**Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements**
**(CMS-1730-F)**

Summary of Final Rule

On November 4, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a final rule addressing updates to the Home Health Prospective Payment System (HH PPS) rates for calendar year 2021,[1] home infusion therapy services requirements, and related matters (85 FR 70298). Among other things, the final rule provides for a 2.0 percent update to the HH PPS rates, adopts new wage area delineations, makes permanent changes with respect to including telecommunication services in the home health plan of care that were adopted for purposes of the COVID-19 public health emergency (PHE), and creates new enrollment requirements for qualified home infusion therapy providers. In addition, the rule finalizes Home Health Value-Based Purchasing Model data submission requirements from the Interim Final Rule with Comment Period (IFC) responding to the COVID-19 PHE that was published on May 8, 2020 (85 FR 27550).

Wage index files and other payment data files are available at CMS' Home Health Agency Center website https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center and at https://www.cms.gov/medicaremedicare-fee-service-paymenthomehealthppshome-health-prospective-payment-system-regulations/cms-1730-f.

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[1] Henceforth in this document, a year is a calendar year unless otherwise specified.

## I. Overview

CMS reviews the statutory and regulatory history of the HH PPS from 1997. Most recently, beginning on or after January 1, 2020, Medicare makes payment under the HH PPS based on a national, standardized 30-day period payment rate that is adjusted for the applicable case-mix and wage index. 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), previously paid through a separate adjustment, are now part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service is not included in the national, standardized 30-day period payment.

The Patient Driven Groupings Model (PDGM), also implemented beginning January 1, 2020, is a new patient case-mix adjustment methodology that shifts the focus from volume of services to a model that relies more on patient characteristics. It uses timing of episode, admission source, clinical groups based on principal diagnosis, and level of functional impairment to case-mix adjust payments resulting in 432 unique case-mix groups. Patient characteristics and other clinical information is drawn from Medicare claims and the Outcome and Assessment Information Set (OASIS). In the proposed rule, CMS details how timing, admission source, clinical grouping, functional impairment level, and comorbid conditions are used to establish the PDGM case-mix weights.

For low-utilization episodes, HHAs are paid national per-visit rates based on the discipline(s) providing the services; this payment adjustment is referred to as a low-utilization payment adjustment (LUPA). The national, standardized 30-day episode payment rate is also adjusted for certain intervening events that are subject to a partial episode payment (PEP) adjustment. In addition, an outlier adjustment may be available for certain cases that exceed a specific cost threshold.

For 2019 through 2022, payment for home health services provided to beneficiaries residing in rural counties is increased based on three categories of rural county classification (high utilization; low population density; and all others.)

## II. Payment Under the Home Health Prospective Payment System

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

As discussed further below, CMS maintains for 2021 the LUPA thresholds and PDGM case-mix weights that were finalized for 2020. As noted, these factors are shown in Table 16 of the 2020 HH PPS final rule. In addition, CMS has reposted them on its HHA Center webpage: https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.

1. 2021 PDGM LUPA Thresholds

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.[2] LUPA thresholds are set at the 10th percentile value of visits or 2 visits, whichever is higher for each payment group. That is, the LUPA threshold for each 30-day period of care varies based on the PDGM payment group to which it is assigned. If the LUPA threshold is met, the 30-day period of care is paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment is made using the per-visit payment amount.

CMS adopted a policy that the LUPA thresholds would be updated each year based on the most current utilization data available. However, because 2020 is the first year of implementation of the PDGM and the 30-day period of care, CMS does not have sufficient data to update the thresholds for 2021. Therefore, CMS maintains the thresholds adopted for 2020, as shown in Table 16 of the HH PPS final rule for 2020 (84 FR 60522). Those thresholds were based on 2018 Medicare home health claims as of July 31, 2019, linked to OASIS assessment data.

2. 2021 PDGM Case-Mix Weights

For 2020, CMS determined the PDGM case-mix weights using a data file based on home health 30-day periods of care, as reported in the 2018 Medicare home health claims available as of July 31, 2019, linked to OASIS assessment data to obtain patient characteristics. The claims data provide visit-level data and data on whether NRS were provided during the period and the total NRS charges. CMS determined the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model, as discussed in detail in the proposed rule. The case-mix weight is then used to adjust the base payment to determine each 30-day period's payment. Table 15 in the 2020 HH PPS final rule (84 FR 60521) shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use for PDGM payment groups. The final 2020 case-mix weights that CMS maintains for 2021 are provided in Table 16 of the 2020 HH PPS final rule (84 FR 60522).

Although CMS plans to annually recalibrate the case-mix weights using the most current data available, due to limited data for 2020, it will continue to use the 2020 case-mix weights for the 2021 HH PPS. As with the decision to maintain the LUPA thresholds into 2021, CMS believes this will be less burdensome to HHAs and software vendors who are still learning the new case-mix methodology.

[2] The thresholds previously in place for 60-day episodes of care resulted in LUPAs accounting for about 7 to 8 percent of episodes, and CMS set 30-day thresholds to achieve about the same percentage of LUPA episodes under the PDGM.

## B. Home Health Wage Index

CMS updates the home health wage index to reflect updates to the Office of Management and Budget (OMB) designations of Metropolitan and Micropolitan Statistical Areas.[3] In particular, for 2021, the wage index reflects changes included in OMB Bulletin No. 18-04, issued on September 14, 2018. That bulletin is available at https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf. Further, CMS notes that on March 6, 2020, OMB issued OMB Bulletin 20-01—available on the web at https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf—but it was not issued in time for development of the proposed rule. CMS plans to assess the changes in that latest bulletin and propose adoption of any updates in future rulemaking.

The changes included in OMB Bulletin No 18-04 result in new Core Based Statistical Areas (CBSAs), changing 34 urban counties to rural, 47 rural counties to urban, and splitting some existing CBSAs. Tables 3, 4, and 6 in the final rule detail these substantive changes; Table 5 identifies areas where only the CBSA name or number is changed, without affecting assignment of a wage index.

To mitigate any negative impact of these changes in the wage index, CMS adopts the changes in OMB Bulletin 18-04 beginning with the 2021 HH PPS wage index, and provides for a 5 percent cap on decreases in any HHA's wage index for 2021 when compared to 2020. The cap provides for a transition to the new wage index areas. No cap will be applied in 2022.

Readers are referred to the final rule wage index tables available on the HHA Center webpage, which includes a crosswalk between the current and revised wage areas. More information regarding the counties that will receive the transition wage index will be provided in the upcoming Home Health Payment Update Change Request located at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2020-Transmittals.

Table 18 in the final rule, reproduced in section V of this summary, shows the impact of the new wage area delineations by type of HHA.

## C. 2021 Home Health Payment Rate Updates

1. 2021 Home Health Market Basket Update for HHAs

Unlike for 2020, there is no specific statutory market basket update for the HH PPS for 2021. The update equals the projected increase in the market basket adjusted for changes in economy-wide productivity. Based on IHS Global Insight Inc.'s third-quarter 2020 forecast for 2021 with historical data through the first quarter of 2020, the final HH PPS market basket update is as follows:

[3] OMB defines a Micropolitan Statistical Area as an area 'associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000. Under previously adopted policies, CMS treats these as rural areas for purposes of the hospital and home health wage indexes.

| Market Basket Update | Change (in %) |
|---|---|
| Market basket forecast | 2.3 |
| Multifactor productivity (MFP) | -0.3 |
| **Net update for HHAs reporting quality data** | **2.0** |
| **Net update for HHAs NOT reporting quality data** | **0.0** |

As discussed below, the payment rates for 2021 are also adjusted to reflect a wage index budget neutrality adjustment.

CMS notes that the 2.3 percent market basket forecast is considerably lower than the 3.1 percent forecast reflected in the proposed rule. That earlier forecast was based on data through the end of 2019 and did not reflect the effects of the COVID-19 pandemic. The lower forecast is primarily driven by the expectation of slower compensation growth for both health-related and other occupations as labor markets are expected to continue to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.

The multifactor productivity (MFP) forecast of 0.3 percent is also less than the 0.4 percent included in the proposed rule. This latest forecast is based on the IGI September 2020 macroeconomic forecast for MFP because it is more recent. However, CMS notes that the third quarter 2020 IGI forecast of MFP is also 0.3 percentage points.

2. 2021 Home Health Wage Index

CMS continues use of the pre-floor, pre-reclassified hospital wage index as the wage index to adjust the labor portion of HH PPS rates for 2021, using FY 2017 hospital cost report data as its source for the updated wage data. As discussed above, CMS will transition to adoption of revisions to the delineations of Metropolitan Statistical Areas (MSAs) and the creation of Micropolitan Statistical Areas, and CBSAs set forth in OMB Bulletin No. 18-04, issued on September 14, 2018. For urban areas without an inpatient hospital, CMS will continue to use the average wage index from all other urban areas in the state; this currently involves only Hinesville, GA. For rural Puerto Rico, the most recently available wage index for the area will continue to be used.

3. 2021 Annual Payment Update

*a. Background*. CMS discusses the methodology it uses to compute the case-mix and wage-adjusted 30-day period rates as set forth in §484.215. It first multiplies the national, standardized 30-day period rate by the patient's applicable case-mix weight. It then divides the case-mix adjusted amount into labor (76.1 percent) and non-labor (23.9 percent) portions. The labor portion is multiplied by the appropriate wage index based on the site of service and summed to the non-labor portion.

Next, CMS may adjust the resulting 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect:

- A LUPA is provided on a per-visit basis (§§484.205(d)(1) and 484.230).

- A partial episode payment (PEP) adjustment (§§484.205(d)(2) and 484.235).
- An outlier payment (§§484.205(d)(3) and 484.240).

Implementation of the PDGM and the 30-day unit of payment began in 2020, and CMS is required to annually analyze data (for 2020 through 2026) to assess the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. For 2021, CMS is not making any additional changes to the 30-day payment rate other than the routine updates described further below. It continues to monitor the impact of the case-mix and unit of payment changes on patient outcomes and program expenditures, but believes that it would be premature to release information based on the limited data available and in light of the COVID-19 public health emergency. In future rulemaking, CMS plans to consider analysis of actual versus assumed behavior change to determine whether any changes need to be made to the national, standardized 30-day period payment rate.

*b. 2021 National, Standardized 30-Day Period Payment Amount*. To determine the 2021 national, standardized 30-day period payment rate, CMS applies a wage index budget neutrality factor and the home health payment update percentage. (No case-mix budget neutrality adjustment is necessary because CMS is maintaining the 2020 case-mix weights for 2021. In future years CMS will apply a case-mix budget neutrality factor to account for changes between the previous year's PDGM case-mix weights and the recalibrated weights.) The following table shows the final standardized amounts, as displayed in final rule Tables 7 and 8.

| **Final 2021 National, Standardized 30-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data** | | |
|---|---|---|
| | HHAs submitting quality data | HHAs not submitting quality data |
| 2020 30-day budget neutral standardized amount | $1,864.03 | |
| Wage index budget neutrality factor | x 0.9999 | |
| HH payment update percentage | x 1.020 | x 1.000 |
| **2021 30-day payment amount** | **$1,901.12** | **$1,863.84** |

CMS describes comments it received regarding the behavior adjustment assumption that was made in establishing the 2020 rates as the PDGM was implemented. Commenters recommended that CMS reduce or eliminate the 4.36 percent behavior assumption reduction to the national standardized 30-day period payment rate for the remainder of 2020 and for 2021 rate setting. They argued that effects of the COVID-19 PHE together with the payment system changes have changed patient mix and reduced use of home health services, so it is unlikely that Medicare spending on home health services in 2020 is budget neutral in comparison to what spending would have been without introduction of the PDGM and a 30-day unit of payment.

In reply, CMS reviews its statutory obligations to include a behavior assumption in calculating budget neutrality under the new payment system, and reminds readers that in finalizing the 2020 HH PPS payment rates it elected to apply a 4.36 percent reduction in response to comments when it had calculated a potential 8.4 percent reduction. In addition, the law requires that based on data for 2020 through 2026, CMS annually compare the effect of assumed and actual behavior changes on expenditures and then make permanent and temporary adjustments to the

30-day payment amounts to correct for any over- or under-estimates. Any changes in utilization of home health services would not affect these calculations, which will be made through notice and comment rulemaking. Finally, CMS notes the actions it has taken to provide HHAs with flexibilities in light of the COVID-19 PHE, which include allowing use of telecommunications technology, extending the requirement for the completion of a comprehensive assessment from 5 days to 30 days, waiving the 30-day OASIS submission requirement, waiving the requirements that limit rehabilitation skilled professionals to performing the initial and comprehensive assessment when only therapy services are ordered, and including physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services.

*c. 2021 National Per-Visit Rates for 30-Day Periods of Care*. Computations are presented for the 2021 per-visit amounts for each type of service. These amounts are used for LUPAs and in outlier calculations. Note that the wage index budget neutrality adjustment is calculated separately for the 30-day episode payment amount and these per-visit rates. The final per-visit amounts for those HHAs submitting the required quality data (Table 9 in the final rule) are as follows:

| **Final 2021 National, Per-Visit Payment Amounts for HHAs that Submit Quality Data** | | | | |
|---|---|---|---|---|
| **HH Discipline** | **CY 2020 Per-Visit Payment** | **Wage Index Budget Neutrality Factor** | **CY 2021 HH Payment Update** | **CY 2021 Per-Visit Payment** |
| Home Health Aide | $67.78 | X 0.9997 | X 1.020 | $69.11 |
| Medical Social Services | $239.92 | X 0.9997 | X 1.020 | $244.64 |
| Occupational Therapy | $164.74 | X 0.9997 | X 1.020 | $167.98 |
| Physical Therapy | $163.61 | X 0.9997 | X 1.020 | $166.83 |
| Skilled Nursing | $149.68 | X 0.9997 | X 1.020 | $152.63 |
| Speech-Language Pathology | $177.84 | X 0.9997 | X 1.020 | $181.34 |

HHAs that do not submit required quality data would have the payment update for per-visit services reduced from 2.0 percent to 0.0 percent, resulting in the following payment rates (from Table 10 in the final rule):

| **Final 2021 National, Per-Visit Amounts for HHAs that Do Not Submit Quality Data** | | | | |
|---|---|---|---|---|
| **HH Discipline** | **CY 2020 Per-Visit Rates** | **Wage Index Budget Neutrality Factor** | **CY 2021 HH Payment Update Minus 2 Percentage Points** | **CY 2021 Per-Visit Rates** |
| Home Health Aide | $67.78 | X 0.9997 | X 1.000 | $67.76 |
| Medical Social Services | $239.92 | X 0.9997 | X 1.000 | $239.85 |
| Occupational Therapy | $164.74 | X 0.9997 | X 1.000 | $164.69 |
| Physical Therapy | $163.61 | X 0.9997 | X 1.000 | $163.56 |
| Skilled Nursing | $149.68 | X 0.9997 | X 1.000 | $149.64 |
| Speech- Language Pathology | $177.84 | X 0.9997 | X 1.000 | $177.79 |

CMS reminds stakeholders that as adopted in the 2020 HH PPS final rule (84 FR 60544), for 2021 all HHAs (both existing and newly-enrolled HHAs) must submit a "no-pay" Request for Anticipated Payment (RAP) at the beginning of each 30-day period. This will establish the home health period of care in the common working file and also trigger the consolidated billing edits. A payment reduction is applied if the HHA does not submit the RAP within 5 calendar days from the start of care. The reduction equals one-thirtieth of the wage and case-mix adjusted 30-day period payment amount, including any outlier payment, for each day from the home health start of care date until the date the HHA submitted the RAP. For LUPA 30-day periods for which an HHA fails to submit a timely RAP, no LUPA payments will be made for days that fall within the period from the start of care prior to submission of the RAP. These days would be a provider liability; the payment reduction cannot exceed the total payment of the claim; and the provider may not bill the beneficiary for these days. Beginning in 2022, HHAs will submit a one-time Notice of Admission (NOA) that includes similar information to the 2021 RAP. The NOA will establish the home health period of care and covers all contiguous periods of care until the patient is discharged from Medicare home health services, and similar penalties for failure to timely submit the NOA will apply.

In response to comments, CMS offers an example to clarify how it calculates non-timely submission payment reductions and disagrees with commenters' recommendation that the penalty begin on day 6 of the 30-day period. CMS also discusses exceptions to the timely filing consequences of the RAP requirements, which include fires, floods, earthquakes, and other damaging events; issues with CMS or Medicare contractor systems; and other situations CMS determines to be out of the HHA's control.

*d. LUPA Add-on Factors.* Under previously adopted policy, to determine the LUPA add-on payment for a 30-day period of care, CMS multiplies the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in a LUPA period that is the first 30-day period of care or the initial 30-day period of care in a sequence of adjacent periods. The add-on factors are 1.8451 for skilled nursing, 1.6700 for physical therapy, and 1.6266 for speech-language pathology.

*e. Rural Add-On Payments for 2021 and 2022*. Section 50208(a)(1)(D) of the BBA of 2018 provides rural add-on payments for episodes and visits ending during 2019 through 2022. In the 2019 HH PPS final rule (83 FR 56443), CMS finalized policies for 2019 through 2022 for these rural add-on payments. The three categories for purposes of rural add-on payments are: (1) High utilization category: 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; (2) Low population density category: rural counties and equivalent areas with a population density of six individuals or fewer per square mile of land area; and (3) All other category: rural counties and equivalent areas not in the above categories.[4]

[4] The data used to categorize each county or equivalent area and an Excel file containing the rural county or equivalent area name, its Federal Information Processing Standards (FIPS) state and county codes, and its designation into one of the three rural add-on categories is available on the CMS website at: https://www.cms.gov/medicaremedicare-fee-service-paymenthomehealthppshome-health-prospective-payment-system-regulations/cms-1730-f.

The HH PRICER module within CMS' claims processing system applies the rural add-on amounts prior to applying any case-mix and wage index adjustments. Table 11 of the final rule lists the 2019 through 2022 rural add-on payments outlined in law.

| Table 11: HH PPS Rural Add-On Percentages, 2020-2022 | | | | |
|---|---|---|---|---|
| **Category** | **2019** | **2020** | **2021** | **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 |

Responding to commenter concerns about the impact of the statutory phase-out of the rural-add on payments, CMS states that it will continue to monitor urban and rural differences in patient access to home health services and the cost of providing these services.

*f. Payments for High-Cost Outliers Under the HH PPS.* Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and a wage-adjusted fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost for the episode that surpasses the wage-adjusted threshold; this proportion is referred to as the loss-sharing ratio.

CMS notes that the FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the aggregate level of 2.5 percent of estimated total payments as required by statute. CMS has historically used a value of 0.80 for the loss-sharing ratio, meaning that Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount. No changes are made to the loss-sharing ratio for 2021.

For 2021 payment CMS maintains the 2020 fixed-dollar loss ratio of 0.56 for 30-day periods of care (84 FR 60544). (CMS apologizes for a typo in the proposed rule which suggested the ratio was 0.63.)

The final rule reviews the history of HH PPS policy regarding outlier payments. In the 2017 HHS PPS final rule (81 FR 76702), CMS finalized changes to its methodology used to calculate outlier payments, switching from a cost-per-visit approach to a cost-per-unit approach. CMS now converts the national per-visit rates into per 15-minute unit rates. CMS also limits 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. CMS will publish the cost-per-unit amounts for 2021 in the rate update change request to be issued after the publication of the 2021 HH PPS final rule.

**D. Use of Telecommunications\Technology Under the Medicare Home Health Benefit**

HHAs can furnish services via a telecommunications system, as long as such services do not: (1) substitute for in-person home health services ordered as part of a plan of care certified by a physician; and (2) are not considered a home health visit for purpose of eligibility or payment. In the 2019 HH PPS final rule (83 FR 56527), CMS finalized that remote patient monitoring is one type of service that can be furnished via a telecommunications system to augment a home health plan of care without substituting for an in-person visit. Remote patient monitoring was defined as the collection of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the HHA. The costs of remote patient monitoring are considered allowable administrative costs if the monitoring is used by the HHA to augment the care planning process.

In the March 2020 Public Health Emergency (PHE) Interim Final Rule with Comment Period (85 FR 19230), CMS amended the regulations at §409.43(a) on an interim basis to provide HHAs with the flexibility to use various types of telecommunications systems, in addition to remote patient monitoring, in conjunction with the provision of in-person visits. Specifically:

- The plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system, and these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment.
- The plan of care must include a description of how the use of such technology will help to achieve the goals outlined in the plan of care.
- The use of the technology must be related to the skilled services being furnished by the nurse/therapist/therapy assistant to optimize the services furnished during the home visit or when there is a home visit.

In addition, on an interim basis, HHAs can report the costs of telecommunications technology as allowable administrative and general costs by identifying the costs using a subscript between line 5.01 through line 5.19. Stakeholders have informed CMS that these technologies are important components of home health services provided outside the PHE.

In addition, section 3707 of the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act (Pub. L. 116-136) requires the Secretary of HHS to consider ways to issue guidance encouraging the use of telecommunications, including remote monitoring, consistent with the plan of care for home health services.

CMS believes that the provision of in-person visits and telecommunications technology is an important part of home health services and proposed to permanently finalize the amendments to §409.43(a) to provide HHAs with the flexibility to use various types of telecommunications systems, in addition to remote patient monitoring, in conjunction with the provision of in-person visits. CMS also proposed to amend the allowable administrative costs in §409.46(e) to include not only the costs of telehealth/telemedicine but also other communications or monitoring services, consistent with the plan of care for the individual.

Commenters overwhelming supported CMS' acknowledgement of the benefits from telecommunications technology in providing home health care. Many supported the proposals to allow the use of telecommunications as part of the home health plan of care beyond the PHE and

to allow telecommunications technology reported as allowable administrative costs on the home health cost report. Some commenters recommended CMS permit telecommunications beyond the PHE to also include audio-only technology. A few commenters thought CMS needed to put safeguards in place to ensure that in-person visits continue and that patients have the ability to choose whether or not they receive services via telecommunications technology. Commenters suggested CMS monitor and analyze the effects of these policy changes on beneficiary care and program costs.

In response to comments, CMS states that telecommunications technologies cannot replace in-person visits, and consistent with in-person care, it expects physicians and allowed practitioners to only order services provided by telecommunications technology when it is in the best interest of the patient and the patient would benefit from services provided by this technology. CMS agrees with comments about the importance of audio-only technology and will clarify in the regulations that any available form of telecommunications technology or audio-only technology may be included on the plan of care when ordered by the physician as a means to furnish a skilled service. CMS plans to monitor and analyze cost report data and will consider potential options for collecting data on the use of telecommunications technology to expand monitoring and evaluation.

Several commenters raised concerns about the proposed plan of care requirement and suggested CMS allow medical record documentation to support the use of telecommunications technology and limit the plan of care requirement to the physician's order permitting the use of the technology. In response, CMS states the home health CoPs at §484.60 require the individualized plan of care to specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including the types of services, supplies, and equipment required to meet these needs. CMS believes requiring that services furnished through telecommunications technology be incorporated into the plan of care ensures that each patient is evaluated during the comprehensive assessment and care planning process for the appropriateness of using this technology. CMS does agree with comments that the medical record could be a source for documenting how the technology is being used and how the patient is benefiting from the technology and will not require as part of the plan of care, a description of how the use of the technology will help to achieve the goals outlined in the plan of care.

*Final Decision*: CMS finalizes its proposal, with modifications, to require that any provision of remote patient monitoring or other services furnished via a telecommunications system or audio-only technology must be included in the plan of care, cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of eligibility or payment. The use of telecommunications technology or audio-only technology is required to be linked to the patient-specific needs identified in the comprehensive assessment, but CMS will not require a description of how the technology will help achieve the goals outlined in the plan of care. CMS modifies its proposal and finalizes that documentation throughout the medical record must indicate how the technology helps achieve the goals outlined in the plan of care when the technology is used. CMS also finalizes the regulation text changes allowing a broader use of telecommunications technology to be considered allowable administrative costs on the home health cost report.

## E. Care Planning for Medicare Home Health Services

CMS makes corrections to regulatory text regarding non-physician practitioners (NPPs) in accordance with changes that were finalized in the May 8, 2020 COVID-19 IFC. That IFC implemented section 3708 of the CARES Act, which allows a Medicare-eligible home health patient to be under the care of an NP, CNS, or a PA who is working in accordance with state law. These NPPs can: (1) order home health services; (2) establish and periodically review a plan of care for home health services (e.g., sign the plan of care), and (3) certify and re-certify that the patient is eligible for Medicare home health services. The CARES Act also allows these NPPs to certify that an individual has a bone fracture related to post-menopausal osteoporosis and that the individual is unable to self-administer the osteoporosis drug. These changes, effective March 1, 2020, are effective for Medicare claims with a "claim through date" on or after March 1, 2020. The changes are permanent and not limited to the period of the COVID-19 PHE.

Specifically, CMS is finalizing in this rule conforming changes at §§409.64(a)(2)(ii), 410.170(b), and 484.110 regarding "allowed practitioner" certification as a condition for payment for home health services. CMS is making the changes under a good cause waiver of proposed rulemaking. The changes were not included in the HH PPS proposed rule or proposed elsewhere. However, CMS describes the changes as conforming regulatory text changes and not substantive policy changes, making further notice and comment rulemaking unnecessary and contrary to the public interest.

## III. Other Home Health Related Provisions

## A. Home Health Care Quality Reporting Program (HH QRP)

CMS provides background on the HH QRP, the pay-for-reporting program implemented in 2007 under which the market basket percentage increase is reduced by 2 percentage points for HHAs that do not report required quality data. The previously adopted and finalized measures are shown in the following table. No changes to the HH QRP are were proposed for 2021.

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**Summary Table: Measures for the 2021 and 2022 HH QRP**
(2022 changes noted *in italics)*

| 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 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) Home Health Quality Reporting Program |
| 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 (NQF #0522) |
| Oral Medications | Improvement in Management of Oral Medication (NQF #0176) |

| Short Name | Measure Name & Data Source |
|---|---|
| Pain | Improvement in Pain Interfering with Activity (NQF #0177) *Removed in 2022* |
| Pressure Ulcers | Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury\ |
| Timely Care | Timely Initiation of Care (NQF #0526) |
| *Transfer of Health Information* | *Transfer of Health Information to the Patient-PAC Measure - Added in 2022*<br>*Transfer of Health Information to the Provider-PAC Measure - Added in 2022* |
| **Claims-based** | |
| ACH | Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) |
| DTC | Discharge to Community-Post Acute Care (PAC) HH QRP* |
| ED Use | Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173) |
| MSPB | Total Estimated Medicare Spending Per Beneficiary (MSPB) –PAC HH QRP |
| PPR | Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health Quality Reporting Program |
| **HHCAHPs-based** | |
| Communication | How well did the home health team communicate with patients |
| Overall Rating | How do patients rate the overall care from the home health agency |
| Professional Care | How often the home health team gave care in a professional way |
| Team Discussion | Did the home health team discuss medicines, pain, and home safety with patients |
| Willing to Recommend | Would patients recommend the home health agency to friends and family |
| *Baseline NF residents excluded from this measure beginning with the 2021 HH QRP. | |

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

CMS finalizes removal of obsolete regulatory text in the CoP for reporting OASIS information. Specifically, §484.45(c)(2) which requires HHAs to successfully transmit test data to the Quality Improvement & Evaluation System Assessment Submission & Processing System or CMS OASIS contractor is removed. Under that requirement, before obtaining a CMS Certification Number (CCN), HHAs would submit data using test or fake CCNs. CMS says this requirement is no longer relevant because the new internet-based CMS data submission system, Internet Quality Improvement & Evaluation System (iQIES), has simplified data submission and no longer supports the use of test or fake CCNs. CMS believes that because 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, they will have a strong incentive to successfully submit their OASIS assessments in the absence of this regulatory requirement.

## C. Home Health Value-Based Purchasing Model (HHVBP) Data Submission

The Home Health Value-Based Purchasing (HHVBP) Model was established in the 2016 Home Health Prospective Payment System final rule (80 FR 68624) as a five-year test in nine states.[5] Participation of all Medicare-certified HHAs providing services in those states is mandatory. The first payment adjustments under the HHVBP were applied to 2018 payments based on data for 2016. HHVBP Model measures include (1) measures drawn from those reported by HHAs under the Home Health Quality Reporting Program (HH QRP), including the Home Health Consumer Assessment of

[5] The nine states (AZ, FL, IA, MD, MA, NE, NC, TN, and WA) were selected using a randomized selection methodology. More information on the HH VBP is available at https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model.

Healthcare Providers and Systems (HHCAHPS) measure; (2) measures calculated from claims data or from data submitted through the Outcome and Assessment Information Set (OASIS) patient assessment instrument; and (3) three HHVBP "New Measures," which are process measures reported by HHAs through a web portal and are not included in the HH QRP.

In this final rule, CMS responds to comments and finalizes without change provisions of the May 8, 2020 IFC affecting the HHVBP Model. The IFC aligned the HHVBP Model data submission requirements with any exceptions or extensions it has provided under the HH QRP during the COVID-19 PHE. Specifically, the IFC provides that if CMS grants an exception from reporting of certain quality data for the HH QRP or extends the deadline for reporting those data during the COVID-19 PHE, the same exception or extension will apply to reporting those same data under the HHVBP Model. The IFC further provides (at a revised §484.315(b)) that reporting of New Measure data under the HHVBP Model is subject to any exceptions or extensions CMS may grant to HHAs during the COVID-19 PHE.

CMS has exempted all HHAs from the HH QRP reporting requirements[6] with respect to the period October 1, 2019 through June 30, 2020. HHAs that do not submit data for those quarters (i.e., Q4 of 2019 (October 1, 2019 – December 31, 2019); Q1 of 2020 (January 1, 2020 – March 31, 2020) and Q2 of 2020 (April 1, 2020 – June 30, 2020)) will not have their annual market basket percentage increase reduced by two percentage points. Under the IFC policy, HHAs in the nine HHVBP Model states do not have to report data for this period on the overlapping measures for purposes of the Model. Any future exceptions or extensions for other CY 2020 reporting periods would similarly be extended to the HHVBP Model. With respect to the three New Measures, the IFC provides an exception to all HHAs participating in the HHVBP Model from the following requirements for reporting on New Measures:

- April 2020 New Measures submission period (data collection period October 1, 2019 – March 31, 2020).
- July 2020 New Measures submission period (data collection period April 1, 2020 – June 30, 2020).

CMS notes that although the April 2020 submission period includes data for 2019, these data are used for calculating total performance scores under the HHVBP for the 2020 performance period. In addition, it notes that under the COVID-19 exceptions, HHAs still have the option to submit part or all of the required data by the submission deadlines.

If further exceptions are provided, CMS will communicate this decision to HHAs participating in the HHVBP Model through normal communication channels, including memos, emails and the HHVBP Connect website.

Finally, CMS acknowledges that the exceptions to reporting of HH QRP measures and New Measures under the HHVBP Model may impact the calculation of performance scores under the Model for the 2020 performance year. Even though claims-based measures would still be calculated, CMS will need to assess the appropriateness of using claims data for the period of the COVID-19 PHE in assessing performance under the HHVBP Model for 2022 payment. It is considering possible

[6]See the March 27, 2020 CMS guidance memo: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf

approaches, such as changing the weighting of measures, and is also evaluating possible changes to public reporting of CY 2020 performance year data. Any changes will be addressed in future rulemaking.

## IV. Home Infusion Therapy

Sections A through C below describes provisions of the 2021 HH PPS final rule that are unchanged (except for updates to payment amounts or other minor changes) from policy CMS adopted in the 2020 HH PPS rule.

### A. Medicare Coverage of Home Infusion Therapy Services

1. Background

The 21st Century Cures Act established a new Medicare home infusion therapy benefit effective January 1, 2021. At the same time, the 21st Century Cures Act changed payment for home infusion drugs from 95 percent of the October 2003 average wholesale price (AWP) to the latest quarter's average sales price plus 6 percent effective January 1, 2017. This statutory change resulted in a large reduction in payment for home infusion drugs. Specialty pharmacies have indicated that they used the margins from 95 percent of AWP to furnish home infusion therapy services. The Balanced Budget Act of 2018 later established a home infusion therapy services benefit transitional payment beginning January 1, 2019, effective two years earlier than the permanent home infusion therapy benefit.

Under the home infusion therapy benefit, Medicare Part B will cover professional services, including nursing services, training and education (not otherwise paid for as durable medical equipment (DME))[7], remote monitoring, other monitoring services and home infusion drugs furnished by a qualified home infusion therapy supplier in the individual's home. The patient must be under a plan of care established by a physician and under the care of a physician, nurse practitioner, or physician assistant. A home infusion drug is a parenteral drug or biological administered for 15 minutes or more through DME. A "qualified home infusion therapy supplier" is a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished.

Beginning January 1, 2021, a single payment will be made to a qualified home infusion therapy supplier. The single payment amount must be adjusted to reflect wages and other costs that may vary by region, patient acuity, and the complexity of drug administration. The single payment may be adjusted to reflect outlier situations. All payment adjustments are budget neutral. CMS is required to apply an annual update based on the Consumer Price Index for all urban consumers (CPI-U) beginning January 1, 2022. Total payment for a calendar day cannot exceed the amount

[7] CMS distinguishes home infusion therapy from DME. Home infusion therapy services are professional services (such as nursing services) furnished in the patient's home associated with home infusion therapy. Medicare Part B will cover a limited number of home infusion drugs as DME if: (1) the drug is necessary for the effective use of an external infusion pump classified as DME and (2) the pump is reasonable and necessary for administration of the drug and the drug is reasonable and necessary for the treatment of an illness or injury. The infusion pump must be appropriate for use in the home.

that would be paid under the Medicare physician fee schedule in a physician's office for 5 hours of infusion therapy.

Under the transitional payment system, Medicare could pay for self-administered drugs and biologicals covered under the DME local coverage determination (LCD) for External Infusion Pumps (L33794). However, the statute prohibits payment for home infusion therapy for a self-administered drug or biological under the permanent payment system.

Under the transitional payment system in effect for 2019 and 2020, home infusion drugs are assigned to three payment categories based on the HCPCS code for the drug administration.

Category 1: Intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs (both initial and subsequent injection/hour).

Category 2: Subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions (both initial and subsequent injection/hour).

Category 3: Intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals (both initial and subsequent injection/hour).

The home infusion therapy payment category for additions to LCD L33794 and compounded infusion drugs not otherwise classified will be determined by the DME Medicare Administrative Contractors (MAC).

Each payment category is paid at amounts consistent with how the HCPCS codes for the drug administration are paid using the Physician Fee Schedule (PFS). If drugs and 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 is made.

2. Summary of 2019 and 2020 Home Infusion Therapy Provisions

CMS 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. The eligible home infusion supplier submits, in line-item detail on the claim, a G-code for each infusion drug administration calendar day on which professional services were furnished in person. The claim should include the length of time, in 15-minute increments, for which professional services were furnished.

CMS indicates that section 1834(u)(7)(E)(i) of the Act restricts payment to the date on which professional services were furnished. The 2019 final rule defined "infusion drug administration calendar day" as the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home. This definition applies for both the transitional and the permanent home infusion therapy benefit. This policy is controversial and has been the subject of litigation. CMS will monitor the effects of this definition on access to care and, if warranted

and within the limits of its statutory authority, engage in additional rulemaking guidance regarding this definition.

**B. Home Infusion Therapy Services for 2021 and Subsequent Years**

1. Scope of Benefit and Conditions for Payment

a. Home Infusion Drugs

For 2019 and 2020, the term "transitional home infusion drug" includes the HCPCS codes for the drugs and biologicals covered under the LCD L33794. In the 2020 HH PPS final rule with comment period (84 FR 60618), CMS indicated that "home infusion drugs" for the permanent benefit 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.

Consistent with the definition of "home infusion therapy," the home infusion therapy 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. Services covered under the home infusion therapy benefit are intended to provide teaching and training on the provision of home infusion drugs besides the teaching and training under the DME benefit.

b. Patient Eligibility and Plan of Care Requirements

The Medicare statute requires that the beneficiary must be under the care of a physician, nurse practitioner, or physician assistant to be eligible for home infusion therapy. In coordination with the furnishing of home infusion drugs, the statute further requires the beneficiary to be under a plan of care that is established by a physician, prescribes the type, amount, and duration of infusion therapy services to be furnished, and is periodically reviewed. CMS set out these requirements in 42 CFR § 486.520 as *conditions of coverage* for home infusion therapy suppliers to furnish services to Medicare beneficiaries. In the 2020 HH PPS final rule, CMS adopted these same requirements as *conditions of payment* for Medicare to pay for a specific instance of home infusion therapy.

c. Qualified Home Infusion Therapy Suppliers and Professional Services

A "qualified home infusion therapy supplier" is a pharmacy, physician, or other provider of services or supplier licensed by the State in which it furnishes items or services that 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.

CMS does not enumerate a list of "professional services" that may be necessary for the care of an individual patient. The rule specifies that no payment can be made for Medicare services under Part B that are not reasonable and necessary for the diagnosis or treatment of illness.

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 on days in which professional services are not being provided in the home. Care coordination furnished by the DME supplier responsible for furnishing equipment and supplies, including the home infusion drug, is paid for under the DME benefit. Care coordination furnished by the physician who establishes the plan of care is separately billable under the PFS.

d. Home Infusion Therapy and the Interaction with Home Health

Effective January 1, 2021, home infusion therapy is excluded from the definition of the home health benefit. A beneficiary may utilize both benefits concurrently. CMS provides the following billing guidance 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:

- If the 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.
- If the home visit is exclusively for the purposes of providing services furnished under the home health benefit, the HHA would submit a claim for payment as an HHA under the home health benefit.

*Comments/Responses*: In a later section of the rule, CMS indicates that section 5012 of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy from the definition of home health services, effective January 1, 2021. Collectively, commenters expressed disagreement with the proposal to amend §409.49 to exclude services covered under the home infusion therapy services benefit from the home health benefit. Among the comments were the following concerns:

- Beneficiaries would be required to pay 20 percent coinsurance for the home infusion therapy services benefit when utilizing both benefits concurrently, whereas they did not have a coinsurance previously under the home health benefit.
- There will be an insufficient number of eligible entities enrolled as home infusion therapy suppliers if HHAs do not enroll as qualified home infusion therapy suppliers, and there are no home infusion therapy suppliers available to be subcontracted. In this situation, HHAs will be forced to provide unreimbursed services.

CMS responded that section 5012 of the 21st Century Cures Act amended section 1861(m) of the Act to exclude home infusion therapy services from the definition of home health services, effective January 1, 2021. The rule goes on to state that an HHA must be accredited and enrolled in Medicare as a qualified home infusion therapy supplier in order to furnish and bill for home infusion therapy services under the home infusion therapy services benefit. If an HHA does not become accredited and enrolled as a qualified home infusion therapy supplier and is treating a patient receiving a home infusion drug, the HHA must contract with a qualified home infusion therapy supplier to furnish the services related to the home infusion drug. CMS is finalizing its policies without modification.

2. Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

For home infusion therapy services effective beginning in 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. CMS is not creating a mandatory form or requiring 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. If this policy is found to be insufficient, CMS may consider additional requirements in future rulemaking.

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

In the 2020 HH PPS final rule, CMS adopted a policy to carry forward the three temporary transitional payment categories for use with the home infusion therapy services payment in 2021, except it caps payment equal to 5 hours of infusion per day rather than 4 hours. The law indicates that the payment cannot exceed 4 hours per day under the transitional system and 5 hours per day under the permanent system. As is occurring under the transitional payment system, 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, will be grouped into the appropriate payment category by the DME MACs.

Payment for an infusion drug administration calendar day would not vary within each category but would vary between categories. CMS indicates that the values of the CPT infusion code amounts, in accordance with the different payment categories, reflect variations in nursing utilization, patient acuity, and complexity of drug administration, as they are directly proportionate to the clinical labor involved in furnishing the infusion services in the patient's home. The rule states that this policy is consistent with the statutory requirement to vary payment by patient acuity and the complexity of drug administration

CMS adopted a policy in the 2020 HH PPS final rule to increase the payment amounts for each of the three payment categories for the first visit by the relative difference in payment for a new patient versus an established patient evaluation and management service for a given year. Overall, this adjustment would be budget-neutral. Using a 2020 PFS base rate of $160.22, the home infusion therapy policy results in a 60 percent increase in the first visit payment amount and a 3.72 percent decrease in subsequent visit amounts.

CMS plans to monitor home infusion therapy service lengths of visits, both initial and subsequent, in order to evaluate whether the data substantiates the increase to the initial visit payment amount or if it should be reevaluated.

The below table provides the payment amounts for home infusion therapy for each of the three categories based on the 2020 PFS. Final 2021 payments for home infusion therapy will be based on the 2021 PFS and are not yet available.

| INFUSION DRUG J-CODES PAYMENT CATEGORIES FOR 2021 | | | | |
|---|---|---|---|---|
| **HCPCS** | **Drug** | **Codes** | **First Visit[1]** | **Subsequent Visit[1]** |
| **Category 1** | | **96365, 96366** | **$188.85** | **$156.83** |
| 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** | | **96369, 96370** | **$256.83** | **$213.27** |
| J1555 | JB* Injection, immune globulin (cuvitru), 100 mg | | | |
| J1558 | Injection, immune globulin (xembify), 100 mg | | | |
| J1561 | JB* Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg | | | |
| J1562 | JB* Injection, immune globulin (vivaglobin), 100 mg | | | |
| J1569 | JB* Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg | | | |
| J1575 | JB* Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin | | | |
| **Category 3** | | **96413, 96415** | **$319.80** | **$256.57** |
| 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 a subcutaneous route of administration.

[1] For each of the payment categories, CMS proposes to pay 1 unit of the initial infusion hour and 1 unit for each subsequent hour up to a total time of 5 hours. Payment amounts are based on 2021 PFS proposed payments amounts.

There are several drugs that are paid for under the transitional benefit that are not defined as home infusion drugs under the permanent benefit beginning with 2021. CMS indicates the following drugs would be excluded from the permanent benefit:

Hizentra: The product is listed on the self-administered drug (SAD) exclusion list by the MACs. SAD drugs are excluded from the permanent home infusion therapy benefit but not the temporary one.

Ziconotide, Floxuridine and Morphine: These drugs are given via intrathecal (Ziconotide and Morphine) or intra-arterial (Floxuridine) routes, and the statute only allows drugs administered via subcutaneous and intravenous routes to be considered home infusion drugs for the permanent benefit.

Xembify and Cutaquig: Xembify (J1558) and Cutaquig (J7799, a not otherwise classified code being used until Cutaquig is assigned a permanent J code) have been added to LCD L33794 and will be assigned to payment category 2.

CMS notes that the rulemaking process is not needed to update the home infusion therapy benefit when the DME MACs update LCD L33794 to add new home infusion therapy drugs. For new drugs billed under unlisted codes (J7799 and J7999), payment category 1 would include intravenous drugs, payment category 2 would include subcutaneous drugs and payment category 3 would include intravenous chemotherapy or other highly complex drug or biological infusions.

*Comments/Responses:* CMS received comments concerned about the safety of administering some home infusion therapy services in the home; requests to grandfather Hizentra and Ziconotide into the home infusion therapy benefit; and requests to add certain antibiotics and central nervous system agents to the home infusion therapy benefit that may have been covered by a beneficiary's previous commercial insurance.

CMS responded that home infusion therapy drugs are covered under the DME benefit not the home infusion therapy benefit. For the remainder of the comments, CMS indicated that it did not propose any changes and is maintaining the current definition of "home infusion drugs" pursuant to the statutory requirements.

## C. Required Payment Adjustments for 2021 Home Infusion Therapy Services

1. Home Infusion Therapy Geographic Wage Index Adjustment

CMS adopted a policy in the 2020 HH PPS to adjust the single payment amount by the PFS geographic adjustment factor (GAF)—a weighted composite of each PFS locality's physician work, practice expense (PE), and malpractice (MP) geographic practice cost index (GPCI). The GAF is calculated by multiplying the physician 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).

The GAF is updated at least every 3 years per statute and reflects a 1.5 work GPCI floor for services furnished in Alaska as well as a 1.0 PE GPCI floor for services furnished in frontier states (Montana, Nevada, North Dakota, South Dakota, and Wyoming).

The policy applies the GAF to the home infusion therapy single payment amount based on the zip code of where the beneficiary is receiving the service. The list of GAFs by locality for the final rule is available as a downloadable file at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview (penultimate link at the bottom of the page).

Application of the GAF is budget neutral so there is no overall cost impact. If the rates were set using the proposed 2021 PFS payment amounts and GAFs, the budget neutrality factor would be 0.9951. The budget neutrality adjustment was determined as the ratio of the estimated unadjusted national spending total to the estimated GAF-adjusted national spending total. The rule details how CMS determined estimated national spending using 2019 utilization.
2. Payment Update

Consistent with the statute, CMS will increase the single payment amount annually beginning in 2022 by the percentage increase in the CPI-U, reduced by the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity.

**D. Enrollment Requirements for Qualified Home Infusion Therapy Suppliers**

A "qualified home infusion therapy supplier" that:

- 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; and
- Meets such other requirements as the Secretary determines appropriate.

Under this last provision, CMS is establishing enrollment criteria to protect the Medicare program from fraud, waste, and abuse. CMS outlines its enrollment authority and actions that it has taken to prevent unqualified and potentially fraudulent individuals and entities from being able to enroll and inappropriately bill Medicare.

CMS proposed to incorporate the statutory definition of "home infusion therapy supplier" into its regulations as enrollment requirements (those listed above). A "home infusion therapy supplier" must enroll in Medicare and adhere to all enrollment requirements. CMS proposed that a home infusion therapy supplier submit Form CMS-855B, certify that it meets and will continue to meet the specific requirements and standards for enrollment, and pay an application fee of $595. Consistent with the statute and regulations previously adopted, CMS proposed to incorporate accreditation requirements into the enrollment regulations specifying that a home infusion

therapy supplier must be currently and validly accredited by a CMS-recognized home infusion therapy supplier accreditation organization in order to enroll and remain enrolled in Medicare.

Similarly, CMS proposed to adopt the home infusion therapy supplier standards as enrollment requirements. These supplier standards would include that 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 as well as specific services that the home infusion therapy supplier must furnish.

CMS proposed to designate home infusion therapy suppliers as subject to "limited risk" categorical enrollment screening (as opposed to "moderate risk" or "high risk"). This designation requires the following screening functions for 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; and
- 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.

If the home infusion therapy supplier does not meet all of the requirements for enrollment, CMS will deny its application. CMS proposed that a home infusion therapy supplier may appeal the denial of its enrollment application.

CMS proposed that upon and after enrollment, a home infusion therapy supplier must:

- Remain currently and validly accredited; and
- Remain in full compliance with all enrollment requirements, requirements for establishing and maintaining Medicare billing privileges, plan of care requirements and conditions of coverage.

If accreditation requirements, enrollment requirements, requirements for establishing and maintaining Medicare billing privileges, plan of care requirements or conditions of coverage are not met, CMS may revoke a home infusion therapy supplier's enrollment. A home infusion therapy supplier may appeal the revocation of its enrollment.

Consistent with existing enrollment provisions, CMS proposed that the effective date of a home infusion therapy supplier's enrollment will be 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. Covered services may be billed retrospectively 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 precluded enrollment in advance of providing services to Medicare beneficiaries.

*Comments/Responses:* A selection of the most salient comments and CMS' response follows:

- By not accepting enrollment applications until after the final rule is issued, CMS is giving home infusion therapy suppliers only 2 months to complete the enrollment process before the home infusion therapy supplier benefit commences on January 1, 2021. CMS responded that it cannot begin accepting enrollment applications until the final rule policies are established. Enrollment applications will be processed as expeditiously as feasible, and home infusion therapy suppliers will be able to bill for services provided before the supplier's enrollment application is approved as noted above.
- As indicated above, there were concerns that HHAs and hospices will not enroll as home infusion suppliers and there will be insufficient access to these services, particularly in rural areas. Based on feedback received from the home infusion therapy community, CMS believes an adequate number of suppliers will enroll in Medicare as home infusion therapy suppliers.
- Several commenters asked CMS to clarify the specific supplier type that the enrolling home infusion therapy supplier should indicate on the Form CMS-855B. CMS responded that a supplier type of "other" should be used until Form CMS-855B can be revised to include "home infusion therapy supplier" as an enrollment category.
- Commenters objected to policies that require the supplier to have a physical presence in each jurisdiction (and perhaps even in each state that the MAC covers) and expressed concerns about needing to enroll using multiple national provider identifiers (NPIs). These commenters requested that home infusion therapy suppliers be permitted to bill all MACs from a single location and enroll once using a single NPI. CMS responded that its proposed policy of requiring a physical presence and enrolling in each MAC jurisdiction where the supplier is furnishing services is longstanding policy and ensures that the applicable MAC can: (1) verify the provider's or supplier's compliance with the state's requirements; and (2) make accurate payments.

  CMS recognizes that home infusion therapy suppliers will often operate out of only one central location, with services occasionally furnished in homes located in various MAC jurisdictions and/or states. This issue will be addressed through subregulatory guidance.

  With regard to enrollment under a single NPI or multiple ones (such as whether a pharmacy can be dual enrolled as a DME supplier and a home infusion therapy supplier), CMS indicates that generally a home infusion therapy supplier would not be required to obtain a separate NPI for each enrollment application it submits to each Part A/B MAC. CMS refers readers to the 2004 NPI final rule[8], the NPI regulations at 45 CFR part 162 subpart D, and the Medicare Program Integrity Manual, Chapter 15, section 15.3[9] for

[8] https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand/downloads/NPIfinalrule.pdf
[9] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c15.pdf

specific situations. The rule reiterates that an enrolled supplier is responsible for a subcontractor meeting all of the enrollment requirements.

*Final Decision*: CMS is finalizing its home infusion therapy supplier enrollment policies as proposed.

**E. Impact of Home Infusion Therapy Policies**

1. Payment for Home Infusion Therapy Services

In the 2020 HH PPS final rule, CMS 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 2021 (84 FR 60639). This decrease results from the net effect of no longer paying for self-administered drugs under the permanent home infusion therapy benefit and paying for a maximum of 5 hours of home infusion therapy under the permanent system rather than 4 hours under the interim payment system. Final 2021 PFS rates were not available at the time of publication of the 2021 HH PPS final rule. Based on the proposed PFS rates for 2021, CMS estimates payments for home infusion therapy services will decline by 0.7 percent ($384,800) in 2021.

2. Home Infusion Therapy Supplier Requirements

CMS estimates that 700 enrollment application fees will be paid by home infusion therapy suppliers over the first three years of the permanent system (600, 50 and 50). Based on the $595 current fee updated by the estimated CPI-U ($608 in 2021, $621 in 2022 and $634 in 2023), CMS estimates an average annual cost over the first 3 years of $142,517. 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.

**V. Waiver of Proposed Rulemaking**

Notice and comment rulemaking is waived with respect to the changes made in this rule to correct inadvertent omissions from the May 8, 2020 COVID-19 IFC (85 FR 27550). These changes are discussed in section II.E above.

**VI. Regulatory Impact Analysis**

CMS estimates that the net impact of the HH PPS policies in this final rule is an increase of 1.9 percent, or $390 million, in Medicare payments to HHAs for 2021, as summarized in the following table.

| **Summary of Overall Impact of Final HH PPS Changes** | | |
|---|---|---|
| **Policy** | **2021 impact** | |
| | **Percentage** | **Dollars** |
| HH PPS update | + 2.0% | +$410 million |
| Statutory rural add-on provision | -0.1% | - $20 million |
| **Net impact** | **+1.9%** | **+$390 million** |

Table 18, reproduced below from the final rule, provides details on the impact by facility type and ownership, by rural and urban area, by census region and by facility size. It breaks out the payment effects of the 2021 wage index update, the change in the wage index resulting from the updated OMB delineations, the rural add-on payment, and the 2021 update percentage.

## TABLE 18: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA, CY 2021

| | Number of Agencies | CY 2021 Updated Wage Index (CY 2020 Payments) | OMB Delineations with 5% Cap | CY 2021 Rural Add-On | CY 2021 HH Payment Update Percentage | Total |
|---|---|---|---|---|---|---|
| **All Agencies** | **9,808** | **0.0%** | **0.0%** | **-0.1%** | 2.0% | **1.9%** |
| **Facility Type and Control** | | | | | | |
| Free-Standing/Other Vol/NP | 970 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| Free-Standing/Other Proprietary | 7,910 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| Free-Standing/Other Government | 198 | 0.3% | 0.1% | -0.4% | 2.0% | 2.0% |
| Facility-Based Vol/NP | 511 | 0.1% | 0.1% | -0.2% | 2.0% | 2.0% |
| Facility-Based Proprietary | 58 | -0.1% | 0.4% | -0.3% | 2.0% | 2.0% |
| Facility-Based Government | 161 | -0.2% | 0.1% | -0.4% | 2.0% | 1.5% |
| Subtotal: Freestanding | 9,078 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| Subtotal: Facility-based | 730 | 0.1% | 0.1% | -0.2% | 2.0% | 2.0% |
| Subtotal: Vol/NP | 1,481 | 0.0% | 0.0% | -0.2% | 2.0% | 1.8% |
| Subtotal: Proprietary | 7,968 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| Subtotal: Government | 359 | 0.0% | 0.1% | -0.4% | 2.0% | 1.7% |
| **Facility Type and Control: Rural** | | | | | | |
| Free-Standing/Other Vol/NP | 234 | 0.3% | 0.0% | -0.8% | 2.0% | 1.5% |
| Free-Standing/Other Proprietary | 817 | 0.1% | 0.0% | -0.5% | 2.0% | 1.6% |
| Free-Standing/Other Government | 133 | 0.1% | 0.1% | -0.9% | 2.0% | 1.3% |
| Facility-Based Vol/NP | 232 | 0.0% | 0.0% | -0.8% | 2.0% | 1.2% |
| Facility-Based Proprietary | 26 | 0.5% | 0.5% | -0.7% | 2.0% | 2.3% |
| Facility-Based Government | 123 | 0.2% | 0.0% | -0.8% | 2.0% | 1.4% |
| **Facility Type and Control: Urban** | | | | | | |
| Free-Standing/Other Vol/NP | 736 | -0.1% | 0.0% | -0.1% | 2.0% | 1.8% |
| Free-Standing/Other Proprietary | 7,093 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| Free-Standing/Other Government | 65 | 0.4% | 0.1% | -0.1% | 2.0% | 2.4% |
| Facility-Based Vol/NP | 279 | 0.1% | 0.1% | -0.1% | 2.0% | 2.1% |
| Facility-Based Proprietary | 32 | -0.4% | 0.3% | -0.1% | 2.0% | 1.8% |
| Facility-Based Government | 38 | -0.5% | 0.1% | -0.1% | 2.0% | 1.5% |
| **Facility Location: Urban or Rural** | | | | | | |
| Rural | 1,565 | 0.1% | 0.0% | -0.6% | 2.0% | 1.5% |
| Urban | 8,243 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| **Facility Location: Region of the Country (Census Divisions)** | | | | | | |
| New England | 336 | -1.0% | -0.1% | -0.1% | 2.0% | 0.8% |
| Mid Atlantic | 452 | 0.7% | 0.2% | -0.1% | 2.0% | 2.8% |
| East North Central | 1,750 | 0.2% | -0.1% | -0.2% | 2.0% | 1.9% |
| West North Central | 652 | -0.6% | 0.0% | -0.3% | 2.0% | 1.1% |
| South Atlantic | 1,569 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |
| East South Central | 381 | 0.0% | 0.0% | -0.3% | 2.0% | 1.7% |
| West South Central | 2,387 | 0.1% | 0.0% | -0.1% | 2.0% | 2.0% |
| Mountain | 689 | -0.3% | -0.1% | -0.1% | 2.0% | 1.5% |
| Pacific | 1,552 | 0.0% | 0.1% | 0.0% | 2.0% | 2.1% |
| Outlying | 40 | -1.2% | -0.2% | -0.1% | 2.0% | 0.5% |
| **Facility Size (Number of 60-day Episodes)** | | | | | | |
| < 100 episodes | 2,491 | -0.1% | 0.0% | -0.1% | 2.0% | 1.8% |
| 100 to 249 | 1,989 | -0.1% | 0.0% | -0.1% | 2.0% | 1.8% |

| | Number of Agencies | CY 2021 Updated Wage Index (CY 2020 Payments) | OMB Delineations with 5% Cap | CY 2021 Rural Add-On | CY 2021 HH Payment Update Percentage | Total |
|---|---|---|---|---|---|---|
| 250 to 499 | 2,044 | -0.1% | 0.0% | -0.1% | 2.0% | 1.8% |
| 500 to 999 | 1,687 | -0.1% | 0.0% | -0.1% | 2.0% | 1.8% |
| 1,000 or More | 1,597 | 0.0% | 0.0% | -0.1% | 2.0% | 1.9% |

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

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

**REGION KEY**:
**New England**=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
**Middle Atlantic**=Pennsylvania, New Jersey, New York;
**South Atlantic**=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
**East North Central**=Illinois, Indiana, Michigan, Ohio, Wisconsin
**East South Central**=Alabama, Kentucky, Mississippi, Tennessee
**West North Central**=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
**West South Central**=Arkansas, Louisiana, Oklahoma, Texas
**Mountain**=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**=Alaska, California, Hawaii, Oregon, Washington
**Other**=Guam, Puerto Rico, Virgin Island