infusion drug administration calendar day in the individual’s home refers to payment only for the date on which professional services, as described in section 1861(iii)(2)(A) of the Act, were furnished to administer such drugs to such individual. This includes all such drugs administered to such individual on such day. Section 1842(u)(7)(F) of the Act defines “eligible home infusion supplier” as a supplier who is enrolled in Medicare as a pharmacy that provides external infusion pumps and external infusion pump supplies, and that maintains all pharmacy licensure requirements in the State in which the

¹³ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

¹⁴ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

applicable infusion drugs are administered.

As set out at section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories, as identified by their corresponding HCPCS codes, for which a single amount will be paid for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 includes subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals. The payment category for subsequent transitional home infusion drug additions to the DME LCD for External Infusion Pumps (L33794) and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the DME MACs.

In accordance with section 1834(u)(7)(D) of the Act, each payment category is paid at amounts in accordance with the Physician Fee Schedule (PFS) for each infusion drug administration calendar day in the individual's home for drugs assigned to such category, without geographic adjustment. Section 1834(u)(7)(E)(ii) of the Act requires that in the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category will be made.

(d) Summary of CY 2019 and CY 2020 Home Infusion Therapy Provisions

In the CY 2019 HH PPS final rule with comment period (83 FR 56579) we finalized the implementation of the home infusion therapy services temporary transitional payments under paragraph (7) of section 1834(u) of the Act, for CYs 2019 and 2020. These services are furnished in the individual's home to an individual who is under the care of an applicable provider (defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician's assistant) and where there is a plan of care established and periodically reviewed by a physician (defined at section 1861(r)(1) of the Act),

prescribing the type, amount, and duration of infusion therapy services. Only eligible home infusion suppliers can bill for the temporary transitional payments. Therefore, in accordance with section 1834(u)(7)(F) of the Act, we clarified that this meant that in addition to other DME suppliers, existing DME suppliers that were enrolled in Medicare as pharmacies that provided external infusion pumps and external infusion pump supplies, who complied with Medicare's DME Supplier and Quality Standards, and maintained all pharmacy licensure requirements in the State in which the applicable infusion drugs were administered, could be considered eligible home infusion suppliers for purpose of the temporary home infusion therapy benefit.

Section 1834(u)(7)(C) of the Act assigns transitional home infusion drugs, identified by the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794),¹⁵ into three payment categories, for which we established a single payment amount per category in accordance with section 1834(u)(7)(D) of the Act. This section states that each single payment amount per category will be paid at amounts equal to the amounts determined under the PFS established under section 1848 of the Act for services furnished during the year for codes and units of such codes, without geographic adjustment. Therefore, we created a new HCPCS G-code for each of the three payment categories and finalized the billing procedure for the temporary transitional payment for eligible home infusion suppliers. We stated that the eligible home infusion supplier would submit, in line-item detail on the claim, a G-code for each infusion drug administration calendar day. We stated that the claim should include the length of time, in 15-minute increments, for which professional services were furnished. The G-codes could be billed separately from, or on the same claim as, the DME, supplies, or infusion drug, and would be processed through the DME MACs. On August 10, 2018, we issued Change Request: R4112CP: Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020¹⁶ outlining the

¹⁵ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=83&Date=05%2f15%2f2019&DocID=L33794&bc=iAAAABAAAA&>

¹⁶ Temporary Transitional Payment for Home Infusion Therapy Services for CYs 2019 and 2020. August 10, 2018. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4112CP.pdf>

requirements for the claims processing changes needed to implement this payment.

And lastly, we finalized the definition of "infusion drug administration calendar day" in regulation as the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel (42 CFR 486.505). Section 1834(u)(7)(E)(i) of the Act clarifies that this definition is with respect to the furnishing of "transitional home infusion drugs" and "home infusion drugs" to an individual by an "eligible home infusion supplier" and a "qualified home infusion therapy supplier." The definition of "infusion drug administration calendar day" applies to both the temporary transitional payment in CYs 2019 and 2020 and the permanent home infusion therapy services benefit to be implemented beginning in CY 2021.

2. Summary of Home Infusion Therapy Services for CY 2021 and Subsequent Years

Upon completion of the temporary transitional payments for home infusion therapy services at the end of CY 2020, we will be implementing the permanent payment system for home infusion therapy services under section 5012 of the 21st Century Cures Act (Pub. L. 114-255) beginning January 1, 2021. In the CY 2020 HH PPS final rule with comment period, we finalized provisions regarding payment for home infusion therapy services for CY 2021 and subsequent years in order to allow adequate time for eligible home infusion therapy suppliers to make any necessary software and business process changes for implementation on January 1, 2021.

(a) Scope of Benefit and Conditions for Payment

Section 1861(iii) of the Act establishes certain provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers. These provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services, outlining beneficiary qualifications and plan of care requirements, and establishing who can bill for payment under the benefit.

(1). Home Infusion Drugs

In the CYs 2019 and 2020 HH PPS proposed rules (83 FR 32466 and 84 FR 34690) we discussed the relationship between the home infusion therapy services benefit and the DME benefit. We stated that, as there is no separate Medicare Part B DME payment for the professional services associated with the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps, we consider the home infusion therapy services benefit to be a separate payment in addition to the existing payment for the DME equipment, accessories, and supplies (including the home infusion drug) made under the DME benefit. We stated that, consistent with the definition of “home infusion therapy,” the home infusion therapy services payment explicitly and separately pays for the professional services related to the administration of the drugs identified on the DME LCD for External Infusion Pumps (L33794),¹⁷ when such services are furnished in the individual’s home. For purposes of the temporary transitional payments for home infusion therapy services in CYs 2019 and 2020, the term “transitional home infusion drug” includes the HCPCS codes for the drugs and biologicals covered under the DME LCD for External Infusion Pumps (L33794).¹⁸ We also noted that although section 1834(u)(7)(A)(iii) of the Act defines the term “transitional home infusion drug,” section 1834(u)(7)(A)(iii) of the Act does not specify the HCPCS codes for “home infusion drugs” for which home infusion therapy services would be covered beginning in CY 2021.

Section 1861(iii)(3)(C) of the Act defines “home infusion drug” as a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. This definition not only specifies that the drug or biological must be administered through a pump that is an item of DME, but references the statutory definition of DME at 1861(n) of

the Act. This means that “home infusion drugs” are drugs and biologicals administered through a pump that is covered under the Medicare Part B DME benefit. Therefore, in the CY 2020 HH PPS final rule with comment period (84 FR 60618), we stated that this means that “home infusion drugs” are defined as parenteral drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME covered under the Medicare Part B DME benefit, pursuant to the statutory definition set out at section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act.

(2). Patient Eligibility and Plan of Care Requirements

Subparagraphs (A) and (B) of section 1861(iii)(1) of the Act set forth beneficiary eligibility and plan of care requirements for “home infusion therapy.” In accordance with section 1861(iii)(1)(A) of the Act, the beneficiary must be under the care of an applicable provider, defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant. In accordance with section 1861(iii)(1)(B) of the Act, the beneficiary must also be under a plan of care, established by a physician (defined at section 1861(r)(1) of the Act), prescribing the type, amount, and duration of infusion therapy services that are to be furnished, and periodically reviewed, in coordination with the furnishing of home infusion drugs under Part B. Based on these statutory requirements, and in accordance with the standards at § 486.520, we finalized the home infusion therapy services conditions for payment at 42 CFR part 414, subpart P via the CY 2020 HH PPS final rule with comment period (84 FR 60618).

(3). Qualified Home Infusion Therapy Suppliers and Professional Services

Section 1861(iii)(3)(D)(i) of the Act defines a “qualified home infusion therapy supplier” as a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider of services or supplier furnishes items or services. The qualified home infusion therapy supplier must: Furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy

on a 7-day-a-week, 24-hour a-day basis; be accredited by an organization designated by the Secretary; and meet such other requirements as the Secretary determines appropriate.

Section 1861(iii)(2) of the Act defines home infusion therapy to include the following items and services: The professional services, including nursing services, furnished in accordance with the plan, training and education (not otherwise paid for as DME), remote monitoring, and other monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier, which are furnished in the individual’s home. Section 1861(iii)(2) of the Act does not define home infusion therapy services to include the pump, home infusion drug, or related services. Therefore, in the CY 2020 HH PPS final rule with comment period, we noted that the infusion pump, drug, and other supplies, and the services required to furnish these items (that is, the compounding and dispensing of the drug) remain covered under the DME benefit.

We stated in the CY 2020 HH PPS proposed rule that we did not specifically enumerate a list of “professional services” for which the qualified home infusion therapy supplier is responsible in order to avoid limiting services or the involvement of providers of services or suppliers that may be necessary in the care of an individual patient (84 FR 34692). However, we noted that, under section 1862(a)(1)(A) of the Act, no payment can be made for Medicare services under Part B that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, unless explicitly authorized by statutes. We stated that this means that the qualified home infusion therapy supplier is responsible for the reasonable and necessary services related to the administration of the home infusion drug in the individual’s home. These services may require some degree of care coordination or monitoring outside of an infusion drug administration calendar day. However, payment for these services is built into the bundled payment for an infusion drug administration calendar day.

Payment to a qualified home infusion therapy supplier is for an infusion drug administration calendar day in the individual’s home, which, in accordance with section 1834(u)(7)(E) of the Act, refers to payment only for the date on which professional services were furnished to administer such drugs

¹⁷ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

¹⁸ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

to such individual. Ultimately, the qualified home infusion therapy supplier is the entity responsible for furnishing the necessary services to administer the drug in the home and, as we noted in the CY 2019 HH PPS final rule with comment period (83 FR 56581), “administration” refers to the process by which the drug enters the patient’s body. Therefore, it is necessary for the qualified home infusion therapy supplier to be in the patient’s home, on occasions when the drug is being administered in order to provide an accurate assessment to the physician responsible for ordering the home infusion drug and services. The services provided would include patient evaluation and assessment; training and education of patients and their caretakers, assessment of vascular access sites and obtaining any necessary bloodwork; and evaluation of medication administration. However, visits made solely for the purposes of venipuncture on days where there is no administration of the infusion drug would not be separately paid because the single payment includes all services for administration of the drug. Payment for an infusion drug administration calendar day is a bundled payment, which reflects not only the visit itself, but any necessary follow-up work (which could include visits for venipuncture), or care coordination provided by the qualified home infusion therapy supplier. Any care coordination, or visits made for venipuncture, provided by the qualified home infusion therapy supplier that occurs outside of an infusion drug administration calendar day would be included in the payment for the visit (83 FR 56581).

Additionally, section 1861(iii)(1)(B) of the Act requires that the patient be under a plan of care established and periodically reviewed by a physician, in coordination with the furnishing of home infusion drugs. The physician is responsible for ordering the reasonable and necessary services for the safe and effective administration of the home infusion drug, as indicated in the patient plan of care. In accordance with this section, the physician is responsible for coordinating the patient’s care in consultation with the DME supplier furnishing the infusion pump and the home infusion drug. We recognize that collaboration between the ordering physician and the DME supplier furnishing the home infusion drug is imperative in providing safe and effective home infusion. Payment for physician services, including any home infusion care coordination services, are

separately paid to the physician under the PFS and are not covered under the home infusion therapy services benefit. However, payment under the home infusion therapy services benefit to eligible home infusion therapy suppliers is for the professional services that inform collaboration between physicians and home infusion therapy suppliers. Care coordination between the physician and DME supplier, although likely to include review of the services indicated in the home infusion therapy supplier plan of care, is paid separately from the payment under the home infusion therapy services benefit.

As discussed in the CY 2020 HH PPS proposed rule, the DME quality standards require the supplier to review the patient’s record and consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s) (84 FR 34692). Follow-up services to the beneficiary and/or caregiver(s), must be consistent with the type(s) of equipment, item(s) and service(s) provided, and include recommendations from the prescribing physician or healthcare team member(s).¹⁹ Additionally, DME suppliers are required to communicate directly with patients regarding their medications.

In summary, the qualified home infusion therapy supplier is responsible for the reasonable and necessary services related to the administration of the home infusion drug in the individual’s home. These services may require some degree of care coordination or monitoring outside of an infusion drug administration calendar day; payment for these services is built into the bundled payment for an infusion drug administration calendar day. Furthermore, as we noted in the CY 2019 HH PPS proposed rule, we consider the home infusion benefit principally to be a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the home infusion therapy services (83 FR 32466). Therefore, the professional services covered under the DME benefit are not covered under the home infusion benefit. While the two benefits exist in tandem, the services are unique to each benefit and billed and paid for under

separate payment systems. While we did not make any proposals regarding policies finalized in the CY 2020 HH PPS final rule with comment period as they relate to the implementation of the permanent home infusion therapy services in CY 2021, we did receive comments making suggestions to change certain aspects of the finalized policies. As we did not make any proposals in the CY 2021 proposed rule, we view these comments outside of the scope of this rule. However, we will keep these comments in mind for future rulemaking.

(4). Home Infusion Therapy and Interaction With the Home Health Benefit

Because a qualified home infusion therapy supplier is not required to become accredited as a Part B DME supplier or to furnish the home infusion drug, and because payment is determined by the provision of services furnished in the patient’s home, we acknowledged in the CY 2019 HH PPS proposed rule the potential for overlap between the new home infusion therapy services benefit and the home health benefit (83 FR 32469). We stated that a beneficiary is not required to be considered homebound in order to be eligible for the home infusion therapy services benefit; however, there may be instances where a beneficiary under a home health plan of care also requires home infusion therapy services. Additionally, because section 5012 of the 21st Century Cures Act amends section 1861(m) of the Act to exclude home infusion therapy from home health services effective on January 1, 2021; we stated that a beneficiary may utilize both benefits concurrently.

Furthermore, because both the home health agency and the qualified home infusion therapy supplier furnish services in the individual’s home, and may potentially be the same entity, the best process for payment for furnishing home infusion therapy services to beneficiaries who qualify for both benefits is as outlined in the CY 2019 HH PPS proposed rule (83 FR 32469). If a patient receiving home infusion therapy is also under a home health plan of care, and receives a visit that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the home health claim. When the home health agency furnishing home health services is also the qualified home infusion therapy supplier furnishing home infusion therapy services, and a home visit is exclusively for the purpose of furnishing items and services related to

¹⁹ Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf>.

the administration of the home infusion drug, the home health agency would submit a home infusion therapy services claim under the home infusion therapy services benefit. If the home visit includes the provision of other home health services in addition to, and separate from, home infusion therapy services, the home health agency would submit both a home health claim under the HH PPS and a home infusion therapy services claim under the home infusion therapy services benefit. However, the agency must separate the time spent furnishing services covered under the HH PPS from the time spent furnishing services covered under the home infusion therapy services benefit. DME is excluded from the consolidated billing requirements governing the HH PPS (42 CFR 484.205) and therefore, the DME items and services (including the home infusion drug and related services) will continue to be paid for outside of the HH PPS. If the qualified home infusion therapy supplier is not the same entity as the home health agency furnishing the home health services, the home health agency would continue to bill under the HH PPS on the home health claim, and the qualified home infusion therapy supplier would bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

The summarized comments and responses related to the separation of home infusion therapy services benefit from the HH PPS are found in section V.A.5 .

(b) Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy Services

Section 1834(u)(6) of the Act requires that prior to the furnishing of home infusion therapy services to an individual, the physician who establishes the plan described in section 1861(iii)(1) of the Act for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

We recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy options. We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716) and the CY 2020 HH PPS proposed rule (84 FR 34694), regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment

options available to his/her patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invited comments on any additional interpretations of this notification requirement. We summarized the comments received in the CY 2020 PFS final rule (84 FR 62568) and the CY 2020 HH PPS final rule with comment period (84 FR 60478), and we stated we would take these comments into consideration as we continue developing future policy through notice-and-comment rulemaking.

Many commenters stated that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning CY 2021, physicians are to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. We did not propose to create a mandatory form nor did we otherwise propose to require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, we stated that if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we might consider additional requirements regarding this notification in future rulemaking.

Comment: One commenter supported the current practice of physicians discussing all infusion therapy options with their patients, especially in regard to understanding the costs.

Response: We appreciate the commenter's support of maintaining this current practice.

Final Decision: At this time, we will not create a mandatory form nor require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we may consider additional requirements regarding this notification in future rulemaking.

3. Payment Categories and Payment Amounts for Home Infusion Therapy Services for CY 2021

Section 1834(u)(1) of the Act provides the authority for the development of a payment system for Medicare-covered home infusion therapy services. In accordance with section 1834(u)(1)(A)(i) of the Act, the Secretary is required to implement a payment system under which a single payment is made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment under this payment system is for each infusion drug administration calendar day in the individual's home, and requires the Secretary, as appropriate, to establish single payment amounts for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the PFS (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting. Furthermore, such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. This permanent payment system would become effective for home infusion therapy items and services furnished on or after January 1, 2021.

In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment for each infusion drug administration calendar day in the individual's home must be established for types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Furthermore, section 1834(u)(1)(B)(ii) of the Act requires that the payment amount reflect factors such as patient acuity and complexity of drug administration. We believe that the best way to establish a single payment amount that varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, is to group home infusion drugs by J-code into payment categories reflecting similar therapy types. Therefore, each payment category would reflect variations in infusion drug administration services.

Section 1834(u)(7)(C) of the Act established three payment categories, with the associated J-code for each transitional home infusion drug (see

Table 13), for the home infusion therapy services temporary transitional payment. Payment category 1 comprises certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including, but not limited to, antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 comprises subcutaneous infusions for therapy or prophylaxis, including, but not limited to, certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(a) CY 2021 Payment Categories for Home Infusion Therapy Services

In the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized our proposal to maintain the three payment categories utilized under the temporary transitional payments for home infusion therapy services. Maintaining the three current payment categories, with the associated J-codes as set out at section 1834(u)(7)(C) of the Act, utilizes an already established framework for assigning a unit of single payment (per category), accounting for different therapy types, as required by section 1834(u)(1)(A)(ii) of the Act. The payment amount for each of these three categories is different, though each category has its associated single payment amount. The single payment amount (per category) would thereby reflect variations in nursing utilization, complexity of drug administration, and patient acuity, as determined by the different categories based on therapy type. Retaining the three current payment categories maintains consistency with the already established payment methodology and ensures a smooth transition between the temporary transitional payments and the permanent payment system to be implemented beginning in 2021.

Table 13 provides the list of J-codes associated with the infusion drugs that fall within each of the payment categories. There are some drugs that are

paid for under the transitional benefit but would not be defined as a home infusion drug under the permanent benefit beginning with 2021. Section 1861(iii)(3)(C) of the Act defines a home infusion drug as a parenteral drug or biological administered intravenously or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. Such term does not include the following: (1) Insulin pump systems; and (2) a self-administered drug or biological on a self-administered drug exclusion list. Hizentra®, a subcutaneous immunoglobulin, is not included in this definition of “home infusion drug” because it is listed on a self-administered drug (SAD) exclusion list by the MACs. This drug was included as a transitional home infusion drug since the definition of such drug in section 1834(u)(7)(A)(iii) of the Act does not exclude self-administered drugs or biologicals on a SAD exclusion list under the temporary transitional payment. Therefore, although home infusion therapy services related to the administration of Hizentra® are covered under the temporary transitional payment, because it is currently on a SAD exclusion list, services related to the administration of this biological are not covered under the benefit in 2021; however, if it is removed from all the SAD lists, it could be added to the home infusion drugs list in the future. Similarly, in accordance with the definition of “home infusion drug” as a parenteral drug or biological administered intravenously or subcutaneously, home infusion therapy services related to the administration of ziconotide and floxuridine are also excluded, as these drugs are given via intrathecal and intra-arterial routes respectively and therefore do not meet the definition of “home infusion drug”. Likewise, home infusion therapy services related to the intrathecal administration of morphine, identified by HCPCS code J2274, is excluded because intrathecal administration does not meet the definition of a “home

infusion drug” under the permanent benefit.

It is important to note that the list of home infusion drugs is maintained by the DME MACs and the drugs or their respective payment categories do not need to be updated through rulemaking every time a new drug is added to the DME LCD for External Infusion Pumps (L33794).²⁰ We acknowledge, however, that two immune-globulins, Xembify® and Cutaquig®, have been added to the DME LCD for External Infusion Pumps (L33794).²¹ Consistent with the definition of “home infusion drug”, the home infusion therapy services will be covered under payment category 2 for these two subcutaneously infused drugs. Xembify® is identified by HCPCS code J1558 and Cutaquig® is currently identified by the not otherwise classified (NOC) code J7799 until it is assigned a unique HCPCS code.

The payment category may be determined by the DME MAC for any subsequent home infusion drug additions to the DME LCD for External Infusion Pumps (L33794)²² as identified by the following NOC codes: J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified). Payment category 1 would include any appropriate subsequent intravenous infusion drug additions, payment category 2 would include any appropriate subsequent subcutaneous infusion drug additions, and payment category 3 would include any appropriate subsequent intravenous chemotherapy or other highly complex drug or biologic infusion additions.

²⁰ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

²¹ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

²² Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

TABLE 13: INFUSION DRUG J-CODES ASSOCIATED WITH HOME INFUSION THERAPY SERVICE PAYMENT CATEGORIES FOR CY 2021

J-Code	Drug
Category 1	
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J1555 JB*	Injection, immune globulin (cuvitru), 100 mg
J1558 JB*	Injection, immune globulin (xembify), 100 mg
J1561 JB*	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB*	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB*	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB*	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

*The JB modifier indicates that the route of administration is subcutaneous.

Comment: We received comments expressing concerns regarding home infusions of the cytotoxic chemotherapy drugs that are on the list of home infusion drugs, especially if they are mishandled or administered incorrectly. Commenters noted that certain safety standards that exist for outpatient clinics may be difficult to satisfy when infusing such drugs in the home environment and thus infusing such drugs at home could potentially put patients and health care personnel at increased risk of dangerous adverse

effects such as genotoxicity, teratogenicity, acute anaphylactic reactions, carcinogenicity, and reproductive risks for patients and the potential for mishandling of the drugs by health care personnel among others. We also received comments with requests for the current list of transitional home infusion drugs to be grandfathered into the list of home infusion drugs for the permanent benefit in effort to continue payment for services related to certain drugs, such as Hizentra® and ziconotide, which do not

meet the definition of “home infusion drugs” according to section 1861(iii)(3)(C) of the Act. Other comments suggested adding certain antibiotics and central nervous system agents to the list of home infusion drugs, especially in consideration for beneficiaries whose previous commercial insurance may have covered home infusion services related to such drugs. Many commenters specifically suggested including two subcutaneously infused immune-globulins, Xembify® and Cutaquig®, on

the list of home infusion drugs. Another commenter suggested revising the requirement that home infusion drugs must be identified by the DME LCD for External Infusion Pumps (L33794)²³ in an effort to expand the list of home infusion drugs more quickly than via the existing LCD reconsideration process.

Response: We appreciate the commenters' interests and concerns regarding the drugs associated with the permanent home infusion therapy services benefit, however, the home infusion therapy services benefit does not cover drugs, as they are covered under the durable medical equipment benefit. Rather, the home infusion therapy services benefit covers the professional services associated with drugs that meet the definition of home infusion drugs and are identified in the DME LCD for External Infusion Pumps (L33794).²⁴ We discussed the LCD Development Process in the CY 2020 HH PPS final rule in order to provide transparency to stakeholders on the criteria and process used to determine which items are included on the LCD for External Infusion Pumps (84 FR 60619). Any requests regarding additions to the DME LCD for External Infusion Pumps must be made to the DME MACs. Finally, as previously

discussed, Xembify® and Cutaquig® were recently added to the DME LCD for External Infusion Pumps (L33794)²⁵ and meet the definition of a home infusion drug with coverage of home infusion therapy services under payment category 2.

Final Decision: We did not propose any changes, therefore we are maintaining the current definition of "home infusion drugs" as finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60618), pursuant to the statutory definition set out at section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act.

(b) CY 2021 Payment Amounts for Home Infusion Therapy Services

Section 1834(u)(1)(A)(ii) of the Act requires that the payment amount take into account variation in utilization of nursing services by therapy type. Additionally, section 1834(u)(1)(A)(iii) of the Act provides a limitation that the single payment shall not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular

therapy in a calendar day. Finally, section 1834(u)(1)(B)(ii) of the Act requires the payment amount to reflect patient acuity and complexity of drug administration.

Currently, as set out at section 1834(u)(7)(D) of the Act, each temporary transitional payment category is paid at amounts in accordance with six infusion CPT codes and units of such codes under the PFS. These payment category amounts are set equal to 4 hours of infusion therapy administration services in a physician's office for each infusion drug administration calendar day, regardless of the length of the visit. In the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized that the payment amounts per category, for an infusion drug administration calendar day under the permanent benefit, be in accordance with the six PFS infusion CPT codes and units for such codes, as described in section 1834(u)(7)(D) of the Act. However, we set the amount equivalent to 5 hours of infusion in a physician's office, rather than 4 hours. Each payment category amount would be in accordance with the six infusion CPT codes identified in section 1834(u)(7)(D) of the Act and as shown in Table 14.

**TABLE 14: PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES
PAYMENT FOR CY 2021**

CPT CODE	DESCRIPTION	UNITS
CATEGORY 1		
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
CATEGORY 2		
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- each additional hour	4
CATEGORY 3		
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- up to one hour	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- each additional hour	4

We also finalized the proposal to increase the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy

supplier in the patient's home by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year, resulting in a small decrease to the

payment amounts for the second and subsequent visits, using a budget neutrality factor. Effective January 1, 2021 there are changes to the office/outpatient E/M visit code set (CPT codes

²³ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

²⁴ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

²⁵ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

99201 through 99215) used to calculate the initial and subsequent visit payment amounts for home infusion. These changes were adopted from the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA’s CPT Editorial Panel (see <https://www.ama-assn.org/practice-management/cpt/cptevaluation-and-management>) and include the deletion of code 99201 (Level 1 office/outpatient visit, new patient), and new values for

CPT codes 99202 through 99215. The initial visit percentage increase will still be calculated using the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year; however, now only new patient E/M codes 99202 through 99205 will be used in the calculation. Using the proposed CY 2021 PFS rates, we estimate a 19 percent increase in the first visit payment amount and a 1.18 percent decrease in subsequent visit amounts. Table 15

shows the updated E/M visit codes and proposed PFS payment amounts for CY 2021, for both new and existing patients, used to determine the increased payment amount for the first visit. The final CY 2021 PFS amounts for E/M visits were not available at the time of publication for this final rule; however, we will post the final home infusion therapy services payment amounts on the PFS rate setting update.

TABLE 15: AVERAGE DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS*

New Patient E/M Code	PFS Amount	Existing Patient E/M Code	PFS Amount	Percent Difference
		99211	\$22.26	NA
99202	\$69.04	99212	\$54.20	27%
99203	\$106.14	99213	\$86.78	22%
99204	\$159.37	99214	\$122.91	30%
99205	\$210.66	99215	\$172.27	22%
Total	\$545.21		\$458.42	19%

Note: Rates are calculated using proposed CY 2021 PFS rates.
 *This represents the average difference between the physician E/M payment amounts for new versus established patients: (the sum of the initial rates – the sum of the existing rates) / (the sum of the existing rates) = 19 percent.

Table 16 shows the 5-hour payment amounts (using proposed CY 2021 PFS rates) reflecting the increased payment for the first visit and the decreased payment for all subsequent visits. The payment amounts for this final rule are estimated using the proposed CY 2021

rates because the final CY 2021 PFS rates are not available at the time of this rule making. The final home infusion 5-hour payment amounts will be released on the Physician Fee Schedule when the final CY 2021 PFS rates are posted. We plan on monitoring home infusion

therapy service lengths of visits, both initial and subsequent, in order to evaluate whether the data substantiates this increase or whether we should re-evaluate whether, or how much, to increase the initial visit payment amount.

TABLE 16: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FOR FIRST AND SUBSEQUENT VISITS

CPT Code	Description	Proposed 2021 PFS Amount	5-hour Payment - First Visit	5-hour Payment - Subsequent Visits
96365	Ther, Proph, Diag IV/IN infusion 1 hr	\$72.26	\$188.85 (category 1)	\$156.83 (category 1)
96366	Ther, Proph, Diag IV/IN infusion add hr	\$21.61		
96369	Sub Q Ther Inf 1 hr	\$156.46	\$256.83 (category 2)	\$213.27 (category 2)
96370	Sub Q Ther Inf add hr	\$14.84		
96413	Chemo Inf 1 hr	\$146.14	\$319.80 (category 3)	\$265.57 (category 3)
96415	Chemo Inf add hr	\$30.65		

Note: Rates are calculated using proposed CY 2021 PFS rates.

We did not propose any new policies related to the HIT services payment system, and did not receive any specific comments on the payment amounts posted in the proposed rule.

Final Decision: The payment policies for the permanent home infusion therapy services benefit were finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60478). We will

maintain the three payment categories currently being utilized under the temporary transitional payments for home infusion therapy services and each category payment amount will be

in accordance with the six CPT infusion codes under the PFS and equal to 5 hours of infusion services in a physician's office. We will increase the payment amounts for each of the three payment categories for the first visit by the relative payment for a new patient rate over an existing patient rate using the Medicare physician evaluation and management (E/M) payment amounts for a given year, in a budget neutral manner, resulting in a small decrease to the payment amounts for any subsequent visits. Payment will be made for each infusion drug administration calendar day in accordance with the definition finalized in the CY 2019 final rule with comment period (83 FR 56583).

4. Payment Adjustments for CY 2021 Home Infusion Therapy Services

(a) Home Infusion Therapy Geographic Wage Index Adjustment

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. In the 2020 HH PPS final rule with comment period (84 FR 60478, 60629) we finalized the use of the Geographic Adjustment Factor (GAF) to adjust home infusion therapy payments based on differences in geographic wages. The GAF is a weighted composite of each PFS locality's work, practice expense (PE), and malpractice (MP) Geographic Price Cost Index (GPCIs) and represents the combined impact of the three GPCI components. The GAF is calculated by multiplying the work, PE, and MP GPCIs by the corresponding national cost share weight: work (50.886 percent), PE (44.839 percent), and MP (4.295 percent).²⁶ The GAF is not specific to any of the home infusion drug categories, so the GAF payment rate would equal the unadjusted rate multiplied by the GAF for each locality level, without a labor share adjustment. As such, based on locality, the GAF adjusted payment rate would be calculated using the following formula:

$$Rate_i^{GAF} = GAF * UnadjRate_i$$

The appropriate GAF value is applied to the home infusion therapy single payment amount based on the site of service of the beneficiary and the adjustment will happen on the PFS based on the beneficiary zip code submitted on the 837P/CMS-1500 professional and supplier claims form.

²⁶ $GAF = (0.50886 \times \text{Work GPCI}) + (0.44839 \times \text{PE GPCI}) + (0.04295 \times \text{MP GPCI})$.

We finalized that the application of the GAF will be budget neutral so there is no overall cost impact. However, this will result in some adjusted payments being higher than the average and others being lower. In order to make the application of the GAF budget neutral we will apply a budget-neutrality factor. If the rates were set using the proposed CY 2021 PFS rates the budget neutrality factor would be 0.9951. The GAF conversion factor equals the ratio of the estimated unadjusted national spending total to the estimated GAF-adjusted national spending total. Estimates of national spending totals are derived from a function of "beneficiary counts," "weeks of care," and "estimated visits of care" by home infusion therapy drug payment category, which were compiled from CY 2019 utilization data. We define home infusion therapy beneficiaries as Medicare beneficiaries with at least one home infusion therapy drug prescription fill in CY 2019, and weeks of care for each home infusion therapy beneficiary equal the number of weeks between (and including) the first prescription fill in CY 2019 and the last prescription fill in CY2019. Weeks of care are then transformed into "estimated visits of care," where we assumed 2 visits for the initial week of care, with 1 visit per week for all subsequent weeks for categories 1 and 3, and we assumed 1 visit per month, or 12 visits per year, for category 2.

The list of GAFs by locality for this final rule is available as a downloadable file at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html>.

(b) Consumer Price Index

Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections we would increase the single payment amount by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). Accordingly, this may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

We did not propose any new policies related to the payment adjustments for HIT services, and did not receive any specific comments on the use of the GAF or the CPI-U.

Final Decision: As finalized in the CY 2020 HH PPS final rule (84 FR 60630), we will use the GAF to geographically adjust the home infusion therapy payment amounts in CY 2021 and subsequent calendar years. And beginning in CY 2022, we will annually update the single payment amount from the prior year for each home infusion therapy payment category by the percent increase in the Consumer Price Index for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) as required by section 1834(u)(3) of the Act.

5. Home Infusion Therapy Services Excluded From the Medicare Home Health Benefit

In the CY 2021 proposed rule (85 FR 39440) we discussed the services covered under the home infusion therapy services benefit as defined under section 1861(iii) of the Act. This section defines "home infusion therapy" as the items and services described in paragraph (2), furnished by a qualified home infusion therapy supplier which are furnished in the individual's home. In accordance with § 486.525, the required items and services covered under the home infusion therapy services benefit are as follows:

- Professional services, including nursing services, furnished in accordance with the plan.
- Training and education (not otherwise paid for as DME).
- Remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified home infusion therapy supplier.

We also noted that the CY 2019 HH PPS proposed rule described the professional and nursing services, as well as the training, education, and monitoring services included in the payment to a qualified home infusion therapy supplier for the provision of home infusion drugs (83 FR 32467). Additionally, while we did not outline an exhaustive list of services that are covered under the home infusion therapy services benefit, we did outline the scope of services covered under the home infusion therapy services benefit in sub-regulatory guidance.²⁷ This

²⁷ MLN Matters: SE19029: Medicare Part B Home Infusion Therapy Services With the Use of Durable Medical Equipment. December 13, 2019. <https://www.cms.gov/files/document/se19029.pdf>. And Temporary Transitional Payment FAQs. February 27, 2019. <https://www.cms.gov/Medicare/Medicare->

guidance states that the home infusion therapy services benefit is intended to be a separate payment explicitly covering the professional services, training and education (not covered under the DME benefit), and monitoring and remote monitoring services for the provision of home infusion drugs. We state that these services may include, for example the following:

- Training and education on care and maintenance of vascular access devices—

- ++ Hygiene Education;
- ++ Instruction on what to do in the event of a dislodgement or occlusion;
- ++ Education on signs and symptoms of infection; and
- ++ Teaching and training on flushing and locking the catheter.

- Dressing changes and site care.
- Patient assessment and evaluation—

- ++ Review history and assess current physical and mental status, including obtaining vital signs;

- ++ Assess any adverse effects or infusion complications;

- ++ Evaluate family and caregiver support ;

- ++ Review prescribed treatment and any concurrent oral and/or over-the-counter treatments; and

- ++ Obtain blood for laboratory work
- Medication and disease management education—

- ++ Instruction on self-monitoring;

- ++ Education on lifestyle and nutritional modifications;

- ++ Education regarding drug mechanism of action, side effects, interactions with other medications, adverse and infusion-related reactions;

- ++ Education regarding therapy goals and progress;

- ++ Instruction on administering pre-medications and inspection of medication prior to use;

- ++ Education regarding household and contact precautions and/or spills;

- Remote monitoring services.

- Monitoring services—

- ++ Communicate with patient regarding changes in condition and treatment plan;

- ++ Monitor patient response to therapy; and

- ++ Assess compliance.

We stated that this list is not intended to be prescriptive or all-inclusive, as the physician is responsible for ordering the reasonable and necessary services for the safe and effective administration of the home infusion drug.

In the CY 2021 proposed rule, we also recognized that section 5012 of the 21st

Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, effective January 1, 2021 (85 FR 39441). We clarified that while patients needing home infusion therapy are not required to be eligible for the home health benefit, they are not prohibited from utilizing both the home infusion therapy and home health benefits concurrently, and that it is likely that many home health agencies will become accredited and enroll as qualified home infusion therapy suppliers. Therefore, because a home health agency may furnish services for a patient receiving both home health services and home infusion therapy services, we stated that it is necessary to exclude in regulation the scope of professional services, training and education, as well as monitoring and remote monitoring services, for the provision of home infusion drugs, as defined at § 486.505, from the services covered under the home health benefit. We also noted that the home infusion therapy services distinct from those which are required and furnished under the home health benefit, are only for the provision of home infusion drugs. Therefore, when a home health agency is furnishing services to a patient receiving an infusion drug not defined as a home infusion drug at § 486.505, those services may still be covered as home health services.

In accordance with the conforming amendment in section 5012(c)(3) of the 21st Century Cures Act, which amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, we proposed to amend § 409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. We stated that any services that are covered under the home infusion therapy services benefit as outlined at § 486.525, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit.

Additionally, we clarified that excluded home infusion therapy services only pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit, and paid under the home health prospective payment system.

Additionally, in the proposed rule we reiterated the billing process as outlined in the CY 2019 HH PPS proposed rule

(83 FR 32469). We stated that if a patient is under a home health plan of care, and a home health visit is furnished that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the same home health claim. If the HHA providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified home infusion therapy supplier, and a home visit is exclusively for the purpose of furnishing home infusion therapy services, the HHA would submit a claim for payment as a home infusion therapy supplier and receive payment under the home infusion therapy services benefit. If the home visit includes the provision of home health services in addition to, and separate from, items and services related to home infusion therapy, the HHA would submit both a home health claim and a home infusion therapy services claim, and must separate the time spent performing services covered under the HH PPS from the time spent performing services covered under the home infusion therapy services benefit.

Collectively, commenters expressed disagreement with the proposal to amend § 409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. The following is our response.

Comment: Commenters suggested that CMS should use its authority to not enforce the prohibition for HHAs to provide the professional services associated with Part B infusion drugs under the home health benefit. Some commenters expressed concern that beneficiaries would receive fragmented care from multiple visits from various entities and would be required to pay a twenty percent coinsurance for the home infusion therapy services benefit when utilizing both concurrently, whereas they did not have a coinsurance previously under the home health benefit. One commenter expressed concern with the number of eligible entities that intend to enroll as home infusion therapy suppliers and whether there will be sufficient suppliers enrolled, particularly in rural areas. The commenter stated that there may be many HHAs that do not enroll as qualified home infusion therapy suppliers, and who plan to subcontract with a home infusion therapy supplier, but the availability of these suppliers is unknown; potentially creating a situation where there may be difficulties in finding qualified home infusion therapy suppliers. This commenter suggested that some HHAs would then

be forced to provide unreimbursed care to patients receiving home infusion drugs.

Response: Section 5012 of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy services from the definition of home health services, effective January 1, 2021, therefore, we are statutorily precluded from making payment for home infusion therapy services to entities other than “qualified home infusion therapy suppliers” for services needed to administer “home infusion drugs.” As described in section V.B of the proposed rule (85 FR 39442), the overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws. This process helps to prevent unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Therefore, an HHA must be accredited and enrolled in Medicare as a qualified home infusion therapy supplier in order to furnish and bill for home infusion therapy services under the home infusion therapy services benefit, which is statutorily required to be implemented by January 1, 2021. If an HHA does not become accredited and enrolled as a qualified home infusion therapy supplier and is treating a patient receiving a home infusion drug, the HHA must contract with a qualified home infusion therapy supplier to furnish the services related to the home infusion drug.

As we noted in the CY 2020 HH PPS final rule (84 FR 60624), it is already the responsibility of the HHA to arrange for the DME and related infusion services for patients under a home health plan of care. In accordance with the Medicare HH CoPs at 42 CFR 484.60, the home health agency must assure communication with all physicians involved in the plan of care, as well as integrate all orders and services provided by all physicians and other healthcare disciplines, such as nursing, rehabilitative, and social services. If the HHA also becomes accredited and enrolls in Medicare as a qualified home infusion therapy supplier, the HHA can either continue to furnish the services or contract with a qualified home infusion therapy supplier to meet these requirements. It is also important to note that the HHA can still provide all infusion services to patients under the home health benefit as home health services, for any drugs not considered home infusion drugs.

Final Decision: In accordance with the conforming amendment in section 5012(c)(3) of the 21st Century Cures Act, which amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, we are finalizing as proposed our amendment to § 409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. Any services that are covered under the home infusion therapy services benefit as outlined at § 486.525, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Excluded home infusion therapy services only pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit, and paid under the home health prospective payment system.

B. Enrollment Requirements for Qualified Home Infusion Therapy Suppliers

As previously alluded to, regulatory provisions pertaining to home infusion therapy have been established in various parts of Title 42 of the CFR, such as in part 414, subpart P and in part 486, subpart I. Sections 486.520 and 486.525 outline standards for home infusion therapy while § 486.505 defines “qualified home infusion therapy supplier.” This latter term means a supplier of home infusion therapy that meets all of the following criteria, which are set forth at section 1861(iii)(3)(D)(i) of the Act:

- Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.
- Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.
- Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.
- Meets such other requirements as the Secretary determines appropriate.

Concerning this final criterion (which reflects section 1861(iii)(3)(D)(i)(IV) of the Act), one of CMS’ principal oversight roles is to protect the Medicare program from fraud, waste, and abuse. This is accomplished in part through the careful screening and monitoring of prospective and existing

providers and suppliers. In our view, section 1861(iii)(3)(D)(i)(IV) of the Act permits the Secretary to take steps in this direction with respect to home infusion therapy suppliers.

1. Background—Provider and Supplier Enrollment Process

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all federal and state requirements to do so. The process is, to an extent, a “gatekeeper” that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare.

Since 2006, we have taken various steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereinafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. One such requirement (outlined in § 424.510) is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System) collects important information about the provider or supplier; such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider’s or supplier’s initial enrollment application, reviewing and confirming the information thereon, and determining whether the provider or supplier meets all applicable Medicare requirements, CMS or the MAC will either: (1) Approve the application and grant billing privileges to the provider or supplier (or, depending upon the provider or supplier type involved, simply recommend approval of the application and refer it to the state agency or to the CMS regional office, as applicable); or (2) deny enrollment under § 424.530.

We believe the Medicare provider and supplier enrollment screening process has greatly assisted CMS in executing its responsibility to prevent Medicare waste and abuse. As emphasized in the June 30, 2020 proposed rule, we believe the safeguards that Medicare enrollment furnishes are equally needed with respect to home infusion therapy suppliers.

2. Legal Bases for Home Infusion Therapy Supplier Enrollment

There are several legal bases for our proposed home infusion therapy supplier enrollment requirements. First, section 5012 of the Cures Act, which amended sections 1834(u), 1861(s)(2), and 1861(iii) of the Act, established a new Medicare home infusion therapy benefit. Second, section 1861(iii)(3)(D)(i)(IV) of the Act permits the Secretary to establish requirements for qualified home infusion therapy suppliers that the Secretary determines appropriate. In doing so, the Secretary shall take into account the standards of care for home infusion therapy established by Medicare Advantage plans under Part C and in the private sector. (However, we interpret this latter provision to apply strictly to the establishment of standards of care as opposed to the creation of enrollment requirements for home infusion therapy suppliers.) Third, section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Fourth, sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

3. Proposed Provisions

This section of this final rule outlines the proposed enrollment requirements for suppliers of home infusion therapy.

a. Definition

We proposed to establish a new § 424.68 that would encapsulate the preponderance of our home infusion therapy supplier enrollment provisions. In paragraph (a) thereof, we proposed to define “home infusion therapy supplier” (for purposes of § 424.68) as a supplier of home infusion therapy that meets all of the following requirements:

++ Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

++ Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

++ Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

++ Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of § 424.68 and part 424, subpart P.

b. General Enrollment and Payment Requirement

In paragraph (b), we proposed that for a supplier to receive Medicare payment for the provision of home infusion therapy supplier services, the supplier must: (1) Qualify as a home infusion therapy supplier (as defined in § 424.68); and (2) be in compliance with all applicable provisions of § 424.68 and part 424, subpart P. (Proposed paragraph (b) would achieve consistency with § 424.505, which states that all providers and suppliers seeking to bill Medicare must enroll in Medicare and adhere to all of subpart P’s enrollment requirements.)

c. Specific Requirements for Home Infusion Therapy Supplier Enrollment

(1) Submission of Form CMS–855 and Certification

In § 424.68(c)(1)(i), we proposed that a home infusion therapy supplier must complete in full and submit the Form CMS–855B application (“Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers”) (OMB Control No.: 0938–0685), or its electronic or successor application, to its applicable Medicare contractor. The Form CMS–855B is typically completed by suppliers other than individual physicians and practitioners. We thus believed that the Form CMS–855B was the most suitable enrollment application for home infusion therapy suppliers.

In § 424.68(c)(1)(ii), we proposed that the home infusion therapy supplier must certify via the Form CMS–855B that it meets and will continue to meet the specific requirements and standards for enrollment described in § 424.68 and part 424, subpart P. This was to help ensure that the home infusion therapy supplier fully understands its obligation to maintain constant compliance with the requirements associated with enrollment.

(2) Payment of Application Fee

Under § 424.514, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the applicable application fee. (For CY 2020, the fee amount is \$595.) In § 424.502, we define an institutional provider as any provider or supplier that submits a paper Medicare

enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and non-physician practitioner organizations, which are exempt from the fee requirement if they are enrolling as a physician or non-physician practitioner organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application. Since a home infusion therapy supplier would need to complete the Form CMS–855B to enroll in Medicare as such (and would not be enrolling as a physician/non-physician organization), we believed that a home infusion therapy supplier would meet the definition of an institutional provider at § 424.502. Therefore, we proposed in § 424.68(c)(2) that a home infusion therapy supplier would be subject to the application fee requirements of § 424.514.

(3) Accreditation

Consistent with section 1861(iii)(3)(D)(i)(III) of the Act (codified in § 486.505), we proposed in new § 424.68(c)(3) that a home infusion therapy supplier must be currently and validly accredited as such by a CMS-recognized home infusion therapy supplier accreditation organization in order to enroll and remain enrolled in Medicare.

(4) Home Infusion Therapy Supplier Standards

Certain provisions in part 486, subpart I, and in part 414, subpart P, outline important quality standards and conditions of payment applicable to home infusion therapy suppliers. To help tie these requirements to the home infusion therapy supplier enrollment process, we proposed the following:

- In new § 424.68(c)(4), we proposed that in order to enroll and maintain enrollment as a home infusion therapy supplier, the latter must be compliant with § 414.1515 and all provisions of 42 CFR part 486, subpart I.

- In § 414.1505, we proposed to add a new paragraph (c) stating that, along with the requirements for home infusion therapy payment in paragraphs § 414.1505(a) and (b), the home infusion therapy supplier must also be enrolled in Medicare consistent with the provisions of § 424.68 and part 424, subpart P.

(5) Categorical Risk Designation

Section 424.518 addresses enrollment application screening categories based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular type of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type

poses, the greater the level of scrutiny with which CMS screens and reviews providers or suppliers within that category.

There are three categories of screening in § 424.518: limited, moderate, and high. Irrespective of which category a provider or supplier type falls within, the MAC performs the following screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location:

- Verifies that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
- Conducts state license verifications.
- Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels, however, must also undergo a site visit. Furthermore, for those in the high categorical risk level, the MAC performs a fingerprint-based criminal history record check of all individuals with a 5 percent or greater direct or indirect ownership interest in the provider or supplier.

As explained in the June 30, 2020 proposed rule, we have no recent evidence to suggest that home infusion therapy suppliers (as a supplier type) pose an enhanced threat of fraud, waste, or abuse that would warrant their placement in the moderate or high screening level. We thus proposed to include home infusion therapy suppliers within the limited screening category. Our specific regulatory revisions in this regard were: (1) Re-designating existing § 424.518(a)(1)(vii) through (xvi) as, respectively, § 424.518(a)(1)(viii) through (xvii); (2) including home infusion therapy suppliers in revised § 424.518(a)(vii); and (3) stating in new § 424.68(c)(5) that home infusion therapy suppliers must successfully complete the limited categorical risk level of screening under § 424.518.

d. Denial of Enrollment and Appeals Thereof

In new § 424.68(d)(1)(i) and (ii), respectively, we proposed that CMS may deny a home infusion therapy supplier's enrollment application on either of the following grounds:

- The home infusion therapy supplier does not meet all of the requirements for enrollment outlined in § 424.68 and in part 424, subpart P of this chapter; or

- Any of the reasons for denial of a prospective provider's or supplier's enrollment application in § 424.530 applies.

In new § 424.68(d)(2), we proposed that a home infusion therapy supplier may appeal the denial of its enrollment application under 42 CFR part 498.

e. Continued Compliance, Standards, and Reasons for Revocation

For reasons identical to those behind § 424.68(c), we proposed several provisions in new § 424.68(e).

In paragraph (e)(1), we proposed that, upon and after enrollment, a home infusion therapy supplier—

- Must remain currently and validly accredited as described in § 424.68(c)(3); and

• Remains subject to, and must remain in full compliance with, all of the provisions of—

- ++ Section 424.68;
- ++ Part 424, subpart P;
- ++ Section 414.1515; and
- ++ Part 486, subpart I.

In paragraph (e)(2), we proposed that CMS may revoke a home infusion therapy supplier's enrollment if—

- The supplier does not meet the accreditation requirements as described in § 424.68(c)(3);
- The supplier does not comply with all of the provisions of—
 - ++ Section 424.68;
 - ++ Part 424, subpart P;
 - ++ Section 414.1515; and
 - ++ Part 486, subpart I; or
- Any of the revocation reasons in § 424.535 applies.

In new paragraph (e)(3), we proposed that a home infusion therapy supplier may appeal the revocation of its enrollment under part 498.

f. Effective and Retrospective Date of Home Infusion Therapy Supplier Billing Privileges

Section 424.520 outlines the effective date of billing privileges for certain provider and supplier types that are eligible to enroll in Medicare. Section 424.520(d) sets forth the applicable effective date for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, and opioid treatment programs. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that physicians, non-physician practitioners, physician and non-physician practitioner organizations,

ambulance suppliers, and opioid treatment programs may retrospectively bill for services when the supplier has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to—

- Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

To clarify the effective date of billing privileges for home infusion therapy suppliers and to account for circumstances that could prevent a home infusion therapy supplier's enrollment prior to the furnishing of Medicare services, we proposed to include newly enrolling home infusion therapy suppliers within the scope of both §§ 424.520(d) and 424.521(a). We believed that the effective and retrospective billing dates addressed therein achieve a proper balance between the need for the prompt provision of home infusion therapy services and the importance of ensuring that each prospective home infusion therapy enrollee is carefully and closely screened for compliance with all applicable requirements.

4. Comments Received and Responses

We received 12 comments from stakeholders regarding our proposed home infusion therapy supplier enrollment requirements. Summaries of these comments and our responses thereto are as follows:

Comment: Several commenters expressed concern that CMS will not accept Medicare enrollment applications from home infusion therapy suppliers until after this final rule is issued. They stated that this will give these suppliers only 2 months to complete the enrollment process before the home infusion therapy supplier benefit commences on January 1, 2021, thus delaying the provision of these services to beneficiaries.

Response: We recognize the limited timeframe between the issuance of this rule and January 1, 2021. However, we cannot accept applications from a new Medicare supplier type before any final regulatory provisions pertaining thereto have been made public. To permit suppliers to submit applications based on proposed regulatory provisions could lead to confusion for stakeholders,

especially if the final rule's provisions ultimately differ from those that we proposed. Nevertheless, and as with all incoming provider and supplier enrollment applications, Form CMS-855B submissions from home infusion therapy suppliers will be processed as expeditiously as feasible. We also note that our previously mentioned proposals to revise §§ 424.520(d) and 424.521(a) would permit home infusion therapy suppliers to back bill for certain services furnished prior to the date on which the MAC approved the supplier's enrollment application.

Comment: Several commenters stated that a number of home health agencies and hospices do not intend to enroll as Part B home infusion therapy suppliers. The commenters believed this could result in an insufficient number of such suppliers, especially in rural areas.

Response: We acknowledge the possibility that some entities that might otherwise qualify as home infusion therapy suppliers will elect not to pursue enrollment as such. This is the entity's independent choice. However, based on feedback received from the home infusion therapy community, we are confident that an adequate number of suppliers will enroll in Medicare, therefore helping to ensure beneficiary access to these services.

Comment: A commenter supported our establishment of measures designed to prevent fraudulent and unqualified home infusion therapy suppliers from entering Medicare. However, the commenter urged CMS to ensure that the measures are reasonable and equitable.

Response: We appreciate the commenter's support. We emphasize that our proposed enrollment requirements (for example, including home infusion therapy suppliers within the limited risk screening category rather than the moderate or high risk category) were carefully tailored to balance the need to protect the Trust Funds and beneficiaries from unqualified suppliers with the importance of limiting supplier burden to the extent possible.

Comment: A commenter agreed with CMS' proposal to place home infusion therapy suppliers in the limited risk screening category under § 424.518.

Response: We appreciate the commenter's support.

Comment: Several commenters asked CMS to clarify the specific supplier type that the enrolling home infusion therapy supplier should indicate on the Form CMS-855B.

Response: Until the Form CMS-855B is revised to include a specific supplier type category for home infusion therapy

suppliers, such suppliers should, in the appropriate section of the current Form CMS-855B: (1) Indicate a supplier type of "Other"; and (2) list "home infusion therapy supplier" in the space next thereto.

Comment: A number of commenters requested that CMS outline the enrollment and licensure requirements for home infusion therapy suppliers that—(1) operate in multiple jurisdictions; and/or (2) perform certain services through subcontractors. Regarding the first issue, several commenters contended that home infusion therapy suppliers should not be required to enroll in each MAC jurisdiction in which it performs services; besides being overly burdensome, they believed this would require the supplier to have a physical presence in each such jurisdiction (and perhaps even in each state that the MAC covers). These commenters requested that home infusion therapy suppliers be permitted to bill all MACs from a single location: (1) Without having to maintain fixed sites in every applicable MAC jurisdiction or state; and (2) with a single National Provider Identifier (NPI).

Response: It has long been general provider enrollment policy that Medicare providers and suppliers must be enrolled in each MAC jurisdiction (and, as applicable, licensed or certified in each state) in which it performs services, even if the provider or supplier does not have a physical practice location in that MAC and/or state. To illustrate, suppose a supplier has a single practice location in State X. The supplier sends its personnel out from this site to perform services in States X, Y, and Z; each of these states falls within a different MAC jurisdiction. The supplier must separately enroll with all three MACs if it wishes to receive Medicare payments for services provided in States X, Y, and Z. The purpose of this policy is to ensure that the applicable MAC can: (1) Verify the provider's or supplier's compliance with the state's requirements; and (2) make accurate payments. For this important reason, we believe home infusion therapy suppliers should be subject to this requirement as well.

Concerning the maintenance of fixed practice locations in each MAC jurisdiction in which services are performed, we recognize that home infusion therapy suppliers will often operate out of only one central location, with services occasionally furnished in homes located in various MAC jurisdictions and/or states. We will issue subregulatory guidance to address this issue for home infusion therapy suppliers in more detail.

As for the specific NPI situation the commenters raised, we refer the latter to the 2004 NPI Final Rule (<https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand/downloads/NPIfinalrule.pdf>), the NPI regulations at 45 CFR part 162, subpart D, and the "Medicare Expectations Subpart Paper" (the text of which is in CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 15, section 15.3, at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf>.) In short, and based solely on the very general circumstances the commenters presented, the home infusion therapy supplier would not be required to obtain a separate NPI for each enrollment application it submits to each Part A/B MAC. Nonetheless, the facts of each case may differ, and we strongly encourage the commenters to review the aforementioned NPI Final Rule, NPI regulations, and Medicare Expectations Subpart Paper for more detailed guidance on how divergent scenarios should be handled.

As for home infusion therapy suppliers that subcontract the provision of certain services to another party, the enrolled supplier is ultimately responsible for ensuring that it meets and operates in compliance with all Medicare requirements, enrollment or otherwise.

Comment: A commenter expressed support for our proposal in § 424.68(b)(3) that a home infusion therapy supplier must be accredited in order to enroll in Medicare.

Response: We appreciate the commenter's support.

Comment: Several commenters stated that some pharmacies are enrolled in Medicare as suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) via the Form CMS-855S (OMB Control No. 0938-1056) in order to furnish external infusion pump items. (The National Supplier Clearinghouse (NSC) is the Medicare contractor that processes Form CMS-855S applications. Durable Medicare Equipment Medicare Administrative Contractors (DME MACs) process DMEPOS claims.) The commenters requested that such pharmacies also enrolling via the Form CMS-855B as home infusion therapy suppliers be able to use their existing NPI (that is, the same NPI utilized for their DMEPOS enrollment) when doing so. A commenter further requested that pharmacies enrolled as DMEPOS suppliers be permitted to have a single enrollment as a qualified home infusion therapy supplier; the commenter

believed this would enable pharmacies to submit all claims for items (for example, drugs and durable medical equipment) and services to the Part A/B MAC alone rather than to the DME MAC and the Part A/B MAC.

Response: Similar to our response to a previous NPI-related comment, we encourage these commenters to review the NPI Final Rule, NPI regulations, and Medicare Expectations Subpart Paper for guidance concerning the acquisition and use of NPIs. We do note (and subject to the provisions of the NPI Final Rule, NPI regulations, and the Medicare Expectations Subpart Paper) that there is no express prohibition against using the same NPI for enrollment with the NSC as a DMEPOS supplier and enrollment with the Part A/B MAC as another provider or supplier type (such as a home infusion therapy supplier). On the other hand, this does not mean that such dually-enrolled providers and suppliers can use a single Form CMS–855 to encompass both their NSC enrollment and their Part A/B MAC enrollment. The Forms CMS–855S and CMS–855B are separate applications specifically tailored to capture certain information unique to the different provider and supplier types they pertain to; as an illustration, allowing an entity to enroll as a DMEPOS supplier via the Form CMS–855B (as opposed to the DMEPOS-specific Form CMS–855S) would deprive the NSC of important data needed to verify the entity's compliance with all DMEPOS enrollment standards and requirements. Accordingly, we must respectfully decline the commenter's request for joint enrollment with the NSC and the Part A/B MAC via a single application.

5. Final Provisions

After reviewing the comments received, we are finalizing our provisions pertaining to home infusion therapy supplier enrollment as proposed.

VI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment before the provisions of a rule take effect in accordance with section 4 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule (5 U.S.C.

553(b)(B)). We amended §§ 409.64(a)(2)(ii), 410.170(b), and 484.110 to include a provision requiring “allowed practitioners” to certify and establish home health services as a condition for payment under the home health benefit. These changes are simply additional regulation text changes that were inadvertently left out of the final regulations text changes in the first IFC (85 FR 27550) and do not reflect any substantive changes in policy. Additionally, this regulatory change was subject to notice and comment rulemaking following the issuance of the first IFC. Therefore, we find that undertaking further notice and comment procedures to incorporate these corrections into the CY 2021 final rule is unnecessary and contrary to the public interest, as these regulation text changes are required by section 3708 of the CARES Act.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. The Use of Telecommunications Technology Under the Medicare Home Health Benefit

As discussed in III.F. of this final rule, we finalized the proposal to require that any provision of remote patient monitoring or other services furnished via a telecommunications system must be included on the plan of care and cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for

the purposes of eligibility or payment. We will still require the use of such telecommunications technology to be tied to the patient-specific needs as identified in the comprehensive assessment, but we will not require a description of how such technology will help to achieve the goals outlined on the plan of care. We also stated that we expect to see documentation of how such services will be used to help achieve the goals outlined on the plan of care throughout the medical record when such technology is used. The expectation to see such documentation in the medical record does not create any additional burden for HHAs given that information describing how home health services help achieve established goals is traditionally documented in the clinical record. Likewise, documenting in the clinical record is a usual and customary practice as described in the supporting statement for the Paperwork Reduction Act Submission, Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies, OMB Control No. 0938–1299.

B. Enrollment

This section discusses our proposed burden estimates for the enrollment of home infusion therapy suppliers as well as the PRA exemption we are claiming for the appeals process. As discussed in section V.B.3 of this final rule, home infusion therapy suppliers would be required to enroll in Medicare via the paper or internet-based version of the Form CMS–855B (“Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers”) (OMB Control Number: 0938–0685), or its electronic or successor application, and pay an application fee in accordance with § 424.514.

Using existing accreditation statistics and our internal data, we generally estimated that approximately: (1) 600 home infusion therapy suppliers would be eligible for Medicare enrollment under our provisions, all of whom would enroll in the initial year thereof; and (2) 50 home infusion therapy suppliers would annually enroll in Year 2 and in Year 3. This results in a total of 700 home infusion therapy suppliers enrolling over the next 3 years.

According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019 (see http://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wages for the following categories are:

TABLE 17: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Healthcare Diagnosing or Treating Practitioners	29-1000	49.26	49.26	98.52
Medical Secretaries and Administrative Assistants	43-6013	18.31	18.31	36.62

Consistent with Form CMS–855B projections made in recent rulemaking efforts, it would take each home infusion therapy supplier an average of 2.5 hours to obtain and furnish the information on the Form CMS–855B. Per our experience, the home infusion therapy supplier's medical secretary would secure and report this data, a task that would take approximately 2 hours. Additionally, a health diagnosing and treating practitioner of the home infusion therapy supplier would review and sign the form, a process we estimate takes 30 minutes. Therefore, we projected a first-year burden of 1,500 hours (600 suppliers × 2.5 hrs) at a cost of \$73,500 (600 suppliers × ((2 hrs × \$36.62/hr) + (0.5 hrs × \$98.52/hr)), a second-year burden of 125 hours (50 suppliers × 2.5 hrs) at a cost of \$6,125 (50 suppliers × ((2 hrs × \$36.62/hr) + (0.5 hrs × \$98.52/hr)), and a third-year burden of 125 hours (50 suppliers × 2.5 hrs) at a cost of \$6,125 (50 suppliers × ((2 hrs × \$36.62/hr) + (0.5 hrs × \$98.52/hr)). In aggregate, we estimated a burden of 1,750 hours (1,500 hrs + 125 hrs + 125 hrs) at a cost of \$85,750. When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 583 hours (1,750 hrs/3) at a cost of \$28,583 (\$85,750/3).

We received no public comments on the foregoing burden estimates and are therefore finalizing them as proposed.

C. Appeals

As mentioned previously in this final rule, proposed § 424.68(d)(2) and (e)(3) state that a home infusion therapy supplier may appeal, respectively, the denial or revocation of its enrollment application under 42 CFR part 498. While there are information collection requirements associated with the appeals process, we believe they are exempt from the PRA. In accordance with the implementing regulations of the PRA at 5 CFR 1320.4(a)(2), the information collection requirements associated with the appeals process are subsequent to an administrative action (specifically, the denial or revocation of a home infusion therapy supplier enrollment application). Therefore, we have not developed burden estimates. We also noted our belief that any costs associated with home infusion therapy

supplier appeals would, in any event, be *de minimis*; this is because we would anticipate, based on past experience, there would be comparatively few denials and revocations of home infusion therapy supplier enrollments.

We received no public comments on burden estimates related to the appeals provisions and are therefore finalizing them as proposed.

D. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit the CMS website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at (410) 786–1326.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the applicable home health percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i)

and (b)(4)(A)(ii) of the Act requires the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115–123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of service, for 30-day periods beginning on and after January 1, 2020. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments. In this final rule, we are adopting the new OMB delineations and applying a 5-percent cap only in CY 2021 on any decrease in a geographic

area's wage index value from the wage index value from the prior calendar year. This transition allows the effects of our adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)).

B. Overall Impact

We have 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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 801(a)(1)(B)(i)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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. Given that, we note the following costs associated with the provisions of this final rule:

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100

million or more in any 1 year). The net transfer impact related to the changes in payments under the HH PPS for CY 2021 is estimated to be \$390 million (1.9 percent). Therefore, we estimate that this rule is “economically significant” as measured by the \$100 million threshold, and hence a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that presents our best estimate of the costs and benefits of this rule.

C. Anticipated Effects

1. HH PPS

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 hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs and home infusion therapy suppliers are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this final rule would not result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS final rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of 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. This rule is not applicable to hospitals. Therefore,

the Secretary has determined that this final rule will not have a significant economic impact on the operations of small rural hospitals.

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 2020, that threshold is approximately \$156 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of \$156 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments.

2. HH QRP

We did not propose any changes to the HH QRP. Therefore, we are not providing any estimated impacts.

3. Change to the CoP OASIS Requirement

No impact was assessed for this provision in the January 13, 2017 final rule titled “Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies (82 FR 4504). Therefore, we do not believe that there are any burden reductions to be assessed when removing this requirement.

4. Reporting Under the Home Health Value Based Purchasing (HHVBP) Model During the COVID–19 PHE

Section IV.C of this rule finalizes a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the COVID–19 PHE. We do not anticipate a change to Medicare expenditures as a result of this policy. The overall economic impact of the HHVBP Model for CYs 2018 through 2022 is an estimated \$378 million in total savings to Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality

improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model as a result of this policy.

5. Payment for Home Infusion Therapy Services

In the CY 2020 HH PPS final rule with comment period, we estimated that the implementation of the permanent home infusion therapy benefit would result in a 3.6 percent decrease (\$2 million) in payments to home infusion therapy suppliers in CY 2021 (84 FR 60639). This decrease reflects the exclusion of statutorily-excluded drugs and biologicals, and is representative of a wage-adjusted 4-hour payment rate, compared to a wage-adjusted 5-hour payment rate.

There were no new proposals related to payments for home infusion therapy services in CY 2021. The CY 2021 final PFS amounts were not available at the time of rulemaking; however any impact to the CY 2021 home infusion therapy payment amounts are attributed to changes in the PFS amounts for 2021. The impact of updating the payment rates for home infusion therapy services for CY 2021, based on the proposed PFS amounts for CY 2021, is a 0.7 percent decrease (\$384,800) in payments to eligible home infusion therapy suppliers in CY 2021.

6. Home Infusion Therapy Supplier Requirements

As stated previously, we proposed that home infusion therapy suppliers be required to enroll in Medicare and pay an application fee at the time of enrollment in accordance with § 424.514.

The application fees for each of the past 3 calendar years were or are \$569 (CY 2018), \$586, (CY 2019), and \$595 (CY 2020). Consistent with § 424.514, the differing fee amounts are predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI-U) for the 12-month period ending on June 30 of the previous year. Although we could not predict future changes to the CPI, the fee amounts between 2018 and 2020 increased by an average of \$13 per year. We believed this was a reasonable barometer with which to establish estimates (strictly for purposes of the final rule) of the fee amounts in the first 3 CYs of this rule (that is, 2021, 2022, and 2023). Thus, we projected a fee amount of \$608 in 2021, \$621 for 2022, and \$634 for 2023.

Applying these prospective fee amounts to the number of projected

applicants in the rule's first 3 years, we estimated a total application fee cost to enrollees of \$364,800 (or $600 \times \$608$) in the first year, \$31,050 (or $50 \times \$621$) in the second year, and \$31,700 (or $50 \times \$634$) in the third year. (This constituted an average annual figure of \$142,517 over the first 3 years of this rulemaking). As referenced in Table 1 of this final rule, this would represent a transfer from home infusion therapy suppliers to the federal government. We received no comments concerning our projected application fee transfers and are therefore finalizing them as proposed.

As noted in Table 1 and section VII.B. of this final rule, the estimated average annual burden associated with home infusion therapy supplier enrollment over the 3-year OMB approval period is 583 hours at a cost of \$28,583.

7. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique reviewers of this year's final rule would be the similar to the number of reviewers on this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. While we solicited comments on the approach in estimating the number of entities which would review the proposed rule and the assumption of how much of the rule reviewers would read, we did not receive any comments.

Therefore, using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$110.74 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 1.80 hours for the staff to review half of this final

rule, which consists of approximately 54,079 words. For each HHA that reviews the rule, the estimated cost is \$199.33 (1.80 hours \times \$110.74). Therefore, we estimate that the total cost of reviewing this final rule is \$32,291 ($\199.33×162 reviewers). For purposes of this estimate, the number of reviewers of this year's rule is equivalent to the number of comments received for the CY 2021 HH PPS proposed rule.

D. Detailed Economic Analysis

This rule finalizes updates to Medicare payments under the HH PPS for CY 2021. The impact analysis of this final rule presents the estimated expenditure effects of policy changes finalized in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case mix. This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based primarily on Medicare claims data for episodes ending on or before December 31, 2019. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 18 represents how HHA revenues are likely to be affected by the policy changes in this final rule for CY 2021. For this analysis, we used an analytic file with linked CY 2019 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2019. The first column of Table 18 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of updating to the CY 2021 wage index. The fourth column shows the effects of

moving from the old OMB delineations to the new OMB delineations with a 5 percent cap on wage index decreases. The fifth column shows the payment effects of the CY 2021 rural add-on payment provision in statute. The sixth column shows the payment effects of the CY 2021 home health payment update percentage and the last column

shows the combined effects of all the policies finalized in this rule.

Overall, it is projected that aggregate payments in CY 2021 would increase by 1.9 percent. As illustrated in Table 18, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same

group may experience different impacts on payments than others due to the distributional impact of the CY 2021 wage index, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

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TABLE 18: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2021

	Number of Agencies	CY 2021 Updated Wage Index (CY 2020 Payments)	OMB Delineations with 5% Cap	CY 2021 Rural Add-On	CY 2021 HH Payment Update Percentage	Total
All Agencies	9,808	0.0%	0.0%	-0.1%	2.0%	1.9%
Facility Type and Control						
Free-Standing/Other Vol/NP	970	0.0%	0.0%	-0.1%	2.0%	1.9%
Free-Standing/Other Proprietary	7,910	0.0%	0.0%	-0.1%	2.0%	1.9%
Free-Standing/Other Government	198	0.3%	0.1%	-0.4%	2.0%	2.0%
Facility-Based Vol/NP	511	0.1%	0.1%	-0.2%	2.0%	2.0%
Facility-Based Proprietary	58	-0.1%	0.4%	-0.3%	2.0%	2.0%
Facility-Based Government	161	-0.2%	0.1%	-0.4%	2.0%	1.5%
Subtotal: Freestanding	9,078	0.0%	0.0%	-0.1%	2.0%	1.9%
Subtotal: Facility-based	730	0.1%	0.1%	-0.2%	2.0%	2.0%
Subtotal: Vol/NP	1,481	0.0%	0.0%	-0.2%	2.0%	1.8%
Subtotal: Proprietary	7,968	0.0%	0.0%	-0.1%	2.0%	1.9%
Subtotal: Government	359	0.0%	0.1%	-0.4%	2.0%	1.7%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	234	0.3%	0.0%	-0.8%	2.0%	1.5%
Free-Standing/Other Proprietary	817	0.1%	0.0%	-0.5%	2.0%	1.6%
Free-Standing/Other Government	133	0.1%	0.1%	-0.9%	2.0%	1.3%
Facility-Based Vol/NP	232	0.0%	0.0%	-0.8%	2.0%	1.2%
Facility-Based Proprietary	26	0.5%	0.5%	-0.7%	2.0%	2.3%
Facility-Based Government	123	0.2%	0.0%	-0.8%	2.0%	1.4%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	736	-0.1%	0.0%	-0.1%	2.0%	1.8%
Free-Standing/Other Proprietary	7,093	0.0%	0.0%	-0.1%	2.0%	1.9%
Free-Standing/Other Government	65	0.4%	0.1%	-0.1%	2.0%	2.4%
Facility-Based Vol/NP	279	0.1%	0.1%	-0.1%	2.0%	2.1%
Facility-Based Proprietary	32	-0.4%	0.3%	-0.1%	2.0%	1.8%
Facility-Based Government	38	-0.5%	0.1%	-0.1%	2.0%	1.5%
Facility Location: Urban or Rural						
Rural	1,565	0.1%	0.0%	-0.6%	2.0%	1.5%
Urban	8,243	0.0%	0.0%	-0.1%	2.0%	1.9%
Facility Location: Region of the Country (Census Divisions)						
New England	336	-1.0%	-0.1%	-0.1%	2.0%	0.8%
Mid Atlantic	452	0.7%	0.2%	-0.1%	2.0%	2.8%
East North Central	1,750	0.2%	-0.1%	-0.2%	2.0%	1.9%
West North Central	652	-0.6%	0.0%	-0.3%	2.0%	1.1%
South Atlantic	1,569	0.0%	0.0%	-0.1%	2.0%	1.9%
East South Central	381	0.0%	0.0%	-0.3%	2.0%	1.7%
West South Central	2,387	0.1%	0.0%	-0.1%	2.0%	2.0%
Mountain	689	-0.3%	-0.1%	-0.1%	2.0%	1.5%
Pacific	1,552	0.0%	0.1%	0.0%	2.0%	2.1%
Outlying	40	-1.2%	-0.2%	-0.1%	2.0%	0.5%

	Number of Agencies	CY 2021 Updated Wage Index (CY 2020 Payments)	OMB Delineations with 5% Cap	CY 2021 Rural Add-On	CY 2021 HH Payment Update Percentage	Total
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,491	-0.1%	0.0%	-0.1%	2.0%	1.8%
100 to 249	1,989	-0.1%	0.0%	-0.1%	2.0%	1.8%
250 to 499	2,044	-0.1%	0.0%	-0.1%	2.0%	1.8%
500 to 999	1,687	-0.1%	0.0%	-0.1%	2.0%	1.8%
1,000 or More	1,597	0.0%	0.0%	-0.1%	2.0%	1.9%

Source: CY 2019 Medicare claims data for episodes ending on or before December 31, 2019 for which we had a linked OASIS assessment (as of July 13, 2020).

Notes: Impacts were calculated using 8,744,171 simulated 30-day periods. This analysis omits 721,240 simulated 30-day periods not grouped under the PDGM (either due to a missing Start of Care (SOC) OASIS, because they could not be assigned to a clinical grouping, or had missing therapy/nursing visits). Additionally, another 42,998 periods were excluded with missing wage index information, a further 7 periods were excluded with missing NRS weights, and 2,074 periods with a missing urban/rural indicator. The standard 30-day payment amount used to achieve impact neutrality does not incorporate any behavioral assumptions. PDGM impacts were modeled using CY2020 payment parameters, wage indexes, and rural add-on policy, with a 30-day standard amount of \$1,864.03.

REGION KEY:

New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Middle Atlantic=Pennsylvania, New Jersey, New York;

South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia

East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin

East South Central=Alabama, Kentucky, Mississippi, Tennessee

West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota

West South Central=Arkansas, Louisiana, Oklahoma, Texas

Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming

Pacific=Alaska, California, Hawaii, Oregon, Washington

Other=Guam, Puerto Rico, Virgin Islands

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E. Alternatives Considered

For the CY 2021 HH PPS proposed rule, we considered alternatives to the proposals articulated in section III.B. of this final rule. We considered not adopting the OMB delineations. However, we have historically adopted the latest OMB delineations as we believe that implementing the new OMB delineations would result in wage index values being more representative of the

actual costs of labor in a given area. Additionally, we considered not implementing the 1-year 5-percent cap on wage index decreases. While there are some minimal impacts on certain HHAs as a result of this 5-percent cap as shown in the regulatory impact analysis of this final rule, we decided that the 5-percent cap was a better option for the transition because it would mitigate potential negative impacts from the transition to the new OMB delineations and allow providers

the opportunity to adjust to the changes in their wage index values gradually.

F. Accounting Statement and Tables

As required by OMB Circular A-4 (available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in Table 19, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2021 HH PPS provisions of this rule.

TABLE 19: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2020 TO 2021

Category	Transfers
Annualized Monetized Transfers	\$390 million
From Whom to Whom?	Federal Government to HHAs

G. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. It has been determined that this final rule is an action that primarily results in transfers and does not impose more than de minimis costs as described previously and thus is not a regulatory or deregulatory action for the purposes of Executive Order 13771.

H. Conclusion

In conclusion, we estimate that the provisions in this final rule would result in an estimated net increase in HH payments of 1.9 percent for CY 2021 (\$390 million). The \$390 million increase in estimated payments for CY 2021 reflects the effects of the CY 2021 home health payment update percentage of 2.0 percent (\$410 million increase) and an estimated –0.1 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2021 (\$20 million decrease).

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays

42 CFR Part 414

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

42 CFR Part 424

Emergency medical centers, Health facilities, Health professions, Medicare, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 409.43 is amended by revising paragraphs (a) introductory text, (a)(1), and (3) to read as follows:

§ 409.43 Plan of care requirements.

(a) Contents. An individualized plan of care must be established and periodically reviewed by the certifying physician or allowed practitioner.

(1) The HHA must be acting upon a plan of care that meets the requirements of this section for HHA services to be covered.

* * * * *

(3)(i) The plan of care must include all of the following:

(A) The identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in § 484.60(a) of this chapter that establish the need for such services.

(B) Any provision of remote patient monitoring or other services furnished via telecommunications technology (as defined in § 409.46(e)) or audio-only technology. Such services must be tied to the patient-specific needs as identified in the comprehensive assessment, cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of patient eligibility or payment.

(ii) All care provided must be in accordance with the plan of care.

* * * * *

■ 3. Section 409.46 is amended by revising paragraph (e) to read as follows:

§ 409.46 Allowable administrative costs.

* * * * *

(e) Telecommunications technology. Telecommunications technology, as indicated on the plan of care, can include: remote patient monitoring, defined as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency; teletypewriter (TTY); and 2-way audio-video telecommunications technology that allows for real-time interaction between the patient and clinician. The costs of any equipment, set-up, and service related to the technology are allowable only as administrative costs. Visits to a beneficiary’s home for the sole purpose of supplying, connecting, or training the patient on the technology, without the

provision of a skilled service, are not separately billable.

■ 4. Section 409.49 is amended by adding paragraph (h) to read as follows:

§ 409.49 Excluded services.

* * * * *

(h) Services covered under the home infusion therapy benefit. Services that are covered under the home infusion therapy benefit as outlined at § 486.525 of this chapter, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Excluded home infusion therapy services pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505 of this chapter. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit.

■ 5. Section 409.64 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 409.64 Services that are counted toward allowable amounts.

* * * * *

(a) * * *

(2) * * *

(ii) The hospital, CAH, SNF, or home health agency had submitted all necessary evidence, including physician or allowed practitioner certification of need for services when such certification was required;

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 6. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 7. Section 410.170 is amended by revising paragraph (b) to read as follows:

§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.

* * * * *

(b) Physician or allowed practitioner certification. For home health services, a physician or allowed practitioner provides certification and recertification in accordance with § 424.22 of this chapter.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395r(b)(1).

■ 9. Section 414.1505 is amended by adding paragraph (c) to read as follows:

§ 414.1505 Requirement for payment.

* * * * *

(c) The home infusion therapy supplier must be enrolled in Medicare consistent with the provisions of § 424.68 and part 424, subpart P of this chapter.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 10. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 424.68 is added to subpart E to read as follows:

§ 424.68 Enrollment requirements for home infusion therapy suppliers.

(a) *Definition.* For purposes of this section, a home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following requirements:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Is enrolled in Medicare as a home infusion therapy supplier consistent with the provisions of this section and subpart P of this part.

(b) *General requirement.* For a supplier to receive Medicare payment for the provision of home infusion therapy supplier services, the supplier must qualify as a home infusion therapy supplier (as defined in this section) and be in compliance with all applicable provisions of this section and of subpart P of this part.

(c) *Specific requirements for enrollment.* To enroll in the Medicare program as a home infusion therapy supplier, a home infusion therapy supplier must meet all of the following requirements:

(1)(i) Fully complete and submit the Form CMS–855B application (or its

electronic or successor application) to its applicable Medicare contractor.

(ii) Certify via the Form CMS–855B that the home infusion therapy supplier meets and will continue to meet the specific requirements and standards for enrollment described in this section and in subpart P of this part.

(2) Comply with the application fee requirements in § 424.514.

(3) Be currently and validly accredited as a home infusion therapy supplier by a CMS-recognized home infusion therapy supplier accreditation organization.

(4) Comply with § 414.1515 of this chapter and all provisions of part 486, subpart I of this chapter.

(5) Successfully complete the limited categorical risk level of screening under § 424.518.

(d) *Denial of enrollment.* (1) Enrollment denial by CMS. CMS may deny a supplier's enrollment application as a home infusion therapy supplier on either of the following grounds:

(i) The supplier does not meet all of the requirements for enrollment outlined in § 424.68 and in subpart P of this part.

(ii) Any of the applicable denial reasons in § 424.530.

(2) Appeal of an enrollment denial. A supplier may appeal the denial of its enrollment application as a home infusion therapy supplier under part 498 of this chapter.

(e) *Continued compliance, standards, and reasons for revocation.* (1) Upon and after enrollment, a home infusion therapy supplier—

(i) Must remain currently and validly accredited as described in paragraph (c)(3) of this section.

(ii) Remains subject to, and must remain in full compliance with, all of the provisions of—

- (A) This section;
- (B) Subpart P of this part;
- (C) Section 414.1515 of this chapter; and
- (D) Part 486, subpart I of this chapter.

(2) CMS may revoke a home infusion therapy supplier's enrollment on any of the following grounds:

(i) The supplier does not meet the accreditation requirements as described in paragraph (c)(3) of this section.

(ii) The supplier does not comply with all of the provisions of—

- (A) This section;
- (B) Subpart P of this part;
- (C) Section 414.1515 of this chapter; and
- (D) Part 486, subpart I of this chapter;

or

(iii) Any of the revocation reasons in § 424.535 applies.

(3) A home infusion therapy supplier may appeal the revocation of its enrollment under part 498 of this chapter.

■ 12. Section 424.518 is amended by redesignating paragraphs (a)(1)(vii) through (xvi) as paragraphs (a)(1)(viii) through (xvii) and adding a new paragraph (a)(1)(vii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(a) * * *

(1) * * *

(vii) Home infusion therapy suppliers.

* * * * *

■ 13. Section 424.520 is amended by revising paragraph (d) introductory text to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers.* The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers is the later of—

* * * * *

■ 14. Section 424.521 is amended by revising the section heading and paragraph (a) introductory text to read as follows:

§ 424.521 Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers.

(a) Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, opioid treatment program, or home infusion therapy supplier has met all program requirements, including State licensure requirements, and services were provided at the enrolled practice location for up to—

* * * * *

PART 484—HOME HEALTH SERVICES

■ 15. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 484.45 [Amended]

- 16. Section 484.45 is amended by—
- a. Removing paragraph (c)(2); and
- b. Redesignating paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3), respectively.

- 17. Section 484.110 is amended by revising the introductory text and paragraph (a)(1) to read as follows:

§ 484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current

information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) or allowed practitioner(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

(a) * * *

(1) The patient's current comprehensive assessment, including all of the assessments from the most

recent home health admission, clinical notes, plans of care, and physician or allowed practitioner orders;

* * * * *

Dated: October 23, 2020.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: October 26, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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