

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 414, 424, and 484

[CMS–1730–P]

RIN 0938–AU–06

Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the home health prospective payment system (HH PPS) payment rates and wage index for calendar year (CY) 2021. This proposed rule also proposes to make permanent the changes to the home health regulations regarding the use of technology in providing services under the Medicare home health benefit as described in the Medicare and Medicaid Programs; Revisions in Response to the COVID–19 Public Health Emergency interim final rule with comment period. This proposed rule also proposes to remove 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. This proposed rule discusses policies finalized in the CY 2020 HH PPS final rule with comment period regarding the permanent home infusion therapy services benefit for CY 2021, and proposes conforming regulations text changes excluding home infusion therapy services from coverage under the Medicare home health benefit. Additionally, this proposed rule discusses Medicare enrollment policies for qualified home infusion therapy suppliers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 31, 2020.

ADDRESSES: In commenting, please refer to file code CMS–1730–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation

to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1730–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1730–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Hillary Loeffler, (410) 786–0456, 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.

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

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This proposed rule would update 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 proposed rule would also set 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; and 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). This rule also proposes to adopt the revised 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 2021. This rule also proposes a cap on wage index decreases in excess of 5 percent. This proposed rule would adopt the new 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. Finally, this proposed rule proposes to permanently finalize the changes to § 409.43(a) as finalized in “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” interim final rule with comment period (First COVID–19 PHE IFC) (85 FR 19230), to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system.

2. Home Health Quality Reporting Program (HH QRP)

We are not proposing any changes for the Home Health Quality Reporting Program.

3. Changes to the CoP OASIS Requirements

This proposed rule would remove 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. Home Infusion Therapy Services

This proposed rule outlines the home infusion therapy policies finalized in

¹ On March 6, 2020, OMB issued the most recent OMB Bulletin No. 20–01. Bulletin No. 20–01 was not utilized for this proposed rulemaking.

the CY 2020 HH PPS final rule with comment period (84 FR 60615), as required by section 1834(u) of the Act. This proposed rule includes conforming regulations text changes excluding home infusion therapy services from coverage under the Medicare home health benefit as required by the conforming amendment in section 5012(c)(3) of the 21st Century Cures Act.

5. Enrollment Standards for Qualified Home Infusion Therapy Suppliers

This proposed rule would set out the Medicare provider enrollment policies for qualified home infusion therapy suppliers.

B. Summary of the Provisions of This Rule

1. Home Health Prospective Payment System (HH PPS)

In section III.A of this rule, we propose to 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 PDGM. The PDGM is our new case-mix adjustment methodology to adjust payments for home health periods of care beginning on and 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 proposes to adopt the OMB statistical area delineations outlined in a September 14, 2018, OMB bulletin No. 18–04. This rule also proposes a transition with a 1-year cap on wage index decreases in excess of 5 percent, consistent with the policy being proposed for other Medicare payment systems. This proposed rule would adopt the new 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 propose to 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 estimated to be 2.7 percent. Additionally, for CY 2021, this proposed rule proposes to maintain the fixed-dollar loss ratio at 0.63, as finalized for CY 2020.

Section III.D. of this proposed rule proposes to permanently finalize the changes to § 409.43(a) as finalized in the first COVID–19 PHE IFC (85 FR 19230),

to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and 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.

Section IV. of this proposed rule discusses the HH QRP and proposed changes to the conditions of participation (CoP) OASIS requirements.

In sections V.A.1. and 2. of this proposed 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 HH PPS final rule with comment period for the CY 2021 implementation (84 FR 60628). In section V.A.5. of this proposed rule, we propose 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 proposed rule, we discuss proposed requirements regarding enrollment standards for qualified home infusion therapy suppliers.

C. Summary of Costs, Transfers, and Benefits

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 \$540 million (2.6 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 are being made therefore, no costs or savings are associated with this provision.		
OASIS	There are no costs associated with this provision.		
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 Physician Fee Schedule amounts for CY 2021, is no more than a 1 to 2 percent increase /decrease (\$1 million or less) 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 proposed requirement of \$142,517.	Enrollment ensures that home infusion therapy suppliers meet all applicable requirements.

III. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. 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 HH 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 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 HH 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 percent market basket increase. Section 50208(a)(1) of the BBA of 2018 again extended the 3 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 Bipartisan Budget Act of 2018 (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, section 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.

2. Current System for Payment of Home Health Services Beginning in CY 2020 and Subsequent Year

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,

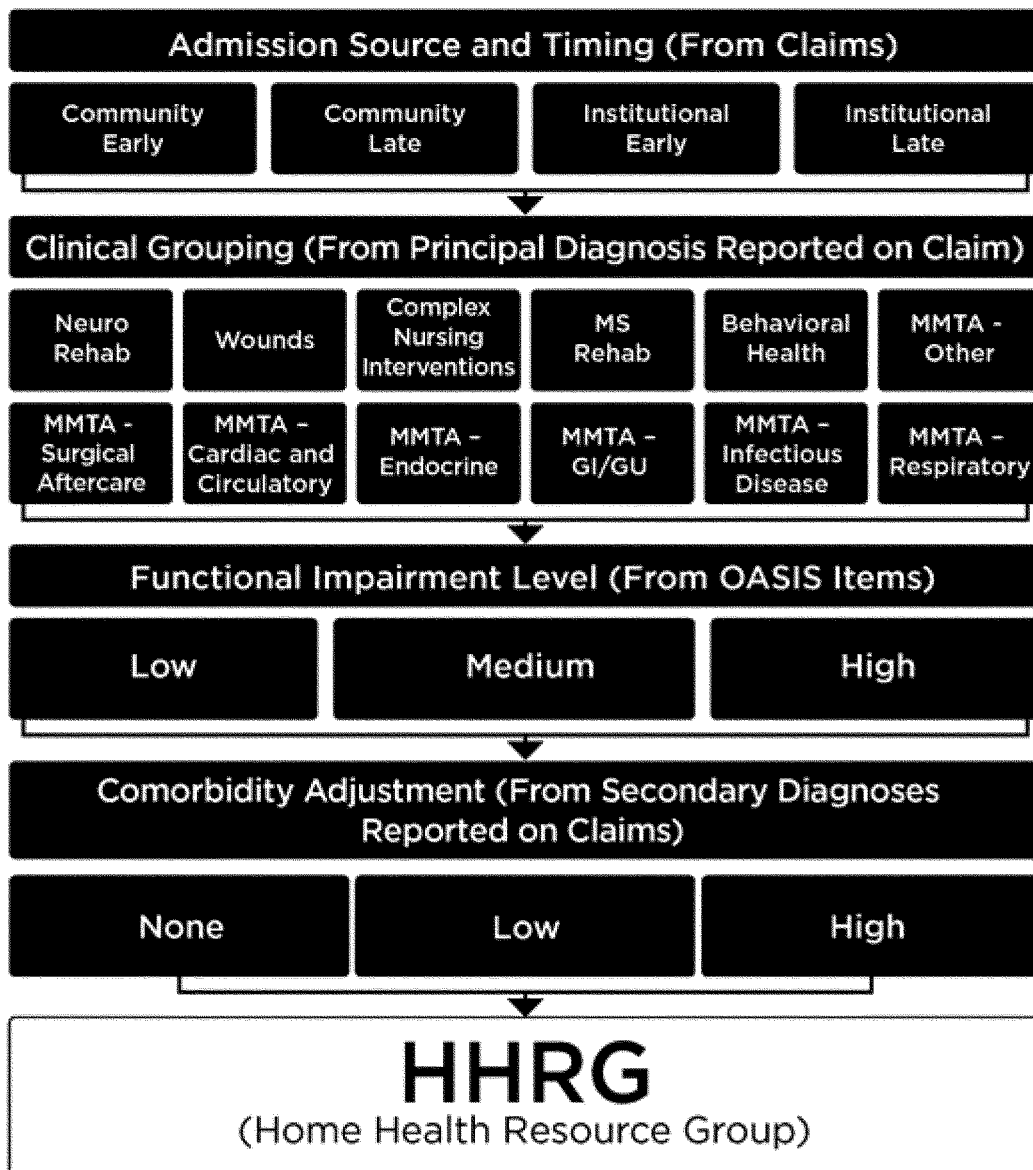
occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is now part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount and is not included in the national, standardized 30-day period payment amount.

To better align payment with patient care needs and better 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 which 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 each 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 proposed 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.



a. 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 be 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.”

b. 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 HH 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 HH claim with a community admission source payment group. If such HH 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 HH 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 purposes 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

c. Clinical Groupings

Each 30-day period of care is grouped into one of 12 clinical groups which 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.

² Medicare Claims Processing Manual Chapter 10—Home Health Agency Billing. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c10.pdf>.

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 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.

d. 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 60478, 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” posted on the 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

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

OASIS assessment based on the claims “from date.”

e. 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.

B. Proposed Provisions for Payment Under the Home Health Prospective Payment System (HH PPS)

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

a. Proposed 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 (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 proposed 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 of 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 to reflect only minor changes. Therefore, we are proposing to maintain the LUPA thresholds 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 these LUPA thresholds (along with the case-mix weights) that will be used for CY 2021 on the HHA Center and PDGM web pages.

b. 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) 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 are proposing 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 proposed 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 will be less burdensome for HHAs and software vendors, who continue to familiarize themselves with this new case-mix methodology.

2. Proposed Home Health Wage Index Changes

a. Proposed 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>). As discussed below, this bulletin was not available in time for the development of this proposed rule. 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 are proposing 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 this proposed rule. We will include any updates from OMB Bulletin No. 20–01 in any changes that would be adopted in the CY 2022 HH PPS proposed rule.

(1) 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 are proposing to continue to treat Micropolitan Areas as “rural” and to include Micropolitan Areas in the calculation of each state’s rural wage index.

(2) Urban Counties Becoming Rural

If we adopt the new OMB delineations (based upon the 2010 decennial Census data), a total of 34 counties (and county equivalents) that are currently considered urban would be considered rural beginning in CY 2021. Table 3 lists the 34 counties that would change to rural status if we finalize our proposal to implement the new OMB delineations.

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TABLE 3: COUNTIES THAT WOULD CHANGE 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

(3) Rural Counties Becoming Urban

If we finalize our proposal to implement the new OMB delineations

(based upon the 2010 decennial Census data), a total of 47 counties (and county equivalents) that are currently designated rural would be considered

urban beginning in CY 2021. Table 4 lists the 47 counties that would change to urban status.

TABLE 4: COUNTIES THAT WOULD CHANGE 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

(4) Urban Counties Moving to a Different Urban CBSA

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the new OMB delineations (Table 5). In other cases, applying the new OMB

delineations would involve a change only in CBSA name or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) would experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain

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

TABLE 5: COUNTIES THAT WOULD CHANGE NAME 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, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. In another type of change, some CBSAs have counties

that would split off to become part of or to form entirely new labor market areas. Finally, in some cases, a CBSA would lose counties to another existing CBSA if we adopt the new OMB delineations. Table 6 lists the urban counties that

would move from one urban CBSA to a newly or modified CBSA if we adopt the new OMB delineations.

TABLE 6: COUNTIES THAT WOULD CHANGE 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**b. Proposed Transition Period**

As discussed above, overall, we believe that our proposal to adopt the revised OMB delineations for CY 2021 would result 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 our proposal.

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 are proposing 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 are proposing 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 would allow the effects of our proposed 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, would be 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 proposed 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 one year 5 percent cap provides home health agencies sufficient time to plan appropriately for CY 2022 and future years. Because we believe that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels we are proposing 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 this 5 percent cap proposal as shown in the regulatory impact analysis of this proposed rule, overall, the impact between the CY 2021 wage index using the old OMB delineations and the proposed 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 invite comments on our proposed transition methodology.

The proposed 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 proposed HH PPS wage index for CY 2021 would be effective January 1, 2021 through December 31, 2021.

The wage index file posted on the CMS website provides a crosswalk between the CY 2021 wage index using the current OMB delineations and the CY 2021 wage index using the proposed revised OMB delineations, as well as the proposed transition wage index values that would be in effect in CY 2021 if these proposed changes are finalized. It also shows each state and county and its corresponding proposed transition wage index along with the previous CBSA number, the new CBSA number or alternate identification number, and the new CBSA name.

3. Proposed CY 2021 Home Health Payment Rate Updates

a. Proposed 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 rebasing of 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 that the labor-related share is 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.

The proposed home health update percentage for CY 2021 is based on the estimated home health market basket update, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.1 percent (based on IHS Global Insight Inc.'s first-quarter 2020 forecast with historical data through fourth-quarter 2019). The estimated CY 2021 home health market basket update of 3.1 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), currently estimated to be 0.4 percentage point for CY 2021. In effect, the proposed home health payment update percentage for CY 2021 is a 2.7 percent increase. Section 1895(b)(3)(B)(v) of the Act requires that the home health update be decreased by 2 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 would be 0.7

percent (2.7 percent minus 2 percentage points). If more recent data becomes available after the publication of this proposed rule and before the publication of the final rule (for example, more recent estimates of the home health market basket update and MFP adjustment), we would use such data, if appropriate, to determine the home health payment update percentage for CY 2021 in the final rule.

b. 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 HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We propose to continue this practice for CY 2021, as we continue to believe that, in the absence of HH-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. As discussed above, we propose 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 propose 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 propose 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 propose 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 adjusted, new delineations wage index value for Hinesville, GA is 0.8478.

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 0.8586. Bulletin No. 17-01 is available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.⁴

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>.

⁴ "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>.

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/wp-content/uploads/2020/03/Bulletin-20-01.pdf>.

The proposed CY 2021 wage index is available on the CMS website at: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>.

c. CY 2021 Annual Payment Update (1) 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 Medicare cost report (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 sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit HH 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 HH 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.

(2) 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. While we continue to monitor the impact of these changes on patient outcomes and Medicare expenditures, we believe 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 current public health emergency resulting from the COVID-19 pandemic outbreak. Therefore, for CY 2021, we are not proposing to make any additional

changes to the national, standardized 30-day payment rate in this proposed rule other than the routine rate updates outlined below. In future rulemaking, we plan to determine whether any changes need to be made to the national, standardized 30-day 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 proposed rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA 30-day periods using the proposed 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 0.9987. We would apply the wage index budget neutrality factor of 0.9987 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 are not proposing 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 would update the 30-day payment rate by the CY 2021 home health payment update percentage of 2.7 percent. The CY 2021 national, standardized 30-day period payment rate is calculated in Table 7.

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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 0.9987	X 1.027	\$1,911.87

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

quality data is updated by the CY 2021 home health payment update of 2.7

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 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 0.9987	X 1.007	\$1,874.64

(3) 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 HH discipline. The six HH 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 0.9985. We apply the wage index budget neutrality factor in order to calculate the CY 2021 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weights budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2021 home health payment update percentage

of 2.7 percent. 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 episodes that occur as the only episode or initial episode in a sequence of

adjacent episodes. The CY 2021 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2021 HH payment update percentage of 2.7 percent and 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 0.9988	X 1.027	\$69.53
Medical Social Services	\$239.92	X 0.9988	X 1.027	\$246.10
Occupational Therapy	\$164.74	X 0.9988	X 1.027	\$168.98
Physical Therapy	\$163.61	X 0.9988	X 1.027	\$167.83
Skilled Nursing	\$149.68	X 0.9988	X 1.027	\$153.54
Speech-Language Pathology	\$177.84	X 0.9988	X 1.027	\$182.42

The CY 2021 per-visit payment rates for HHAs that do not submit the

required quality data are updated by the CY 2020 HH payment update percentage

of 2.7 percent minus 2 percentage points and are shown in Table 10.

TABLE 10: CY 2020 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 0.9988	X 1.007	\$68.17
Medical Social Services	\$239.92	X 0.9988	X 1.007	\$241.31
Occupational Therapy	\$164.74	X 0.9988	X 1.007	\$165.69
Physical Therapy	\$163.61	X 0.9988	X 1.007	\$164.56
Skilled Nursing	\$149.68	X 0.9988	X 1.007	\$150.55
Speech- Language Pathology	\$177.84	X 0.9988	X 1.007	\$178.87

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We are reminding 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 lowering of the up-front 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 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 also stated that the information required for submitting an NOA for CYs 2022 and beyond 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. Also, for both the submission of the RAP in CY 2021 and the one-time NOA for CYs 2022 and beyond, we finalized a payment reduction if the HHA does not submit the RAP for CY 2021 or NOA for CYs 2022 and beyond 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 beyond, 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).

(4) 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 occur as the only episode or as an initial episode in a sequence of adjacent episodes are 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 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 proposed 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 \$283.30 (1.8451 multiplied by \$153.54), subject to area wage adjustment.

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 HH 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 HH 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 HH 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 HH 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 HH 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 proposed 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 2021-2022

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

e. Proposed 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 HH 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 update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost-per-unit used to determine 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. 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 that the FDL ratio for 30-day periods of care in CY 2020 would need to be set at 0.63 for 30-day periods of care based on our simulations looking at both 60-day episodes that would span into CY 2020 and 30-day periods that begin in CY 2020. Given that CY 2020 is the first year of the PDGM and the change to a 30-day unit of payment, for CY 2021, we are proposing to maintain the fixed-dollar loss ratio of 0.63, as finalized for CY 2020.

4. The Use of Technology Under the Medicare Home Health Benefit

In the first COVID-19 PHE IFC (85 FR 19230), we changed the plan of care requirements at § 409.43(a) on an interim basis, for the purposes of Medicare payment, to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and

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. In the first COVID-19 PHE IFC, we stated that we believe that this change will help to increase access to technologies, such as telemedicine and remote patient monitoring during the public health emergency for the COVID-19 pandemic (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 emergency period. Specifically, section 3707 of the CARES Act requires, with respect to home health services furnished during the PHE for COVID-19, that the Secretary shall 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. We believe that the policies finalized on an interim basis meet the requirements of section 3707 of the CARES Act.

We have also heard from stakeholders about the important role that technologies can play in the delivery of appropriate home health services outside of the current pandemic. In the first COVID-19 PHE IFC (85 FR 19230), we discussed the various applications of the technology that HHAs and industry representatives have reported utilizing prior to taking the steps necessary in meeting the social distancing required during the public health emergency for the COVID-19 pandemic. 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. We acknowledged that technology has

become an integral part of medicine across the entire spectrum of healthcare, and that telemedicine, in particular has the potential to play a large role in enhancing the delivery of healthcare in the home. In the first COVID-19 PHE IFC, we included the following illustrative example of in-person visits and the use of telecommunications technology:

A patient recently discharged from the hospital after coronary bypass surgery was receiving home health skilled nursing visits 3 times a week for medication management, teaching and assessment. The patient developed a fever, cough, sore throat and moderate shortness of breath and now has a confirmed COVID-19 diagnosis, which the doctor has determined can be safely managed at home with home health services. The patient has been prescribed new medications for symptom management and oxygen therapy to support the patient's respiratory status. The patient's home health plan of care was updated to include an in-person skilled nursing visit once a week to assess the patient and to monitor for worsening symptoms. The plan of care was updated also to include a video consultation twice a week between the skilled nurse and the patient for medication management, teaching and assessment, as well as to obtain oxygen saturation readings that the patient relays to the nurse during the consultation.

With regards to payment under the HH PPS, if the primary reason for home health care is to provide care to manage the symptoms resulting from COVID-19, this 30-day period of care would be grouped into the Medication, Management, Teaching and Assessment (MMTA)-Respiratory clinical group, and it would be an early 30-day period of care with an institutional admission source. Assuming a medium functional impairment level with "low" comorbidities, the low-utilization payment adjustment (LUPA) threshold would be 4 visits. Regardless if the patient continued to receive the original 3 in-person skilled nursing visits per week (12 visits total in the 30-day period) rather than the once per-week in-person skilled nursing visits (4 visits total in the 30-day period), the HHA would still receive the full 30-day payment amount (rather than paying per visit if the total number of visits was below the LUPA threshold). In this example, the use of technology is not a substitute for the provision of in-person visits as ordered on the plan of care, as the plan of care was updated to reflect a change in the frequency of the in-

person visits and to include “virtual visits” using telecommunications technology as part of the management of the home health patient. We believe the provision of in-person visits and encounters using telecommunications technology can also apply outside of the public health emergency. Decisions regarding the use of telecommunications technology would be determined based on patient needs identified during the comprehensive assessment and would be included as part of the individualized plan of care established and reviewed by the physician who establishes the plan of care.

For these reasons, we are proposing to permanently finalize the amendment to § 409.43(a) as outlined in the first COVID–19 PHE IFC (85 FR 19230). We are also proposing 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 propose to modify the instructions regarding this line on the cost report to reflect a broader use of telecommunications technology. Additionally, we propose to amend § 409.46(e) to include not only remote patient monitoring, but other communications or monitoring services, consistent with the plan of care for the individual. Because stakeholders have identified significant up-front costs in incorporating and evaluating various forms of telecommunications systems into home health care, this would allow HHAs to confidently plan for the continued inclusion of telecommunications systems under the Medicare home health benefit and increase the tools available to promote patient involvement and autonomy and potentially more efficient home health care.

We remind stakeholders that access to telecommunications technology must be inclusive, especially for those patients who may have disabilities where the use of technology may be more challenging. Section 504 of the Rehabilitation Act and the Americans with Disabilities Act 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 504 should be referred to the Office of Civil Rights for further review. Likewise, we remind HHAs that the home health CoPs at § 484.50(f)(1) require that information must 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 Americans with Disabilities Act 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”.⁵

We also reiterate the expectation that services provided by telecommunications technology are services that could also be provided through an in-person visit. 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. Furthermore, a HHA cannot discriminate against any individual who is unable or unwilling to receive home health services that could be provided via telecommunications technology. In those circumstances, the HHA must provide such services through in-person visits as the intent of the Medicare home health benefit as defined in section 1861(m) of the Act is to provide items and services on a visiting basis in the individual’s home.

We solicit comments on our proposal to finalize the amendment to § 409.43(a) as outlined in the first COVID–19 PHE IFC (85 FR 19230) to allow the use of telecommunications technology included as part of the home health plan of care as long as the use of such technology does not substitute for ordered in-person visits. We also solicit comments on our proposal 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.

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 rules:

- 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

⁵ State Operations Manual Appendix B—Guidance to Surveyors: Home Health Agencies. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf.

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, as outlined in Table 28 of the CY 2020 HH PPS final rule (84 FR 60555).⁶

TABLE 28: 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.

⁶ The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

There are no proposals or updates in this proposed rule for the Home Health Quality Reporting Program.

B. Proposed 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 2 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 2 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 are proposing 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.

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 Bipartisan Budget Act (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 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 on the basis of 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.⁷ The MACs update Self-Administered Drug (SAD) exclusion lists on a quarterly basis.⁸

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 for home infusion therapy under traditional Medicare, 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.⁹ 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 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

⁷ 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/Manuals/Downloads/bp102c15.pdf>.

⁸ Self-Administered Drug (SAD) Exclusion List Report. www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx?bc=AQAAAAAAAAAAAA%3D%3D.

⁹ National Coverage Determinations Manual. <https://www.cms.gov/Regulations-and-Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html>.

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),¹⁰ 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 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 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

¹⁰ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>.

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 LCD 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 Home Health Prospective Payment System (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 means that existing DME suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies, who comply with Medicare's DME Supplier and Quality Standards, and maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered, are considered eligible home infusion suppliers.

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),¹¹ into three payment categories, for which we established a single payment amount 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 can be billed separately from, or on the same claim as, the DME, supplies, or infusion drug, and are 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 2020¹² outlining the requirements for the claims processing changes needed to implement this payment.

And last, 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

¹¹ 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=iAAAAABAAAAA&>

¹² 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>.

"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 Home Health Prospective Payment System (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),¹³ 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).¹⁴ 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 34690).

(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 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

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>.

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).¹⁵ 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.

(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 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

¹⁵ 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>.

bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

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 are not proposing to create a mandatory form nor are we otherwise proposing 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, 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 12), 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 outlined in 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 with 2021. Table 12 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. As noted previously in this proposed rule, 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 drugs 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 on a SAD exclusion list, services related to the administration of this biological are not covered under the benefit in 2021. 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. Subsequent drugs added to the DME LCD for external infusion pumps, and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, would be grouped into the appropriate payment category by the DME MACs. Payment category 1 would include any subsequent intravenous infusion drug additions, payment category 2 would include any subsequent subcutaneous infusion drug additions, and payment category 3 would include any subsequent intravenous chemotherapy or other highly complex drug or biologic infusion additions.

TABLE 12: 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
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.

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 13.

**TABLE 13: 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. Table 14 shows the E/M visit codes and PFS payment amounts for CY 2020, for both new and existing patients, used to determine the

increased payment amount for the first visit. Using the CY 2020 PFS rates, this results in a 60 percent increase in the first visit payment amount and a 3.72 percent decrease in subsequent visit amounts.

TABLE 14: 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
99201	\$46.56	99211	\$23.46	98%
99202	\$77.23	99212	\$46.19	67%
99203	\$109.35	99213	\$76.15	44%
99204	\$167.09	99214	\$110.43	51%
99205	\$211.12	99215	\$148.33	42%
Total	\$611.35		\$404.56	51%

Note: Rates are calculated using CY 2020 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)=60 percent.

Table 15 shows the 5-hour payment amounts (using CY 2020 PFS rates) reflecting the increased payment for the first visit and the decreased payment for all subsequent visits. The payment amounts for this proposed rule are estimated using CY 2020 rates because

the 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 in a CR 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 15: 5-HOUR PAYMENT AMOUNTS REFLECTING PAYMENT RATES FOR FIRST AND SUBSEQUENT VISITS

Description	2020 PFS Amount	5-hour Payment - First Visit	5-hour Payment - Subsequent Visits
Ther, Proph, Diag IV/IN infusion 1 hr	\$72.18	\$256.35 (category 1)	\$154.26 (category 1)
Ther, Proph, Diag IV/IN infusion add hr	\$22.01		
Sub Q Ther Inf 1 hr	\$162.04	\$358.59 (category 2)	\$215.78 (category 2)
Sub Q Ther Inf add hr	\$15.52		
Chemo Inf 1 hr	\$142.55	\$424.43 (category 3)	\$255.40 (category 3)
Chemo Inf add hr	\$30.68		

Note: Rates are calculated using CY 2020 PFS rates

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) 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).¹⁶ 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: $Rate^{GAF}_i = GAF * UnadjRate_i$.

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. 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 for 2020 the budget neutrality factor would be 0.9957. 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 proposed 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.

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

Section 1861(iii) of the Act 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.

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

¹⁶ $GAF = (.50886 \times \text{Work GPCI}) + (.44839 \times \text{PE GPCI}) + (.04295 \times \text{MP GPCI})$.

32467). In accordance with the definition of “infusion drug administration calendar day”, the skilled services provided on an infusion drug administration calendar 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. Additionally, although we do not specify the entities that may provide the home infusion therapy services, we do state that the skilled provider must be furnishing services within the scope of his/her practice. While we do not outline an exhaustive list of services that are covered under the home infusion therapy services benefit, we outline the scope of services covered under the home infusion therapy services benefit in sub-regulatory guidance.¹⁷ This 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.

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.

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 on January 1, 2021. 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. It is also 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, 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. It is important to note 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. 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 propose to amend § 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. Additionally, excluded home infusion therapy services 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.

As discussed in the CY 2019 HH PPS proposed rule (83 FR 32469), 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.

B. Proposed Enrollment Standards 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. For example, part 414, subpart P outlines policies concerning home infusion therapy conditions of payment and plan of care requirements. Part 486, subpart I, outlines standards for home infusion therapy suppliers and specifies a definition of “qualified home infusion therapy supplier” at § 486.505. 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:

¹⁷ 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-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf>.

- 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. This final criterion, which reflects section 1861(iii)(3)(D)(i)(IV) of the Act, is of particular importance for purposes of this section V.B. of this proposed rule. One of our 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. We believe that 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. Medicare Provider and Supplier Enrollment

a. Background

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 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. 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. As further explained later in this section, CMS and its Medicare Administrative Contractors (MACs; hereafter occasionally referred to as “contractors”) carefully and closely screen and review Medicare enrollment applicants to verify that they meet all applicable legal requirements.

We have taken various steps via regulation to outline a process for enrolling providers and suppliers in the Medicare program. In the April 21, 2006 **Federal Register** (71 FR 20754), we published the “Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment” final rule that set forth certain requirements in 42 CFR part 424, subpart P (currently §§ 424.500

through 424.570) (hereinafter occasionally referenced as subpart P) that providers and suppliers must meet to obtain and maintain Medicare billing privileges. In the April 21, 2006 final rule, we cited sections 1102 and 1871 of the Act as general authority for our establishment of these requirements, which were designed for the efficient administration of the Medicare program.

Following the April 21, 2006 final rule, we published additional provider enrollment regulations. These were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. One such regulatory document was the February 2, 2011 final rule with comment period titled “Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers” (76 FR 5862). Implementing various provisions of the Affordable Care Act, this final rule with comment period did the following:

- Added a new § 424.514 that required submission of application fees by institutional providers (as that term is defined in § 424.502) as part of the Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) provider enrollment processes.
- Added a new § 424.518 that established Medicare, Medicaid, and CHIP provider enrollment screening categories and requirements based on the CMS-assessed level of risk of fraud, waste, and abuse posed by a particular category of provider or supplier.

To further address existing provider enrollment vulnerabilities, we also published the following rules:

- The December 5, 2014 final rule titled “Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment” (79 FR 72499).
- The September 10, 2019 final rule with comment period titled “Medicare, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process” (84 FR 47794).

Both rules expanded the number and types of grounds on which CMS can: (1) Deny a prospective provider’s or supplier’s enrollment in the Medicare program under § 424.530; or (2) revoke

the Medicare enrollment of an existing provider or supplier under § 424.535. In addition, the September 10, 2019 final rule with comment period:

- Implemented section 1866(j)(5) of the Act, which permits the Secretary to deny the enrollment of a Medicare, Medicaid, and CHIP provider or supplier if the latter has or had an affiliation with a provider or supplier that—(1) has uncollected debt; (2) has been or is subject to a payment suspension under a federal health care program; (3) has been or is excluded by the Office of Inspector General (OIG) from Medicare, Medicaid, or CHIP; or (4) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked.

- Increased the maximum reenrollment bar that prohibits a provider or supplier from reenrolling in Medicare after it is revoked from 3 to 10 years, with certain exceptions.

- Prohibited a provider or supplier from enrolling in Medicare for up to 3 years if its enrollment application is denied because the provider or supplier submitted false or misleading information on or with (or omitted information from) its application in order to enroll in Medicare.

We have also conducted rulemaking that established enrollment requirements for specific, newly-recognized types of providers and suppliers, such as Medicare Diabetes Prevention Program suppliers in 2017 (82 FR 52976) and Opioid Treatment Program providers in 2019 (84 FR 62568).

b. Form CMS–855—Medicare Enrollment Application

Under § 424.510, a provider or supplier must complete, sign, and submit to its assigned MAC the appropriate Form CMS–855 (OMB Control No. 0938–0685) application in order to enroll in the Medicare program and obtain Medicare billing privileges. 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) captures information about the provider or supplier that is needed for CMS or its MACs to determine whether the provider or supplier meets all Medicare requirements. Data collected on the Form CMS–855 is carefully reviewed and verified by CMS or its MACs and includes, but is not limited to, the following:

- General identifying information (for example, legal business name, tax identification number).

- Licensure and/or certification data.
- Any final adverse actions (as that term is defined in § 424.502) of the provider or supplier, such as felony convictions, OIG exclusions, or state license suspensions or revocations.
- Practice locations and other applicable addresses of the provider or supplier.

- Information regarding the provider's or supplier's owning and managing individuals and organizations and any final adverse actions those parties may have.

- As applicable, information about the provider's or supplier's use of a billing agency.

The Form CMS–855 application is used for a number of provider enrollment transactions, such as the following:

- Initial enrollment: The provider or supplier is enrolling in Medicare for the first time, enrolling in another MAC's jurisdiction, or seeking to enroll in Medicare after having previously been enrolled.

- Change of ownership: The provider or supplier is reporting a change in its ownership.

- Revalidation: The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515.

- Reactivation: The provider or supplier is seeking to reactivate its Medicare billing privileges after being deactivated under § 424.540.

- Change of information: The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving a 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, and it has been our longstanding experience, that the provider enrollment process is invaluable in helping to ensure that: (1) All potential providers and suppliers are carefully screened for compliance with all applicable requirements; (2)

problematic providers and suppliers are kept out of Medicare; and (3) beneficiaries are protected from unqualified providers and suppliers. Given CMS' responsibility in preventing waste and abuse in the Medicare program, we believe that the safeguards that Medicare enrollment furnishes are needed with respect to home infusion therapy suppliers.

2. Proposed Home Infusion Therapy Supplier Enrollment Provisions

There are several principal legal bases for our proposed home infusion therapy enrollment requirements. First, as stated previously, 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. (We interpret this latter proviso, however, to apply strictly to the establishment of standards of care as opposed to the creation of home infusion therapy supplier enrollment requirements.) 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.

a. Definition

We propose to establish a new § 424.68 that would encapsulate the preponderance of our home infusion therapy enrollment provisions. In paragraph (a) thereof, we propose to define "home infusion therapy supplier." This definition would be largely consistent with the definition of "qualified home infusion therapy supplier" in section 1861(iii)(3)(D)(i)(IV) of the Act and the aforementioned definition of the same term in § 486.505, though with the addition of a specific enrollment requirement. A home infusion therapy supplier under § 424.68, for purposes of § 424.68, would mean 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 propose 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. This overarching requirement would be consistent with that in § 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 Enrollment

Paragraph (c) would outline specific home infusion therapy supplier enrollment requirements. Some of these mirror the general enrollment provisions in subpart P, so we are duplicating them in § 424.68 to clarify their applicability to home infusion therapy suppliers. However, the other requirements in § 424.68(c) are unique to this supplier type.

(1) Submission of Form CMS–855

In § 424.68(c)(1)(i), we propose 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 believe that the Form CMS–855B is the most suitable enrollment application for home infusion therapy suppliers. In addition, we propose in § 424.68(c)(1)(ii) 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 is to help ensure that the home infusion therapy supplier fully understands its obligation

to maintain constant compliance with the requirements associated with home infusion therapy supplier enrollment.

(2) Payment of Application Fee

As mentioned previously in our discussion of the February 2, 2011 final rule with comment period, prospective and revalidating institutional providers that are submitting an enrollment application generally must pay the applicable application fee in accordance with § 424.514. (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. Because a home infusion therapy supplier would be required to complete the Form CMS–855B to enroll in Medicare as a home infusion therapy supplier (and would not be enrolling as a physician/non-physician organization), we believe that a home infusion therapy supplier would meet the definition of an institutional provider under § 424.502. Therefore, home infusion therapy suppliers would be required to pay an application fee consistent with § 424.514, and we accordingly propose to clarify this fee payment requirement in new § 424.68(c)(2).

(3) Accreditation

In general, accreditation of applicable CMS provider and supplier types helps ensure that the provider or supplier meets certain minimum requirements for furnishing health care services. The accreditation process frequently includes, but is not limited to, an accreditation survey. Such a survey typically involves an onsite review and evaluation of the provider's or supplier's operations, structure, and procedures to determine compliance with applicable federal standards. Title 42, part 488, subpart L, outlines, among other things, standards for accreditation organizations for home infusion therapy suppliers.

We already indicated that the definition of “qualified home infusion supplier” in section 1861(iii)(3)(D)(i)(III) of the Act (codified in § 486.505) requires the supplier to be accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act. To this end, we

propose 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

Part 486, subpart I, outlines certain standards to which home infusion therapy suppliers must adhere. For instance, § 486.520 identifies required components of a home infusion therapy supplier's plan of care; one such component is that all of the home infusion therapy supplier's patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services to be furnished. Section 486.525, meanwhile, lists specific services that the home infusion therapy supplier must furnish.

Additional home infusion therapy supplier provisions are contained in part 414, subpart P. For purposes of our proposed enrollment requirements, we believe the most pertinent of these are—

- Section 414.1505, which outlines several requirements that must be met for home infusion therapy services to be paid.
- Section 414.1515, which identifies plan of care requirements supplemental to those in § 486.520(b).

The aforementioned provisions in parts 486 and 414 reflect important quality standards and payment safeguards that should not, in our view, be entirely separate from our enrollment requirements. Indeed, these provisions, like our enrollment process, help ensure that the home infusion therapy supplier is qualified to furnish such services. Consequently, we propose the following:

- In new § 424.68(c)(4), we propose 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 propose to add a new paragraph (c) stating that, along with the requirements for home infusion therapy payment listed 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) Home Infusion Therapy Suppliers: Categorical Risk Designation

We previously referenced § 424.518, which outlines screening categories and

requirements based on a CMS assessment of the level of risk of fraud, waste, and abuse posed by a particular category 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 two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are intended to correspond to the heightened risk involved with such provider or supplier type.

We propose to add home infusion therapy suppliers to the types of providers and suppliers that are subject to the limited risk level of categorical screening. 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; more precisely, our review of home infusion therapy services furnished by other existing provider and supplier types generally

has not uncovered aberrant billing practices or significant fraud, waste, or abuse.

Our specific regulatory revisions would involve: (1) Redesignating 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

We propose in new § 424.68(d)(1)(i) and (ii), respectively, 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 title; 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 are proposing that a home infusion therapy supplier may appeal the denial of its enrollment application under 42 CFR part 498.

Section 424.68(d)(1)(i) is needed so CMS can ensure that unqualified home infusion therapy suppliers are kept out of the Medicare program. Concerning paragraphs (d)(1)(ii) and (2), the requirements in part 424, subpart P and the appeals provisions in part 498 would apply to home infusion therapy suppliers to the same extent as they would to all other providers and suppliers. Thus, we believe it is appropriate to include paragraphs (d)(1)(ii) and (2) within § 424.68.

e. Continued Compliance, Standards, and Reasons for Revocation

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

In paragraph (e)(1), we propose to state 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 are proposing 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 propose 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 propose to include newly enrolling home infusion therapy suppliers within the scope of both §§ 424.520(d) and 424.521(a). We believe 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.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

The following discusses the information collection requirements associated with § 424.68. Specifically, 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.

1. Enrollment

As discussed in section V.B.2. of this proposed 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 the application fee in accordance with § 424.514.

Using existing accreditation statistics and our internal data, we generally estimate that: (1) There are about 600 home infusion therapy suppliers that would be eligible for Medicare enrollment under our proposed

provisions, all of whom would enroll in the initial year of our requirements; 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 16: 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 be responsible for securing and reporting data on the Form CMS-855B and that this task takes approximately 2 hours. Additionally, the form would be reviewed and signed by a health diagnosing and treating practitioner of the home infusion therapy supplier, a process we estimate takes 30 minutes. Therefore, we project 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 estimate 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 welcome comments on all of these estimates.

2. Appeals

As stated earlier in the preamble, newly proposed § 424.68(d)(2) and (e)(3) state that a home infusion therapy supplier may appeal 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; that is, the denial or revocation of a home infusion therapy supplier enrollment application. Therefore, we have not developed burden estimates. We also note 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, comparatively few denials and revocations of home infusion therapy supplier enrollments.

VII. 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 HH 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 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 proposed rule,

we are proposing to adopt the new OMB delineations and apply 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 would allow the effects of our proposed 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 Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 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 proposed 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 \$540 million (2.6 percent). Therefore, we estimate that this rule is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a 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 proposed in this 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 proposed rule would have a not have 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 603 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 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 proposed 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 are not proposing 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. 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 are no new proposals in this rule related to payments for home infusion therapy services in CY 2021. However, we estimate that the impact of updating the payment rates for home infusion therapy services for CY 2021, based on the PFS amounts for CY 2021, is no more than a 1 to 2 percent increase/decrease in payments (\$1 million or less). The CY 2021 proposed PFS amounts were not available at the time of rulemaking; therefore, this estimate is based on the impact between the CY 2019 PFS amounts compared to the CY 2020 PFS amounts outlined in the CY 2020 HH PPS final rule with comment period (84 FR 60639).

5. Home Infusion Therapy Supplier Requirements

As stated previously, we are proposing 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 cannot predict future changes to the CPI, the fee amounts between 2018 and 2020 increased by an average of \$13 per year. We believe this is a reasonable barometer with which to establish estimates (strictly for purposes of the proposed rule) of the fee amounts in the first 3 CYs of this rule (that is, 2021, 2022, and 2023). Thus, we project 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 estimate 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 constitutes an average annual figure over the first 3 years of this proposed requirement of \$142,517). As referenced in Table 1 of this proposed rule, this would represent a transfer from home infusion therapy suppliers to the federal government.

As noted in Table 1 and section VI.B.1. of this proposed 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.

6. 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 proposed rule would be the similar to the number of commenters on last 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 welcome any comments on the approach in estimating the number of entities which would review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$109.36 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 1.3 hours for the staff to review half of this proposed rule, which consists of approximately 39,000 words. For each HHA that reviews the rule, the estimated cost is \$142.17 (1.3 hours \times \$109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is \$79,614 ($\142.17×560 reviewers). For purposes of this estimate, the number of anticipated reviewers in this year's rule is equivalent to the number of commenters on the CY 2020 HH PPS proposed rule.

D. Detailed Economic Analysis

This rule proposes updates to Medicare payments under the HH PPS for CY 2021. The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed 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 HH 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 17 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2021. For this analysis, we used an analytic file with linked CY 2019 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2019. The first column of Table 17 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 proposed in this rule.

Overall, it is projected that aggregate payments in CY 2021 would increase by 2.6 percent. As illustrated in Table 17, 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 17: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2021

	Number of Agencies	CY 2021 Updated Wage Index (CY2020 Payments)	OMB Delineations with 5 percent Cap	CY 2021 Rural Add-On	CY 2021 HH Payment Update Percentage	Total Impact
All Agencies	9,758	0.0%	0.0%	-0.1%	2.7%	2.6%
Facility Type and Control						
Free-Standing/Other Vol/NP	961	-0.1%	0.0%	-0.1%	2.7%	2.5%
Free-Standing/Other Proprietary	7,867	0.0%	0.0%	-0.1%	2.7%	2.6%
Free-Standing/Other Government	196	0.3%	0.1%	-0.3%	2.7%	2.8%
Facility-Based Vol/NP	514	0.1%	0.1%	-0.2%	2.7%	2.7%
Facility-Based Proprietary	57	-0.2%	0.3%	-0.2%	2.7%	2.6%
Facility-Based Government	163	-0.1%	0.1%	-0.3%	2.7%	2.4%
Subtotal: Freestanding	9,024	0.0%	0.0%	-0.1%	2.7%	2.6%
Subtotal: Facility-based	734	0.1%	0.1%	-0.2%	2.7%	2.7%
Subtotal: Vol/NP	1,475	0.0%	0.0%	-0.1%	2.7%	2.6%
Subtotal: Proprietary	7,924	0.0%	0.0%	-0.1%	2.7%	2.6%
Subtotal: Government	359	0.1%	0.1%	-0.3%	2.7%	2.6%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	228	0.1%	0.0%	-0.7%	2.7%	2.1%
Free-Standing/Other Proprietary	814	0.2%	0.0%	-0.5%	2.7%	2.4%
Free-Standing/Other Government	131	0.2%	0.1%	-0.8%	2.7%	2.2%
Facility-Based Vol/NP	233	0.1%	0.0%	-0.7%	2.7%	2.1%
Facility-Based Proprietary	26	0.5%	0.5%	-0.6%	2.7%	3.1%
Facility-Based Government	125	0.3%	0.0%	-0.7%	2.7%	2.3%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	733	-0.1%	0.0%	-0.1%	2.7%	2.5%
Free-Standing/Other Proprietary	7,053	0.0%	0.0%	-0.1%	2.7%	2.6%
Free-Standing/Other Government	65	0.4%	0.1%	-0.1%	2.7%	3.1%
Facility-Based Vol/NP	281	0.1%	0.1%	-0.1%	2.7%	2.8%
Facility-Based Proprietary	31	-0.5%	0.2%	-0.1%	2.7%	2.3%
Facility-Based Government	38	-0.4%	0.1%	-0.1%	2.7%	2.3%
Facility Location: Urban or Rural						
Rural	1,557	0.2%	0.0%	-0.6%	2.7%	2.3%
Urban	8,201	0.0%	0.0%	-0.1%	2.7%	2.6%
Facility Location: Region of the Country (Census Divisions)						
New England	335	-1.1%	-0.1%	-0.1%	2.7%	1.4%
Mid Atlantic	452	0.5%	0.3%	-0.1%	2.7%	3.4%
East North Central	1,740	0.0%	-0.1%	-0.1%	2.7%	2.5%
West North Central	648	-0.5%	0.0%	-0.3%	2.7%	1.9%
South Atlantic	1,566	0.1%	0.0%	-0.1%	2.7%	2.7%
East South Central	381	0.0%	0.0%	-0.3%	2.7%	2.4%
West South Central	2,378	0.2%	0.0%	-0.1%	2.7%	2.8%
Mountain	683	-0.2%	0.0%	-0.1%	2.7%	2.4%
Pacific	1,535	0.1%	0.1%	0.0%	2.7%	2.9%
Outlying	40	-1.1%	-0.2%	-0.1%	2.7%	1.3%

	Number of Agencies	CY 2021 Updated Wage Index (CY2020 Payments)	OMB Delineations with 5 percent Cap	CY 2021 Rural Add-On	CY 2021 HH Payment Update Percentage	Total Impact
Facility Size (Number of 60-day Episodes)						
< 100 episodes	2,578	-0.1%	0.0%	-0.1%	2.7%	2.5%
100 to 249	2,087	-0.1%	0.0%	-0.1%	2.7%	2.5%
250 to 499	2,004	-0.1%	0.0%	-0.1%	2.7%	2.5%
500 to 999	1,612	0.0%	0.0%	-0.1%	2.7%	2.6%
1,000 or More	1,477	0.0%	0.0%	-0.1%	2.7%	2.6%

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 March 13, 2020)

Notes: This analysis omits 710,316 simulated 30-day periods not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). Additionally, another 38,192 periods were excluded with missing wage index information, a further 7 periods were excluded with missing NRS weights, and 2,040 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 Home Health Prospective Payment Rate Update, we considered alternatives to the proposals articulated in section III.D of this proposed 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 proposal as shown in the regulatory impact analysis of this proposed 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 18, 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 18: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2020 TO 2021

Category	Transfers
Annualized Monetized Transfers	\$540 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 proposed 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 proposed rule would result in an estimated net increase in HH payments of 2.6 percent for CY 2021 (\$540 million). The \$540 million increase in estimated payments for CY 2021 reflects the effects of the CY 2021 home health payment update percentage of 2.7 percent (\$560 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).

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

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 proposes to amend 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 a telecommunications system and 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.

(C) A description of how the use of such technology will help to achieve the goals outlined on the plan of care.

(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) technology; 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.

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

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

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

■ 6. 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

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

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

■ 8. 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 of part 424, subpart P of this chapter.

(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 part 424, subpart P of this chapter.

(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 part 424, subpart P of this chapter.

(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 of this title.

(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 part 424, subpart P of this chapter.

(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) Part 424, subpart P of this chapter;

(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) Part 424, subpart P of this chapter;

(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.

■ 9. 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.

* * * * *

■ 10. 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—

* * * * *

■ 11. 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

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

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

§ 484.45 [Amended]

■ 13. 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.

Dated: June 12, 2020.

Seema Verma,

*Administrator, Centers for Medicare and
Medicaid Services.*

Dated: June 19, 2020.

Alex M. Azar II,

*Secretary, Department of Health and Human
Services.*

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