

**Summary of “CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements”**

On October 31, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2020 Home Health Prospective Payment System Rate Update final rule, which finalized requirements for the permanent Medicare home infusion therapy services benefit for CY 2021 and beyond. For the most part, CMS did not accept changes recommended by commenters and finalized the provisions as proposed in July. Below is a summary of CMS’s responses to NHIA’s main concerns.

**Infusion Drug Administration Calendar Day**

CMS stated that it received comments that “continued to disagree” with the agency’s final definition of “infusion drug administration calendar day” and which asked CMS to modify the definition to allow reimbursement on each day that an infusion drug enters the patient’s body regardless of whether a skilled professional is in the home. CMS also noted that the Medicare Payment Advisory Commission (MedPAC) continued to support its definition.

CMS did not make changes to the definition of infusion drug administration calendar day, stating that it is consistent with the statute, which only requires payment to be “issued on certain days – days on which professional services are provided in the patient’s home.” CMS reiterated that it would continue to monitor home infusion therapy utilization to determine the effects on access to care, if any, that occur following implementation of the temporary transitional payments for home infusion therapy. CMS stated that claims data “shows a steadily increasing trend across all three care settings (home, outpatient, and physician’s office) in the fourth quarter of 2018. CMS stated that both the numbers of prescription fills and claims for the transitional infusion drugs in the home increased “steadily” in the fourth quarter of 2018 relative to the prior quarter.

CMS also reported that while the number of DME suppliers has fluctuated during the data collection period, the number of suppliers increased between the third and fourth quarter of 2018 and that access to services has not been impacted negatively since the drug pricing change from average wholesale price (AWP) to average sales price (ASP) plus six percent took place. CMS added that it has been collecting quarterly data since January 1, 2019 and that home infusion utilization for the first quarter of 2019 has been stable and shown slight increases since the first quarter of 2017. CMS also maintained that this “monitoring and analysis is unrelated to CMS’s legal interpretation of the term ‘infusion drug administration calendar day.’”

**Definition of “Professional Services”**

CMS stated that it had not previously defined “professional services” or provided a list of services that are covered under the home infusion therapy services benefit, as it did not want to be overly prescriptive. In the final rule, CMS does enumerate more clearly how they define the professional services provided under the home infusion therapy benefit, emphasizing that these services are distinct from those under the durable medical equipment (DME) benefit and may include:

- Training and education on care and maintenance of vascular access devices
  - Hygiene education
  - Instruction on what to do in the event of a dislodgment or occlusion
  - Education on signs and symptoms of infection
  - Teaching and training on flushing and locking the catheter
  - Dressing changes and site care
- Patient assessment and evaluation
  - Review of patient’s history and assessment of current physical and mental status, including obtaining vital signs
  - Assessment of any adverse effects or infusion complications; evaluation of family and caregiver support
  - Review of prescribed treatment and any concurrent oral and/or over-the-counter treatments; and obtaining blood for lab-work
- Medication and disease management education:
  - Instruction on self-monitoring; education on lifestyle and nutritional modification
  - Education regarding drug mechanism of action, side effects, interactions with other medications, adverse and infusion-related reactions
  - Education regarding therapy goals and progress;
  - Instruction on administering pre-medications and inspection of medication prior to use
  - Education regarding household and contact precautions and/or spills;
- Remote monitoring services; and
- Monitoring services
  - Communicating with patient regarding changes in condition and treatment plan,
  - Monitoring patient response to therapy
  - Assessing compliance
  - Patient Eligibility and Plan of Care Requirements

### Plan of Care

CMS stated that for payment purposes, the plan of care must be established and reviewed by a physician, but that it will consider for future rule-making whether an “applicable provider” can update the plan of care.

In response to recommendations that CMS adopt a standardized timeframe for physician plan of care review, CMS stated that the physician responsible for the home infusion therapy plan of care should review the plan on a “regular basis” in coordination with the DME supplier. CMS did note that it was aware of “the integral part the plan of care plays in care coordination between providers, particularly when the physician ordering the home infusion drug is not the same physician establishing the home infusion therapy plan of care.” CMS added that it would consider for future rule-making the recommendation regarding establishing a timeframe for physician review. Regarding additional documentation under the plan of care, CMS noted that any additional plan of care elements would need to go through notice and comment rule-making.

In response to the request that CMS require the same physician be responsible for signing the DME detailed written work order (DWO) and the home infusion therapy plan of care, CMS noted that it recognized the concerns raised about potential medication errors and conflicting orders. CMS stated, however, that the statute does not require that the same physician establish the home infusion plan of care and order the DME. CMS stated that regardless of whether there are different physicians in this circumstance, there is a requirement for care coordination between both entities under the plan of care requirements.

#### Qualified Home Infusion Therapy Suppliers and Professional Services

In response to concerns raised about care coordination between different entities providing services under various benefits, CMS stated that the statute does not require that the DME supplier also furnish the home infusion therapy services and no provision requiring the home infusion therapy supplier to furnish the pump, drug or other supplies. CMS stated that it does not anticipate a lapse in care coordination when the home infusion therapy supplier is different from the entity furnishing the DME, drug and related services as the plan of care requires coordination between the physician and DME supplier. CMS also declined to add a new requirement that the home infusion therapy supplier be enrolled in the DME program as a pharmacy that provides external infusion pumps and supplies and maintains all pharmacy licensure and accreditation requirements.

#### Payment Categories and Amounts for Home Infusion Therapy Services for CY 2021

CMS finalized its proposal to maintain the three payment categories currently being utilized under the temporary transitional payments for home infusion therapy services. CMS had proposed to pay a single amount for each infusion drug administration calendar day in the individual’s home for drugs assigned under each proposed payment category and had proposed that the single payment amount be set at an amount equal to five hours of infusion therapy administration services in a physician’s office for each infusion drug administration calendar day. MedPAC opposed moving to the equivalent of a five-hour infusion, stating that there was

no evidence that the current rates are inadequate. MedPAC stated that it did “not believe that increasing the aggregate level of payment to the maximum level permitted by statute is an appropriate approach for addressing variation in costs across patients.” MedPAC asked CMS to reconsider using five hours as the basis of payment for home infusion therapy services “unless it can provide evidence that the current rates are inadequate.” Despite MedPAC’s comments, CMS finalized the proposal to set the payment rate at five hours of infusion in a physician’s office. CMS acknowledged MedPAC’s concern regarding the lack of evidence that such an increase in the number of hours is warranted. However, CMS reasoned that because the home infusion therapy payment must take into account, as appropriate, types of infusion therapy, including variations in utilization of services by therapy type, yet also provide a single payment amount, CMS believed that setting the payment rate to the maximum amount set in statute recognizes the variety and amount of services included in the payment.

CMS noted that commenters were overwhelmingly in support of the proposed payment adjustment for the first visit (and a lower rate for subsequent visits). MedPAC also supported this proposal. CMS added that it plans to monitor visit lengths in order to determine if the data substantiates this adjustment.

CMS is seeking additional comments in response to stakeholder concerns regarding the limitations of the DME LCDs for external infusion pumps that preclude coverage to certain infused drugs. CMS solicited comments on the criteria CMS could consider allowing coverage of additional drugs under the DME benefit. However, given the new permanent home infusion therapy benefit to be implemented beginning January 1, 2021, which includes payment for professional services, including nursing; CMS is asking for comments on options to enhance future efforts to improve policies related to coverage of eligible drugs for home infusion therapy (for example, whether coverage could include instances where diseases or conditions prevent a patient from being able to self-infuse, such as due to a neurodegenerative disease). CMS notes that any changes to the DME and home infusion therapy benefits must prioritize ensuring that the DME and supplies covered fall within the scope of the DME benefit, and also balance concerns of promoting access to innovative treatments with patient safety and cost-efficient delivery and monitoring of drug infusions relative to the facility setting.

#### Other Optional Payment Adjustments/Prior Authorization for CY 2021 Home Infusion Therapy

##### Services

CMS confirmed that prior authorization is not necessary for home infusion therapy at this time, but that it will continue to monitor the provision of home infusion therapy services and revisit the need for prior authorization if issues arise.

Billing Procedures for CY 2021 Home Infusion Therapy Services

CMS explained that DME suppliers are not required to enroll with the A/B MACs but instead will continue to enroll with the National Supplier Clearinghouse, and their billing processes for equipment and supplies, including infusion drugs, will not change. CMS noted that only if DME suppliers become accredited as a home infusion therapy supplier, would they complete an additional enrollment with the A/B MACs in order to submit home infusion therapy service claims. CMS explained that it understood that some current DME suppliers enrolling as home infusion therapy suppliers may not have brick-and-mortar locations per the A/B MAC requirements and stated that it plans to issue more complete guidance for these providers in the future. CMS also acknowledged that there is currently not a “home infusion therapy supplier” type on the 855B enrollment form and said that it is considering creating one for home infusion supplier enrollment. In the meantime, CMS instructed providers to enroll using the “other” option. CMS is examining and working on all other aspects of the enrollment process and welcomes all commenter suggestions as it continues to develop guidance for suppliers.