Medicare Home Health
Prospective Payment System

2021 Final Payment Rule Summary by the Wisconsin Hospital Association

Overview and Resources

On October 29, 2020 the Centers for Medicare and Medicaid Services (CMS) released its final calendar year (CY) 2021 payment rule for the Medicare Home Health Prospective Payment System (HH PPS). The final rule includes updates to the Medicare fee-for-service (FFS) HH PPS payment rates based on changes set forth by CMS and those previously adopted by the US Congress. Among the finalized updates are:

- Adoption of the revised OMB area delineations described in the September 14, 2018 Office of Management and Budget (OMB) Bulletin for labor market delineations used in the home health wage index;
- Changes to the Conditions of Participation (CoPs) Outcome and Assessment Information Set (OASIS) requirements for new home health agencies (HHAs); and
- Making the provisions regarding Home Health set forth 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) permanent, which requires that a plan of care must include any provision of remote patient monitoring or services furnished via telecommunications.

A copy of the *Federal Register* (FR) with this final rule and other resources related to the HH PPS are available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.

An online version of this final rule is available at https://www.federalregister.gov/d/2020-24146/.

A brief summary of the final rule is provided below. Program changes adopted by CMS are effective for services provided on or after January 1, 2021 unless otherwise noted. CMS estimates the overall economic impact of this finalized payment rate to be an increase of $390 million in aggregate payments to HHAs in CY 2021 over CY 2020.

Note: Text in italics is extracted from the October 29, 2020 Final Rule in the Federal Register (*FR)*.

HH PPS Payment Rates

FR pages 70305-70306, 70312-70313, and 70314-70320

The tables below show the final CY 2021 conversion factor compared to the final CY 2020 conversion factor and the components of the annual update factor:

	Final CY 2020	Final CY 2021	Percent Change
30-Day Standard Payment Rate	**$1,864.03**	**$1,901.12** (proposed at $1,911.87)	**+1.99%** (proposed at +2.57%)

Final CY 2021 Update Factor Components	30-Day Standard Rate
Marketbasket (MB) Update	2.3% (proposed at 3.1%)
Affordable Care Act (ACA)-Mandated Productivity MB Reduction	-0.3 percentage points (proposed at -0.4 ppt)
Wage Index Budget Neutrality	0.9999 (proposed at 0.9987)
Overall Final Rate Update	**+1.99%** (proposed at +2.57%)

CMS continues to monitor the impacts that the implementation of the Patient Driven Grouping Model (PDGM) has on behavioral changes which would affect aggregate spending. They believe that it is premature to release any behavioral data and, in light of the current public health emergency, did not finalize any other updates to the standardized 30-day payment rate other than the routine updates shown above.

National Per-Visit Amounts

FR pages 70305-70306 and 70314-70320

CMS uses national per-visit amounts by service discipline to pay for "Low-Utilization Payment Adjustment" (LUPA) episodes as well as to compute outliers. LUPA payments are made when the number of visits is less than the LUPA threshold for their PDGM classification. This threshold is set at 2 visits or the 10th percentile value of visits, whichever is higher. CMS will maintain the LUPA thresholds finalized in the CY 2020 final rule. National per-visit payments include a wage index budget neutrality factor of 0.9997 (proposed at 0.9988).

Per-Visit Amounts	Final CY 2020	Final CY 2021	Percent Change	Final CY 2021 With LUPA Add-On *
Home Health Aide	$67.78	$69.11 (proposed at $69.53)	+1.97% (proposed at +2.58%)	N/A
Medical Social Services	$239.92	$244.64 (proposed at $246.10)		N/A
Occupational Therapy	$164.74	$167.98 (proposed at $168.98)		N/A
Physical Therapy (PT)	$163.61	$166.83 (proposed at $167.83)		$278.61 (1.6700 adj.) (proposed at $280.28)
Skilled Nursing (SN)	$149.68	$152.63 (proposed at $153.54)		$281.62 (1.8451 adj.) (proposed at $283.30)
Speech Language Pathology (SLP)	$177.84	$181.34 (proposed at $182.42)		$294.97 (1.6266 adj.) (proposed at $296.72)

* For SN, PT, or SLP visits in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, CMS will continue to the use of the LUPA add-on factors established in the CY 2014 final rule.

Summary of Flexibilities Granted by COVID-19 IFCs

FR pages 70317 and 70325-70326

Over the course of the COVID-19 PHE, CMS has released several IFCs which provide flexibilities to HHAs so that more attention can be given to care of beneficiaries. These flexibilities include:

- *"Allowing HHAs to provide more services to beneficiaries using telecommunications technology within the 30-day period of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care;*
- *Allowing the face-to-face encounter for home health to be conducted via telehealth (i.e., 2-way audio-video telecommunications technology);*
- *Extending the 5-day completion requirement for the comprehensive assessment to 30 days;*

- *Waiving the 30-day OASIS submission requirement (though HHAs must submit OASIS data prior to submitting their final claim in order to receive Medicare payment);*
- *Waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered; and*
- *Changing the home health regulations to include physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services."* CMS inadvertently left this policy out of the HH CY2021 proposed rule even though it was finalized in the Coronavirus Aid, Relief, and Economic Security (CARES) Act. In this final rule, CMS is updating HHA regulation text to conform to this already implemented policy.

Wage Index and Labor-Related Share

FR pages 70306–70312, 70313-70315, and 70317-70318

As has been the case in prior years, CMS finalized using the most recent inpatient hospital wage index, the FFY 2021 pre-rural floor and pre-reclassified hospital wage index, to adjust payment rates under the HH PPS for CY 2021. The wage index is applied to the labor-related portion of the HH payment rate. CMS is maintaining the labor-related share at 76.1% for CY 2021 based on the FFY 2016 Medicare cost report.

CMS is adopting a wage index and labor-related share budget neutrality factor of 0.9999 (proposed at 0.9987) for the standard rate and 0.9997 (proposed at 0.9988) for the per diem rates for CY 2021 to ensure that aggregate payments made under the HH PPS are not greater or less than would otherwise be made if wage adjustments had not changed.

For CY 2021, CMS is adopting updates to the Core-Based Statistical Areas (CBSA) for all providers based on the delineations published in the Office of Budget and Management (OMB) Bulletin No. 18-04 released on September 14, 2018. Included in this bulletin are new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs which are split apart or otherwise changed. CMS believes that these delineations better represent current rural and urban areas. As a result, provider wage indexes change depending on which CBSA they are assigned to. In order to alleviate significant losses in revenue, CMS finalized a 2-year phase in period. Adopted delineations will be effective beginning January 1, 2021 and include a 5% cap on the reduction of a provider's wage index for CY 2021 compared to its wage index for CY 2020, with the full reduction of a provider's wage index beginning in CY 2022. Due to how wage index is calculated, some CBSAs and rural areas will have more than one associated wage index value. However, each county will only have one wage index value. Counties that have a transition wage index that differs from their CBSA are designated a special five digit code in the format "50xxx" which will be needed to identify the appropriate wage index for CY2021 claims. These codes are shown in the last column of the CY2021 HH wage index file.

A complete list of the wage indexes adopted for payment in CY 2021, including new CBSA designations as well as the wage index if the provider was affected by the 5% cap, is available on the CMS website at https://www.cms.gov/files/zip/cy-2021-hh-pps-wage-index.zip-0. OMB Bulletin 18-04 can be found at https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.

The March 6, 2020 OMB Bulletin 20-01 was not issued in time for integration into the rule. This bulletin can be found at https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf. CMS intends to propose any updates from this OMB bulletin to further update CBSA delineation in future rulemaking.

Patient Driven Grouping Model (PDGM)

CY 2021 FR pages 70302-70306 and 70318-70319
CY 2020 FR pages 60485-60534

The PDGM 30-day periods of care groupings are consistent with how clinicians differentiate between patients and the primary reason for needing home health care. Case-mix adjustment for home health payment are based solely on patient characteristics, relying more heavily on clinical characteristics and other patient information to place patients into 432 clinically meaningful payment categories.

In the PDGM, the first 30-day period is classified as early and all subsequent periods are late. A 30-day period is not considered early unless there was a gap of more than 60 days between the end of a prior period and the beginning of the next. Each period is then classified into one of two admission source categories depending on what healthcare setting was utilized in the 14 days prior to home health:

Admission Source Category	30-Day Period Classification
Community	No acute or post-acute care stay occurred in the 14 days prior to the start of the 30-day period of care
Institutional	Acute or post-acute care stay occurred in the prior 14 days to the start of the 30-day period

PDGM then groups 30-day periods into one of twelve clinical groups based on principal diagnosis reported on the claim:

- Musculoskeletal Rehabilitation;
- Neuro/Stroke Rehabilitation;
- Wounds- Post-Op Wound Aftercare and Skin/Non-Surgical Wound Care;
- Complex Nursing Interventions;
- Behavioral Health Care (including Substance Use Disorder); or
- Medical Management, Teaching and Assessment (MMTA) which includes
    - Surgical Aftercare;
    - Cardiac/Circulatory;
    - GI/GU;
    - Infectious Disease/Neoplasms/Blood-forming Diseases;
    - Respiratory; and
    - Other.

Each period is then placed into one of three functional levels, with roughly 33% of periods within each clinical group assigned to each functional level. Criteria for assignment to each of the three functional levels may differ across each clinical group. Afterwards, a comorbidity adjustment may be made depending on a patient's secondary diagnosis. The 30-day period may receive a "no", "low", or a "high" comorbidity adjustment.

Admission Source and Timing	Clinical Grouping (One of Six Groups From Principal Diagnosis)	Functional Level	Comorbidity Adjustment?	PDGM Classification
Community Early *(First 30-Day Period)*	Medication Management, Teaching and Assessment (MMTA), Neuro/Stroke Rehab, Wounds, Complex Nursing Interventions, Musculoskeletal (MS) Rehab, or Behavioral Health	Low	No	
			Low	
			High	
		Medium	No	
			Low	
			High	
		High	No	
			Low	
			High	
Community Late *(Subsequent 30-Day Periods)*	MMTA, Neuro/Stroke Rehab, Wounds, Complex Nursing Interventions, MS Rehab, or Behavioral Health	Low	No	
			Low	
			High	
		Medium	No	
			Low	
			High	
		High	No	
			Low	
			High	
			No	

Institutional Early *(First 30-Day Period)*	MMTA, Neuro/Stroke Rehab, Wounds, Complex Nursing Interventions, MS Rehab, or Behavioral Health	Low	Low	
			High	
		Medium	No	
			Low	
			High	
		High	No	
			Low	
			High	
Institutional Late *(Subsequent 30-Day Periods)*	MMTA, Neuro/Stroke Rehab, Wounds, Complex Nursing Interventions, MS Rehab, or Behavioral Health	Low	No	
			Low	
			High	
		Medium	No	
			Low	
			High	
		High	No	
			Low	
			High	

CMS is eliminating the split-percentage payments for 30-day periods of care beginning on or after January 1, 2021. All HHAs would submit a "no-pay" request for anticipated payment (RAP) and receive the full 30-day period of care payment once the final claim is submitted to CMS, which will mirror CMS' finalized Notice of Admission (NOA) policy. Beginning in 2022, RAP will be phased out and HHAs will be required to make one-time submissions of a Notice of Admission (NOA) within 5 calendar days of the start of HH care to establish the start of the care period. This would include a verbal or written order from the physician that contains services required of the initial visit and that the HHA has conducted the initial visit.

Failure to submit timely NOAs would result in a reduction of the wage-adjusted 30-day period payment amount for those days of service from the start of care to the day before the NOA is submitted. CMS would reduce payment by 1/30th per day that the NOA is late. CMS implemented that LUPA payments will not be made for tardy NOAs; that these days be a provider liability; that the reduction cannot exceed the total payment; and that the provider cannot bill the beneficiary for any penalized days. CMS is able to waive these penalties for extraordinary circumstances.

CMS did not adopt any updates to case-mix payment weights for CY 2021 and they will be held at the final CY 2020 values. These weights can be found on pages 60522-60533 of the November 8, 2019 Federal Register.

Payment Add-On for Rural HH Agencies

FR pages 70320-70321

In the CY 2019 HH PPS final rule, CMS finalized rural add-on payments for episodes and visits ending during CYs 2019 through 2022 as required by the Bipartisan Budget Act of 2018. This includes varying add-on amounts depending on the rural county (or equivalent area) by classifying each into one of three distinct categories:

- High home health utilization category - rural counties and equivalent areas in highest quartile of all counties and equivalent areas based on number of Medicare home health episodes furnished per 100 Medicare beneficiaries excluding areas with 10 or fewer episodes during 2015;
- Low population density category - rural counties and equivalent areas with a population density of 6 individuals or less per square mile and that are not included in the high utilization category; or
- All other rural counties and equivalent areas.

Categorization of counties (using FIPS county codes) for the rural add-on can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/CY2019-CY2022-Rural-Add-On-Payments-Analysis-and-Designations.zip

The add-on percentages for CY 2021 and CY 2022 are as follows:

Category	CY 2021	CY 2022
High utilization	0.0%	0.0%
Low population density	2.0%	1.0%
All other	1.0%	0.0%

Outlier Payments

FR pages 70321-70322

Outlier payments are intended to mitigate the risk of caring for extremely high-cost cases. An outlier payment is provided whenever a HHA's cost for an episode of care exceeds a fixed-loss threshold (the HH PPS payment amount for the episode plus a fixed dollar loss [FDL] amount).

Currently there is a cap of 8 hours or 32 units per day (1 unit = 15 minutes, summed across the six disciplines of care) on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier. The discipline of care with the lowest associated cost per unit is discounted first in the calculation of episode cost, in order to cap the estimation of an episode's cost at 8 hours of care per day.

The FDL amount is a FDL ratio multiplied by the wage index-adjusted 30-day period payment. This is added to the HH PPS payment amount for that episode. If calculated cost exceeds the threshold, the HHA receives an additional outlier payment equal to 80% of the calculated excess costs over the fixed-loss threshold.

Each HHA's outlier payments are capped at 10% of total PPS payments. By law, a limit of 2.5% of total HH PPS payments are set aside for outliers. CMS will maintain the fixed-dollar loss ratio (FDL) at 0.56 (proposed at 0.63 due to typographical error) for CY 2021.

CMS will publish the cost-per-unit amounts for CY 2021 in the rate update change request which is released after the publication of this final rule.

Mandatory HH VBP Model Demonstration Project

FR pages 70328-70330
CY 2020 FR pages 60551-60553

CMS implemented an ACA mandated HHVBP demonstration model for certain Medicare-certified HHAs, which started January 1, 2016 and concludes December 31, 2022. The Medicare-certified HHAs required to participate are from 9 randomly selected states: Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington. The demonstration program resembles the VBP Program for inpatient acute care hospitals.

In the May 2020 COVID-19 IFC, CMS implemented a policy to align HHVBP exceptions or extensions to submission requirements with those of the HH QRP during the COVID-19 PHE. CMS also adopted a policy that would allow exceptions or extensions to New Measure reporting in the HHVBP during this PHE.

HH Quality Reporting Program (HH QRP)

FR pages 70326-70328

CMS collects quality data from HHAs on process, outcomes, and patient experience of care. HHAs that do not successfully participate in the HH QRP are subject to a 2.0 percentage point reduction to the marketbasket update for the applicable year.

Summary Table of Measure Currently Adopted for the CY 2022 HH Quality Reporting Program	
Measures	**Data Source**
Improvement in Ambulation/Locomotion (NQF #0167)	OASIS
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)	OASIS
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)	OASIS
Improvement in Bathing (NQF #0174)	OASIS
Improvement in Bed Transferring (NQF # 0175)	OASIS
Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP	OASIS
Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care	OASIS
Improvement in Dyspnea	OASIS
Influenza Immunization Received for Current Flu Season	OASIS
Improvement in Management of Oral Medications (NQF #0176)	OASIS
Changes in Skin Integrity Post-Acute Care	OASIS
Timely Initiation Of Care (NQF #0526)	OASIS
Transfer of Health Information to Provider-Post-Acute Care	OASIS
Transfer of Health Information to Patient-Post-Acute Care	OASIS
Acute Care Hospitalization During the First 60 Days of HH (NQF #0171)	Claims-based
Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (NQF #3477)	Claims-based
Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173)	Claims-based
Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP	Claims-based
Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program	Claims-based
How well did the home health team communicate with patients	HHCAHPS
How do patients rate the overall care from the home health agency	HHCAHPS
How often the home health team gave care in a professional way	HHCAHPS
Did the home health team discuss medicines, pain, and home safety with patients	HHCAHPS
Will patients recommend the home health agency to friends and family	HHCAHPS

CMS did not make any proposals or updates for the HH QRP in the proposed rule and thus nothing to adopt in this final rule.

Change to the Conditions of Participation OASIS Requirement

FR page 70328

The HHA conditions of participation (CoPs) requires that new HHAs must successfully transmit test data to the Quality Improvement and Evaluation System (QIES) or CMS OASIS during the process of becoming a Medicare HHA. CMS has recently enhanced the system HHAs use to submit OASIS data to be internet based and no longer has the previous system's two user limitation. As such, the new system does not allow for the use of test data to be submitted, making it impossible for new HHAs to submit such data for their CoP requirement. Due to this, CMS is waiving the requirement for new HHAs to submit test data. HHAs must be able to submit assessments in order for the claims match process to occur and relay data needed for payment under PDGM, and therefore gives HHAs incentive to submit their OASIS data with the new software.

Use of Technology under the Medicare Home Health Benefit

FR pages 70322-70325

The March 2020 COVID-19 PHE IFC changed the HH plan of care requirements on an interim basis to require "*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*." These services cannot substitute for a home visit and cannot be considered a home visit for purposes of eligibility or payment. Specifically, the CARES Act requires that the secretary encourage the use of telecommunications, remote patient monitoring, and other communications and monitoring services with regards to HH services furnished during the PHE.

CMS is finalizing the interim requirements outlined in the March 2020 COVID-19 PHE IFC as well as to allow HHAs to continue reporting telehealth and telemedicine beyond the PHE as allowable costs on line 5 of the HHA cost report.

CMS is also amending that telecommunication technology allowable administrative costs regulation text includes *"not only remote patient monitoring, but other communications or monitoring services, consistent with the plan of care for the individual."*

Home Infusion Therapy Services

FR pages 70330-70347

The CY 2019 and CY 2020 final rules finalized numerous provisions regarding home infusion therapy services to be effective January 1, 2021, including payment for these services being excluded in the HH PPS. Following is a summary previously finalized provisions as well as finalized policies set forth in the HH PPS CY 2021 final rule.

The Medicare Part B home infusion therapy benefit was established by the 21st Century Cures Act to cover professional services including nursing services furnished in accordance with the plan of care, patient training and education, remote monitoring, and monitoring services for the provision of home infusion therapy and drugs furnished by a qualified home infusion therapy supplier.

CMS has previously implemented a transitional payment as required by the Bipartisan Budget Act of 2018, in which payment for home infusion therapy is based on infusion drug calendar days. CY 2020 was the second and final year of this transition.

Payment amounts during the transition period were made using three payment categories:

- Payment Category 1 – 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 - subcutaneous infusions for therapy or prophylaxis, including, but not limited to, certain subcutaneous immunotherapy infusions; and
- Payment Category 3 – intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

These three categories were finalized to become permanent in CY 2021. Table 13 on *Federal Register* pages 70338 shows the J-Codes associated with each category.

For services per visit furnished January 1, 2021 and onwards, the CY 2020 final rule finalized that home infusion payments will continue to be bundled and set at an amount equal to 5 hours of home infusion therapy for each infusion drug administration day. This ensures that payment covers differing patient needs and complexity of services provided while remaining a single payment. Finalized CPT codes for home infusion drug payments for 2021 are listed in table 14 on *Federal Register* page 70399.

In this final rule, CMS is adopting that home infusion therapy services covered under the home infusion therapy benefit would be excluded from the home health benefit. The supplier cannot bill for such services under the home infusion therapy benefit until January 1, 2021. More information can be found in the Frequently Asked Questions (FAQ) for home infusion therapy available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Home-Infusion-Therapy-Services-Temporary-Transitional-Payment-Frequently-Asked-Questions.

Additionally, CMS recognized that the first visit by a home infusion therapy supplier may be longer or more resource intensive than subsequent visits. Thus, for CY 2021 and forward, CMS will increase the payment amounts for the three payment categories for the first visit of a given year by the relative payment rate for a new patient rate over an existing patient using the physician evaluation and management (E/M) payment amounts, which would decrease subsequent payments in a budget-neutral manner. A patient must be discharged for more than 60 days for a first visit to be billed again. At the time of this final rule, CY 2021 payment rates are not yet finalized and will be posted with the final CY 2021 Physician Fee Schedule (PFS) rates.

Beginning in CY 2021, qualified home infusion therapy suppliers would submit claims on the 837P/CMS-1500 claims form and submit them to their MAC that processes Medicare Part A and B claims (A/B MAC). DME suppliers who are enrolled as qualified infusion therapy suppliers will need to submit a claim for both the DME and the drug on the 837P/CMS-1500 to the A/B MAC as well as to the DME MAC.

Beginning in CY 2022, CMS will increase the single payment amount by the percent increase in the Consumer Price Index for all urban customers (CPI-U) for the 12-month period ending with June of the preceding year. This is then reduced by the 10-year moving average of economy-wide private nonfarm multifactor productivity (MFP). This may result in payments being lower than the preceding year.

For home infusion therapy services beginning in CY 2021, physicians should continue the current practice of discussing options for infusion therapy for part B and noting these discussions in the patient's records prior to establishing a plan of care. CMS may consider additional requirements if this practice is found insufficient for providing infusion therapy options in the future.

Patient Eligibility and Plan of Care Requirements

FR page 70334

In the CY 2020 HH final rule, CMS adopted regulatory revisions to the home infusion therapy payment system beginning on January 1, 2021:

- Services must be furnished to an eligible beneficiary by, or under arrangement of a qualified home infusion therapy supplier that meets the qualified home infusion therapy supplier health and safety standards;

- Suppliers must ensure beneficiaries meet eligibility criteria for coverage of services and that plan of care requirements are met;
- Beneficiaries must be under the care of a physician, nurse practitioner, or physician assistant; and
- Beneficiaries must be under a plan of care established by a physician, including the frequency of the furnished services and the healthcare professional who will furnish each service.

Home Infusion Geographic Wage Adjustments

FR page 70341

CMS finalized the adjustment of home infusion therapy payments to reflect differences in geographic wages using the geographic adjustment factor (GAF) for CY 2021 and forward. The GAF is a weighted composite of each region's Geographic Practice Cost Indices (GPCIs), which include work, practice expense (PE), and malpractice (MP) and is calculated as:

$$GAF = (0.50886\ x\ Work\ GPCI) + (0.44839\ x\ PE\ GPCI)\ +\ (0.04295\ x\ MP\ GPCI).$$

The locally adjusted GAF is multiplied by the home infusion therapy payment based on the site of the beneficiary. The adjustment would be budget neutral nationally. A list of GAFs can be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html

Enrollment Standards for Qualified Home Infusion Therapy Suppliers

FR pages 70343-70347

Regulatory provisions for home infusion therapy have been established in various parts of Title 42 of the Code of Federal Regulations (CFR) as well as within the Social Security Act (SSA), including a definition of "qualified home infusion therapy supplier" and standards which must be met. For a supplier of home infusion therapy to qualify, the following criteria must be met:

- *"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."*

CMS believes that the final criteria permits them to adopt additional requirements, for both existing and new suppliers, which would protect the Medicare program from fraud, waste, and abuse. The following requirements are effective for home infusion therapy suppliers on January 1, 2021:

- "Home infusion therapy supplier" defined to include the first three criteria for a "qualified home infusion therapy supplier" as well as being enrolled in Medicare as a home infusion therapy supplier.
- For a supplier to receive Medicare payment for home infusion therapy supplier services, the supplier must qualify as a home infusion therapy supplier and be in compliance with all applicable provisions.
- A home infusion therapy supplier must complete in full and submit the Form CMS-855B, 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.
- A home infusion therapy supplier must certify via form CMS-855B that it meets and will continue to meet published requirements and standards.
- Home infusion suppliers will be required to pay an application free, for which CMS will provide clarification. This fee is $595 for CY 2020.
- A home infusion therapy supplier must be accredited as such by a CMS-recognized home infusion therapy supplier accreditation organization.

- In order for a home infusion therapy supplier to enroll and maintain enrollment, it must comply with the plan of care requirements in § 414.1515 as well as all provisions for Home Infusion Therapy Suppliers found in the Code for Federal Regulations (42 CFR part 486, subpart I).
- Adding a new paragraph (c) to § 414.1515 that a supplier must also be enrolled in Medicare consistent with requirements for establishing and maintaining Medicare billing privileges.
- Add home infusion therapy suppliers to the types of suppliers that are subject to the limited risk level of screening. CMS has no recent evidence or reviews that would suggest these suppliers warrant being placed in the moderate or high screening levels.
- CMS may deny a home infusion therapy supplier's enrollment application if it does not meet all of the published requirements for enrollment or if any published reasons for denial apply. A denied supplier may appeal their denial.
- Upon enrollment, a supplier must remain accredited and remain in full compliance with all published provisions. Failure to do so, or if the supplier meets any revocation criteria, would allow CMS to revoke the supplier's enrollment. The supplier may appeal this revocation.
- Clarify the effective date of billing privileges and account for circumstances that could prevent a supplier's enrollment prior to furnishing services, new suppliers would fall under previously established Medicare billing policies.

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