September 9, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

The National Home Infusion Association (NHIA) submits the following comments on the Centers for Medicare and Medicaid Services’ (CMS’) proposed rule entitled “Medicare and Medicaid Programs; 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” [CMS-1711-P] RIN 0938-AT68 (hereafter, the proposed rule).

The National Home Infusion Association (NHIA) is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion industry, we write to share our serious concerns about the proposed rule and the impact it will have on patients who need home infusion therapy (HIT). We submit the following considerations, information, and recommendations for your consideration.

Overview

Congress included provisions in the 21st Century Cures Act1 and the Bipartisan Budget Act of 20182 requiring CMS to create both a permanent and transitional payment system for home infusion professional services related to Medicare Part B home infusion drugs. These benefits were intended to cover all professional services and both pieces of legislation specified that providers would be reimbursed for each “infusion drug administration calendar day.” Unfortunately, in its CY 2019 Final Rule, CMS adopted a very narrow definition of infusion drug administration calendar day that only reimburses when a skilled professional is present in the patient’s home, effectively providing reimbursement only for nursing services.

As detailed in NHIA’s August 31, 2018 comment letter, December 27, 2018 comment letter, and our legal complaint filed in Case No. 1:19-cv-393 in February 2019, NHIA contends that CMS exceeded its statutory authority by defining infusion drug administration calendar day to include only a day on which a nurse or other skilled professional is physically present in the beneficiary’s home. This policy cannot be reconciled with the plain language of the statute and irrationally denies reimbursement for many home infusion therapy services. As the CY 2020 proposed rule perpetuates this policy, we maintain that CMS is exceeding its authority and that the rule should be revised to reflect Congress’s intent.

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2 Pub. L. No. 115-123 (Feb. 9, 2018)
NHIA also refutes CMS’ contention that this benefit will allow “beneficiaries the option to receive critical infusion drug therapies at home.” Since implementation of the transitional benefit, two large national providers have consolidated, a move that could potentially reduce access and inhibit competition in certain markets. Further, NHIA has heard from many of its members that the policy is having the exact opposite effect as providers are no longer accepting new patients under the Part B benefit. One provider reported that it turned away almost half of Medicare referrals who needed inotrope infusions in 2018. If that pattern extended to all home infusion providers, as many as 1,800 beneficiaries could face access barriers. Without home infusion, these patients likely will receive infusions in costlier settings such as skilled nursing facilities or hospital outpatient departments, or require costlier, more invasive medical procedures such as a heart transplant or surgical insertion of a left-ventricular access device (LVAD). This policy is creating a real burden for frail, seriously ill patients and will drive up costs elsewhere in the Medicare program. We request that CMS make utilization data from 2019 available for public review to allow for a full assessment of how the current policy has impacted access and/or contributed to provider consolidation.

**Home Infusion Therapy and the DME Supplier Standards**

Throughout the proposed rule, CMS contends that certain home infusion-related professional services, such as compounding, care coordination, assessments, as well as recommendations to the physician regarding adjustments to the equipment, items, and services remain covered under the Durable Medical Equipment (DME) benefit, which CMS considers separate from the home infusion therapy professional services benefit. Unfortunately, reimbursement under the DME benefit is inadequate to cover those services. CMS’s logic is flawed in this regard as Congress understood that home infusion services are so inherently complex that the breadth and frequency of professional services required far exceeds the scope of the DME benefit. It is for this reason that Congress created the home infusion therapy professional services benefit.

As we stated in our comment letter dated August 31, 2018, the statute provides coverage of the following services for home infusion:

(A) Professional services, including nursing services, furnished in accordance with the plan.

(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

*Congress exempted training and education that was not otherwise paid for as DME from the professional services reimbursement, but made no such exemption for professional services, remote monitoring and monitoring services or the other professional services referenced in the proposed rule.* Congress intended that the professional services for home infusion – notably those provided remotely by a pharmacist – be sufficiently reimbursed without regard to overlap with DME or contingent on the patient’s nursing needs. NHIA contends that the professional services including: pharmacist assessments, drug therapy evaluation and design, drug preparation and compounding, care planning, care coordination, nursing professional services, monitoring services and remote monitoring, and all other associated professional work are not covered in the DME benefit at all, rather they are intended to be covered under the home...
infusion therapy professional services benefit. CMS has exceeded its authority by exempting the above enumerated services from the home infusion therapy benefit.

Recommendations:

Consistent with our August 2018 comment letter, December 2018 comment letter, and our legal complaint filed in Case No. 1:19-cv-393 in February 2019, NHIA calls on CMS to:

1. Revise the existing definition of infusion drug administration calendar day to allow for reimbursement of home infusion professional services each day that an infusion drug physically enters the patient’s body, irrespective of whether a skilled professional is in the individual’s home.
2. Refine the definition of “professional services” to include nursing, as well as those services that are performed remotely by a pharmacist, notably assessments, drug therapy evaluation and design, drug preparation and compounding, care planning, care coordination, monitoring services and remote monitoring, and all other associated professional work.

Fragmented Care and Impacts on Quality

Beyond our policy and legal arguments, NHIA has several concerns about the practical and operational viability of CMS’ proposed policy. NHIA believes CMS’ proposal will impair quality, increase the potential for medication errors and adverse events, and lead to higher rates of emergency department visits and rehospitalizations. Typically, commercial payers structure the home infusion benefit as a pharmacy-coordinated service, where the pharmacy assumes responsibility for case-managing the therapy and provides oversight of all the professional services. Further, the pharmacy is the entity contracted to supply the drugs, equipment, and supplies. Because of the dependency between these two components of care, commercial payers and accreditation organizations never separate the case management from the supplier of the drug, equipment, and supplies.

Under the proposed rule, CMS fragments the provision of the DME from the provision of professional services and allows them to be assigned to different entities. Specifically, the proposed rule tasks the home infusion therapy supplier with “furnishing the necessary services to administer the drug in the home,” but does not require the qualified home infusion therapy supplier to furnish the pump, home infusion drug, or related pharmacy services. CMS states that the infusion pump, drug, and other supplies, including the services required to furnish them remain covered under the DME benefit. Under CMS’ interpretation, the DME supplier and the home infusion therapy supplier could be separate entities, creating confusion about roles and responsibilities.

Further, CMS makes no requirement for the provider of HIT services to coordinate directly with the DME supplier. This omission will put Medicare beneficiaries at a higher risk of medication errors, visits to the emergency room, increased rates of rehospitalization, and negative clinical outcomes.
The following scenario (using fictitious providers) illustrates the potential challenges and confusion that could result from CMS’s current policy that lacks a requirement for care coordination between different suppliers of DME and professional services.

*Patient is an 85-year-old woman with Congestive Heart Failure. Her physician prescribed milrinone, a medication that is dosed by weight and continuously infused (i.e., 24 hours a day, 7 days a week). The patient has a capable caregiver who helps with drug administration, thus the infusion services supplier schedules once weekly nursing visits. The patient’s infusion pump, supplies and drugs are supplied by Acme Pharmacy and her Home Infusion Therapy professional services are provided by AAA Home Care Agency.*

*One Saturday evening, the patient experiences significant swelling and shortness of breath. The AAA Home Care Agency dispatches a night-nurse to assess the patient. The nurse consults with the on-call physician who subsequently orders a dose increase. The nurse proceeds to change the infusion pump settings increasing the infusion rate to provide the higher dose of medication. The nurse does not consult a pharmacist about the change, and the order change is not communicated to the DME supplier until the following Monday. As a result, the patient’s supply of drug runs out sooner than expected because the previous shipment of drug was based on a conflicting prescription with the lower dose of the medication. The patient becomes distressed and goes to the emergency room for an urgent supply of medication.*

Today, the pharmacist routinely takes the lead in contacting the physician when infusion medication orders require adjustment, and then works with the nursing organization to determine the best and safest way to implement a change in therapy. Order changes generally result in the pharmacist providing the nurse with a copy of the updated order and revised plan of care, followed by communication regarding the plan for implementation. For dose changes, best practice is for the pharmacy to send a new, pre-programmed pump to the home rather than have the nurse change the pump settings independently. When this is not feasible due to time constraints, two clinicians (e.g. one pharmacist and one nurse) will typically confirm the pump settings to ensure the pharmacy label and pump match. When needed, a new supply of medication is provided to ensure the patient does not run out of medication due to the change in orders.

**Recommendation**

3. The 21st Century Cures Act provided the Secretary with broad authority to set requirements for “qualified home infusion therapy suppliers” to include standards established by Medicare Advantage plans and in the private sector. We urge the Secretary 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 that maintains all pharmacy licensure and accreditation requirements, and that all components of the home infusion benefit should be billed by the same provider, including professional services, drugs, pumps and supplies.
Plan of Care

CMS notes that in order to be eligible for home infusion therapy services, a beneficiary must be under the care of an applicable provider (a physician, nurse practitioner, or physician assistant). In addition, the qualified home infusion therapy supplier must ensure that the beneficiary is under a plan of care (POC) that is established by a physician and includes the type, amount, and duration of home infusion therapy services that are to be furnished, as well as the professional services to be utilized for treatment, the frequency with which those services would be furnished, and the health care professional that would furnish each of the ordered services. In addition, the qualified home infusion therapy supplier would be required to ensure that the patient’s POC is periodically reviewed by a physician. CMS makes no mention of how care is to be coordinated between the DME and home infusion therapy services suppliers.

CMS has stated that these provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services, outlining beneficiary qualifications and plan of care requirements, and establishing who can bill for payment under the benefit. If CMS does not adopt our previous recommendation that all components of the home infusion benefit should be billed by the same provider, it is imperative that the plan of care include all professional services necessary – including those that are provided by the DME supplier – to ensure the safe and effective delivery of high-quality home infusion care.

Recommendation

4. NHIA requests that CMS require home infusion therapy suppliers to document the following in the plan of care:
   - Drug name, strength, and dosage
   - Frequency of administration
   - Route of administration (e.g., subcutaneous, intravenous)
   - Method of administration (e.g., electronic infusion pump)
   - Care plan for the following professional services, whether performed by pharmacist or the nurse (see Appendix A):
     - Patient assessments (e.g., Medication Adherence, Complication Management, Response to Therapy)
     - Drug therapy evaluation and design
     - Drug preparation and compounding (DME Supplier)
     - Care coordination
     - Monitoring and remote monitoring
     - Nursing services (e.g., physical assessment, vascular access care, triage, patient education, and administration)

Physician Oversight Requirements

As noted earlier, in the commercial sector, the pharmacy is responsible for designing the home infusion therapy and providing the comprehensive plan of care to the nursing provider upon obtaining the
medication order from the physician and the nurse provides critical information from the home visits back to the pharmacist and physician.

The Medicare program requires DME suppliers to receive a Detailed Written Order (DWO) that is signed by the physician before the supplier can submit a claim. Because the CMS rule allows for the supplier of DME and home infusion therapy professional services to be different entities, there is a risk for medication errors resulting from conflicting orders being obtained by the individual providers involved in the patient’s care. We are most concerned about drugs with weight-based dosing that are frequently adjusted, such as dobutamine, milrinone, deferoxamine, epoprostenol, immune globulin, and many chemotherapy agents.

**Recommendation**

5. To avoid the potential for increased errors and adverse outcomes, we recommend that CMS add a requirement that the same physician be responsible for signing the DME DWO and home infusion therapy plan of care. This requirement would not prohibit other providers from issuing individual orders for drugs, labs, nursing services, etc.; but would ensure the full range of home infusion services are consolidated under the care of a single physician.

**Plan of Care Review Requirements**

Most state pharmacy laws require physician review upon prescription renewal (i.e., annually for non-controlled substances). Some states, however, require nursing orders to be more frequently reviewed. This can result in confusion for the physician and create discrepancies across orders and plans of care and allow discrepancies in orders to go unrecognized for long periods of time.

**Recommendation**

6. To ensure the care for home infusion beneficiaries is carefully coordinated and consistent, NHIA recommended CMS adopt a standardized timeframe for physician care plan review. We recommend the HIT plan of care be reviewed by the physician at least every 90 days.

**Proposed Payment Categories and Amounts for Home Infusion Therapy Services**

The statute requires the Secretary to implement a payment system under which a single payment is made for items and services furnished for each infusion drug administration calendar day, by the supplier in coordination with the furnishing of home infusion drugs. The Secretary is required, as appropriate, to establish single payment amounts for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. The Secretary also is required to take into account patient acuity and the complexity of the drug administration in determining the payment amounts.

CMS proposes to maintain the three payment categories currently in place under the home infusion therapy services temporary transitional payment system for the permanent payment system beginning
in 2021. The categories in the proposed rule correspond to categories established in the Bipartisan Budget Act of 2018. The drug categories and payment amounts are based on how those same services would be reimbursed if they were performed in a physician’s office. Unfortunately, the categories as presented do not necessarily reflect the acuity or complexity of drug administration. Patients in category 1 typically have conditions such as advanced heart disease and pulmonary hypertension and require 24/7 infusions, which cannot be done in a physician’s office. These patients require more frequent monitoring, are more likely to require modifications to their therapy, and are at higher risk for hospitalizations. NHIA believes that the acuity of the patient, as delineated in the statute, is more significant than the therapeutic categories suggest.

CMS also proposes that the bundled payment amount for home infusion therapy services furnished on or after January 1, 2021 be set at five hours, the maximum allowed by statute. NHIA appreciates the recognition that the current payment for professional services is too low to cover the wide range of services needed by these complex patients. While CMS states that this proposal is intended to ensure that payment for home infusion therapy “adequately covers the different patient care needs and level of complexity of services provided”, we note that it is rendered almost meaningless given CMS’ unnecessarily narrow definition of “administration calendar day” discussed above.

The following example (using the same patient profile as identified above) illustrates the inadequacy of the proposed rate structure:

Patient is an 85-year-old woman with Congestive Heart Failure. Her plan of care requires weekly nursing visits; weekly assessment of her labs, response to therapy, and monitoring for adverse drug reaction; weekly correspondence with her caregiver(s); regular updates to her primary care provider and cardiologist; and weekly review and preparation of her drugs and supplies.

The nurse generally spends two hours with the patient and must also travel approximately a half-hour to and from the patient’s home. According to the U.S. Bureau of Labor Statistics, the median hourly wage for nursing is $33.23. As such, approximately two-thirds of the proposed reimbursement under this benefit ($154.70) would be consumed by nursing alone. That leaves approximately $55 to cover all of the pharmacy related professional services outlined under the plan of care. Given that the median hourly wage for pharmacists is $60.64, this rate would cover less than an hour of a pharmacist’s time per patient per week. This amount is wholly inadequate to cover the array of professional services necessary to safely deliver home infusion therapy.

As noted above, the categories and rates established in the Bipartisan Budget Act were based on the understanding that reimbursement would take place on each day that the patient receives the drug, irrespective of whether a nurse is present in the patient’s home. In fact, the statute requires the Secretary to take into account variation in utilization of nursing services. If Congress had intended only to reimburse for professional services when a nurse was physically present in the patient’s home, there would have been no need to account for variation in utilization of nursing services (since reimbursement presumably would hinge on the nursing visit).

If CMS were to reimburse on each day the patient receives an infusion drug, then NHIA would favor retaining the three-category system and the rates that were established in the Bipartisan Budget Act.
Unfortunately, because CMS is proceeding with its interpretation that reimbursement takes place only on days on which a professional is present in the patient’s home, and given the inadequacy of the rates identified in the proposed rule, NHIA recommends that CMS reimburse all categories at the highest (category 3) rate. NHIA notes that the American Medical Association’s Current Procedural Terminology® (CPT manual) description for this CPT code is more expansive than only chemotherapy drugs, and references that it can be used for “injection and intravenous infusion chemotherapy and other highly complex drug or highly complex biologic agent administration.”

Recommendation

7. CMS should reimburse all home infusion professional services at the proposed rate for category 3 (1 hour at CPT 96413 and 4 hours at CPT 96415).

CMS also proposes to increase the payment amounts for each of the three categories for the first visit. CMS proposes this increase to be equal to the average difference between the physician fee schedule amounts for evaluation and management of existing patients and new patient visits in a given year. CMS also proposes that the provision would be budget neutral, resulting in a decrease in the payment amounts for subsequent visits. NHIA appreciates that CMS recognizes that new patients require more time and education and supports this adjustment.

Contractor Billing

The proposed rule states, “DME suppliers, also enrolled as qualified home infusion therapy suppliers, would continue to submit DME claims through the DME MACs; however, they would also be required to submit home infusion therapy service claims to the A/B MACs for processing.”

Home infusion pharmacies are typically enrolled as DME suppliers and can currently bill each of the four Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for infusion pumps and supplies, including infusion drugs (see Figure 1) with a single National Provider Identification (NPI) number. This administrative flexibility allows home infusion therapy suppliers to distribute drug products (some of which may be sourced to a single provider) and supplies across a broad geographical region. This also allows for continued service for Medicare beneficiaries who spend parts of the year in different states.
Conversely, there are 13 A/B Medicare Administrative Contractors (A/B MACs) (see Figure 2). The proposed rule would require most home infusion pharmacies to enroll with the A/B MACs. While some home infusion pharmacy DME suppliers are also enrolled with the A/B MACs, the majority are not. Currently, the 855B A/B MAC enrollment form does not include a category for home infusion therapy provider. We urge CMS to offer guidance to inform home infusion therapy suppliers on how they should enroll with the A/B MAC.

Further, we understand that for some supplier types, the A/B MAC jurisdictions require that the address of the NPI be within the jurisdiction or state in which services are rendered and billed. As we noted earlier, however, home infusion products and services are sometimes provided over a wide geographic region, covering numerous states, from a single location. The fact that DME-enrolled home infusion pharmacies service multiple states can be seen in the publicly available data file, by comparing number of providers for specific HCPCS codes in the Medicare National DMEPOS HCPCS Aggregate Table to the number of providers in the Medicare State DMEPOS HCPCS Aggregate Table. Further, as noted in the DME taxonomy code below, home infusion therapy professional services are primarily pharmacy-based and do not require the provider to be in the same state as the patient.
Pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics, and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance.

An A/B MAC’s requirement for home infusion service suppliers to have a physical brick-and-mortar location in their jurisdiction or state would limit patient access to home infusion. Based on the 2017 publicly available data, the DME infused drug associated with the highest number of unique providers is milrinone with 374 providers.

The A/B MAC enrollment process allows for some supplier types to designate geographic areas that they render services in the patient’s home from a base operation, where scheduling and dispatch take place. If services are provided in more than one state and those states are serviced by different Medicare fee-for-service contractors, suppliers must complete a separate CMS-855B enrollment application for each Medicare fee-for-service contractor’s jurisdiction.

Figure 2.
Recommendations

8a) Provide clear guidance regarding how to enroll with the A/B MACs in order to be recognized and bill for HIT services.
8b) Ensure that home infusion therapy suppliers are able to enroll in such a way that they can identify their pharmacy as a practice location and base-operation from which they schedule and dispatch nursing-related home infusion services.
8c) Allow for jurisdictional enrollment and billing of HIT services without the requirement to have a physical location within the Jurisdiction.
8d) Allow for DME suppliers, also accredited as qualified home infusion therapy suppliers, to complete a single A/B MAC application identifying all areas that they schedule and dispatch the nursing component of home infusion therapy.

If the creation of and supplier education for a A/B MAC enrollment process requires time to implement, we recommend preserving the existing arrangement and requiring qualified home infusion therapy suppliers to submit home infusion therapy service claims to the DME MACs for processing.

Score and Cost Projections

The Congressional Budget Office (CBO) estimated that the 21st Century Cures Act would save the federal government approximately $660 million over 10 years by reimbursing home infusing drugs using the Average Sales Price (ASP) plus six percent, rather than the Average Wholesale Price (AWP). That policy change would save $60 million in 2020 -- approximately the same amount that CMS estimates it will cost to cover home infusion therapy professional services in 2020.

It is important to note, however, that in 2016, there was no published ASP for several commonly used infusion therapies, including milrinone lactate. CBO was not using comprehensive data to assess the cost to home infusion suppliers of transitioning from AWP to ASP. Looking to the public data recently made available, the actual reduction to providers for DME-infused drug associated with the HIT services benefit was -$220 million for 2017. CMS is proposing to fill a $220 million hole with a $60 million reimbursement. This represents a 73% rate cut for home infusion suppliers, which is simply unsustainable and will result in a utilization shift.

Recommendation

9. We recommend that CMS collect the data necessary to construct a permanent rate that reflects the complexity and duration of services necessary to deliver home infusion therapy; will incentivize the delivery of safe, effective, and high-quality care; and will inform future policy discussions as new and emerging medications become available.
Summary and Conclusion

In summary, we believe the current proposed rule is problematic for many reasons, and will require the following, significant modifications to assure beneficiary access to high-quality care.

1. Revise the definition of infusion drug administration calendar day to include every day an infusion drug physically enters the patient’s body and remove the requirement that a skilled professional be physically present in the beneficiary’s home for reimbursement to take place.
2. Refine the definition of “professional services” to include those services that are performed remotely by a pharmacist, notably pharmacist assessments, drug therapy evaluation and design, drug preparation and compounding, care planning, care coordination, nursing professional services, monitoring services and remote monitoring, and all other associated professional work.
3. Add a new requirement that the home infusion therapy (HIT) supplier be enrolled in the Durable Medical Equipment (DME) program as a pharmacy that provides external infusion pumps and supplies, and that maintains all pharmacy licensure requirements.
4. Require that the plan of care include all professional services necessary – including those that are provided by the DME supplier – to ensure the safe and effective delivery of high-quality home infusion care.
5. Add a requirement that a single physician be responsible for signing both the detailed written order and the home infusion therapy plan of care. This requirement would not prohibit other providers from issuing individual orders for drugs, labs, nursing services, etc.; but would ensure the full range of home infusion services are consolidated under the care of a single physician.
6. Adopt a standardized timeframe (90 days) for physician care plan review.
7. Reimburse all home infusion professional services at the proposed rate for category 3 (1 hour at CPT 96413 and 4 hours at CPT 96415).
8. a) Provide clear guidance regarding how to enroll with the A/B MACs in order to be recognized and bill for HIT services.
   b) Ensure that home infusion therapy suppliers are able to enroll in such a way that they can identify their pharmacy as a practice location and base-operation from which they schedule and dispatch nursing relate home infusion services.
   c) Allow for jurisdictional enrollment and billing of HIT services without the requirement to have a physical location within the Jurisdiction.
   d) Allow for DME suppliers, also accredited as qualified home infusion therapy suppliers, to complete a single A/B MAC application identifying all areas that they schedule and dispatch the nursing component of home infusion therapy.
9. Collect the data necessary to construct a permanent rate that reflects the complexity and duration of services necessary to delivery home infusion therapy; will incentivize the delivery of safe, effective, and high-quality care; and will inform future policy discussions as new and emerging medications become available.

In closing, NHIA appreciates CMS’ continued efforts to create a benefit to cover home infusion therapy professional services. We stand ready to work with CMS to modify the rule to assure that beneficiaries can access safe, high quality home infusion therapy services.
Please contact me at Connie.Sullivan@nhia.org if you have question or would like to further discuss our recommendations. Thank you for your consideration of these issues.

Sincerely,

Connie Sullivan, BS Pharm
President and CEO