Medicare Home Health
Prospective Payment System

2021 Proposed Payment Rule Summary by the Wisconsin Hospital Association

Overview and Resources

On June 25, 2020, the Centers for Medicare and Medicaid Services (CMS) released its proposed calendar year (CY) 2021 payment rule for the Medicare Home Health Prospective Payment System (HH PPS). The proposed 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 proposed updates are:

- Adopt 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;
- Change to the Conditions of Participation (CoPs) Outcome and Assessment Information Set (OASIS) requirements for new home health agencies (HHAs); and
- Make 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 proposed 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 the *Federal Register* with this proposed rule is available at https://federalregister.gov/d/2020-13792.

A brief summary of the proposed 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 proposed payment rate to be an increase of $540 million in aggregate payments to HHAs in CY 2021 over CY 2020.

On July 20, 2020, CMS released a correction notice to this proposed rule stating that comments are due to CMS by August 24, 2020 and can be submitted electronically at http://www.regulations.gov by using the website's search feature to search for file code "1730-P."

Note: Text in italics is extracted from the June 30, 2020 *Federal Register (FR)*.

HH PPS Payment Rates

FR pages 39421, 39422-39452

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

	Final CY 2020	Proposed CY 2021	Percent Change
30-Day Standard Payment Rate	**$1,864.03**	**$1,911.87**	**+2.57%**

Proposed CY 2021 Update Factor Components	30-Day Standard Rate
Marketbasket (MB) Update	+3.1%
Affordable Care Act (ACA)-Mandated Productivity MB Reduction	-0.4 percentage points
Wage Index Budget Neutrality	0.9987
Overall Proposed Rate Update	**+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, are not proposing any other updates to the standardized 30-Day payment rate other than the routine updates shown above.

National Per-Visit Amounts

FR pages 39423-39425

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 proposed to maintain the LUPA thresholds finalized in the CY 2020 final rule.

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

* 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.

Wage Index and Labor-Related Share

FR pages 39415-39422

The wage index is applied to the labor-related portion of the HH payment rate. CMS is proposing to maintain the labor-related share at 76.1% for CY 2021 based on the 2016 Medicare cost report.

CMS is proposing a wage index and labor-related share budget neutrality factor of 0.9987 for the standard rate and 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 proposing to update 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 is

proposing a 2-year phase in period. Adopted delineations would 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.

A complete list of the wage indexes proposed 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. 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. For CY 2022, CMS intends to propose any updates from this OMB bulletin to further update CBSA delineation.

Patient Driven Grouping Model (PDGM)

CY 2021 FR pages 39411-39415,
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	
Institutional Early *(First 30-Day Period)*	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	
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 is not proposing 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 39425-39426

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 39425-39426

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 is proposing to maintain the fixed-dollar loss ratio (FDL) at 0.63 for CY 2021.

Mandatory HH VBP Model Demonstration Project

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, Maryland, Massachusetts, Nebraska, North

Carolina, Tennessee, and Washington. The demonstration program resembles the VBP Program for inpatient acute care hospitals. CMS is not proposing any changes to the HHVBP.

Updates to the HH Quality Reporting Program (HH QRP)

FR pages 39428-39430

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 has no new proposals or updates for the HH QRP in this proposed rule.

Change to the Conditions of Participation OASIS Requirement

FR page 39430

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 proposing to waive 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 39427-39428, 39451

The first 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 Coronavirus Aid, Relief, and Economic Security (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 proposing to permanently finalize the interim requirements outlined in the first COVID-19 PHE IFC as well as to allow HHAs to continue reporting telehealth and telemedicine as allowable costs on line 5 of the HHA cost report.

CMS is also proposing to amend telecommunication technology allowable administrative costs to include *"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 39430-39445, 39451-39452

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 new proposals set forth in the HH PPS CY 2021 proposed 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 12 on *Federal Register* page 39438 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 13 on *Federal Register* page 39439.

In the CY 2021 HH PPS proposed rule, CMS is proposing 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 increases 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 proposed rule, CY 2021 payment rates are not yet available and will be posted when the final CY 2021 Physician Fee Schedule (PFS) rates are posted.

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 39434

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 39440

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

Proposed Enrollment Standards for Qualified Home Infusion Therapy Suppliers

FR pages 39441-39445

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 propose additional requirements, for both existing and new suppliers, which would protect the Medicare program from fraud, waste, and abuse. The following proposals would be effective for home infusion therapy suppliers on January 1, 2021:

- Define "home infusion therapy supplier", 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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