National Home Infusion Association

Providing solutions for the home and specialty infusion therapy community

December 27, 2018

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1869-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, Maryland 21244-8013

Submitted via: regulations.gov

Re: Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations

Dear Administrator Verma,

The National Home Infusion Association (NHIA) appreciates the opportunity to provide additional comment on the final rule related to transitional payment for home infusion therapy services, specifically, on the Center for Medicare and Medicaid Services' (CMS) interpretation of "infusion drug administration calendar day," and the potential effect this policy will have on beneficiary access to home infusion therapy services.

Representing more than 800 home infusion individual providers, suppliers, manufacturers, and other infusion industry stakeholders, **NHIA submits that this policy as currently published will have significant negative effects on home infusion patients and their families, and calls on CMS to issue additional rule-making or guidance to correctly interpret "infusion drug administration calendar day" to include the diverse array of services required to safely furnish infusion services in the patient's home**

By withholding payment from home infusion suppliers for all the professional services provided to patients under the current delivery model that is recognized by nearly every commercial payer, CMS would create challenges and disincentives for home infusion suppliers to provide Part B infused drugs to

Medicare beneficiaries. Congress manifestly intended for Medicare beneficiaries to continue to have access to home infusion services and enacted the transitional payment to ensure that such services would be available. By stipulating that payment is only available on a day when a skilled professional is present in the patient's home, CMS has violated the spirit and intent of the law by rendering the payment so inadequate that Medicare beneficiaries will lose access to home infusion services. No other payer places such a restriction on the home infusion benefit.

Further, CMS recently issued clarification to the National Association for Home Care (NAHC) stating that home infusion therapy can still be considered a Medicare home health service prior to January 1, 2021. This is in direct contradiction to the final rule, which states "Home infusion therapy is excluded from the Medicare home health benefit, and separately payable, beginning January 1, 2019." If home care providers continue to bill for home infusion nursing as a home health service, home infusion providers would effectively be precluded from billing and getting reimbursed for all home infusion professional services. NHIA does not intend to prevent access to the Part A home care benefit, therefore NHIA encourages CMS to engage in further discussions with NHIA and NAHC to ensure future clarifications ensure access to both the home infusion and the home care benefits.

As detailed in NHIA's August 2018 comment letter, 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. And while CMS states in its final rule that this statute is quite prescriptive, as we see in CMS's evolving interpretation of the interplay between the home health and home infusion benefits, CMS has more flexibility than it claims. Further, we read CMS's invitation to provide further comment on the definition of infusion drug administration calendar day as an acknowledgement that there are other interpretations of this statutory definition. As we set forth below, we believe that there is an alternative way to interpret infusion drug administration calendar day that is consistent with law, and provides for payment on all days that professional services are furnished to administer home infusion drugs.

CMS can remedy this situation by revising its definition of infusion drug administration calendar day to capture a broader cross-section of professional services to include those that do not occur in the patient's home, but that are critical to ensure the safe and effective provision of home infusion therapy services. These remote pharmacy services include performing initial and ongoing pharmacist assessments, clinical care planning, drug preparation, care coordination, medication reconciliation, monitoring for adverse events and response to therapy, pharmacist interventions and subsequent therapeutic recommendations to prescribers, and patient education. Remote pharmacy professional services are fluid and occur at various frequencies depending on the patient acuity and frequency of administration. NHIA strongly urges CMS to utilize a mechanism of payment that differentiates and allows for billing of pharmacy professional services provided remotely - whether or not the patient is receiving a home health episode. This approach is legally consistent with Congress' intent to reimburse for days "on which professional services…were furnished to administer such drugs to" the patient as there is nothing within the existing statute that prevents payment when these professional services are furnished remotely. Providing payment on days that these remote professional services are furnished is more closely aligned with the statutory definition of infusion drug administration calendar day.

Proposed Remote Pharmacy Services

Initial and Ongoing Infusion Therapy Assessment
Pharmacist professional services begin the day the patient is referred for home infusion services. The original order for home infusion is often a simple prescription containing the basic parameters related to the infused drug. The pharmacist works in conjunction with the patient and their caregiver(s), nursing agency, physician/prescriber, and referring agency (e.g., hospital, SNF, clinic, physician) to develop and coordinate the initiation of home infusion. This involves a thorough review of the patient's past medical history, history of present illness, complete medication list, laboratory reports, home environment, ambulatory status or other physical limitations, vascular access, infusion medication order, and more. Once this assessment is complete, the pharmacy's home infusion team will determine whether the patient and the prescribed therapy are appropriate for home infusion. Often, the pharmacist proposes modifications to the therapy to accommodate the home environment. Physicians are typically unaware of potential safety or logistical issues related to home drug administration when ordering home infusion therapy. It is uniquely up to the pharmacist to determine if the medication ordered can be administered in the home. This assessment process often occurs over a period of several days prior to the patient being admitted to the home infusion service.

Infusion Plan of Care Development and Implementation
While the final rule stipulates that a physician prescribe the type, amount, and duration of home infusion therapy services that are to be furnished, it is the home infusion pharmacist who works with the patient/caregiver and nurse to develop a comprehensive plan of care delineating all aspects of home infusion therapy. The home infusion plan of care articulates the goals of therapy, confirms the medication to be infused, provides specific instructions for administration (e.g., whether a pump will be used), assures access device care, sets a schedule for lab orders, nursing visit frequency, and monitoring, and identifies other special orders such as pre-medications to be administered and standing orders for treatment of acute infusion reactions. The complete plan of care is sent to the physician to review and approve, and is re-evaluated each time home infusion drugs are furnished. These are critically important services that require the professional expertise and knowledge that is unique to home infusion pharmacists, but are done collaboratively with the prescribing physician, nurse, and patient.

Infusion Therapy Care Coordination
Under the final rule, CMS reimburses only for care coordination services that are performed as part of a visit that takes place in the patient's home. However, all aspects of the home infusion plan of care must be communicated and coordinated to avoid medication errors, missed or delayed doses, or unplanned hospitalizations. The pharmacy care team provides comprehensive case management of the infusion therapy and ensures that all members are informed of changes to the plan of care, changes in patient clinical status, adverse events, changes in supply needs, or schedule changes. Communication for the purposes of coordinating care takes place continuously during treatment. Communication with the patient and/or caregiver often occurs several times a week to assess for therapy effectiveness, adverse events, proper use of equipment and supplies, and to plan deliveries. Communication with the nursing provider and physician also occur frequently as needed.

Information gleaned during these frequent communications to provide a coordinated service is used to adjust the plan of care. For example, the pharmacist might learn of a recent weight change that requires the medication dose to be adjusted; or the pharmacist may recommend an adjustment to the frequency of administration in response to a lab report showing a decrease in renal function. The execution of any

change requires a plan of care update that is reviewed and approved by the prescriber, revisions to the compounding record, and prompt communication to the patient and nurse.

Drug Preparation and Compounding
CMS has argued incorrectly that pharmacy services associated with the preparation and dispensing of home infusion therapy drugs are covered under the Medicare Part B Durable Medical Equipment (DME) benefit and are not part of this specific home infusion therapy benefit. CMS has made this point in support of the argument that any shortfall in service payments will be made up by a payment for DME.

Depending on how frequently the drugs are prepared, home infusion suppliers are reimbursed approximately $30/day for DME. That payment is used to cover the equipment and supplies that patients need each time they infuse (e.g., pumps, tubing, dressing changes, cassettes, bags, etc.). It is not sufficient to cover costs necessary to prepare compounded sterile products in compliance with nationally recognized standards of practice (e.g., personal hygiene and garbing, facilities and engineering controls, microbiological air and surface monitoring, cleaning and disinfecting requirements, sterilization, etc.).

Value of Pharmacy Professional Services

Home infusion pharmacists provide the above services incident to a physician order and plan of care to achieve positive clinical outcomes, avoid adverse therapy reactions, maximize healthcare resources, and improve patient's quality of life. Without adequate reimbursement for these services, patients will be at risk for higher rates of hospitalization and emergency room visits; and may experience more adverse events. Pharmacists frequently identify and resolve issues that arise between home visits by the nurse. The provision of an infused drug in the home requires pharmacists to have ongoing interactions with patients to prevent serious adverse events. Examples of issues that frequently occur include, but are not limited to: addressing sudden weight changes in patients with heart failure by notifying the physician and recommending initiation of a diuretic, modifying the infusion needle length for patients on subcutaneous immune globulin due to swelling at the injection site, and providing counseling to nurses and patients regarding the safe administration and disposal of hazardous drugs. The benefits of home infusion therapy are significant and quantifiable, but only if the necessary services are effectively provided by the pharmacist.

Additional Considerations

As CMS revisits the definition of infusion drug administration calendar day, it is also important to note that, as written, the final rule:

- Reimburses suppliers at a rate that is far below other payers' rates, making traditional Medicare reimbursement an outlier in the marketplace;
- Limits reimbursement to a level that is insufficient to cover the expenses of maintaining a sterile compounding facility that is compliant with accreditation standards;
- Does not recognize the contributions of pharmacist professional services;
- Underpays for infusions (such as subcutaneous immunoglobulin) that are administered by patients independently (without the presence of a nurse); and
- Is tied to a budget estimate that significantly underestimated the reduction in drug reimbursement.

Home Infusion Reimbursement Below the Rates of Other Payers

Other payers – including commercial insurers, Medicare Advantage plans and the TRICARE program – typically reimburse home infusion suppliers using a fixed rate for each day the patient receives an

infusion medication. That rate covers the cost of durable medical equipment (DME) and supplies, remote pharmacy professional services (drug preparation, care plan development and review, clinical assessments, care coordination, etc.), and any other administrative costs. Under most other coverage, nursing and drugs are coded and billed separately. Below is an illustration of how TRICARE would reimburse for an infusion drug administration calendar day for milrinone in the state of Oregon (a state chosen at random):

Service	**Average Rate Per Day**
Drug	$ 18.86
Per Diem (DME and Pharmacy Professional Services)	$ 201.25
Nursing (2 hour visit, one time per week)	$ 19.28
Total	**$ 239.39**

Medicare Advantage and commercial plans use a similar methodology. While individual contract rates are proprietary, NHIA member companies confirm that their reimbursement for pharmacy professional services range from 60 to 80 percent of the TRICARE reimbursement.

Due to unique features of the Medicare program (notably, the need to bill for DME separately), and in response to technical assistance from CMS, Congress used a slightly different formula for reimbursing for home infusion professional services. Under the formula established in the *21st Century Cures Act* and further defined in the *Bipartisan Budget Act of 2018,* Medicare would reimburse for an infusion drug administration calendar day for milrinone:

Service	Average Rate Per Day
Drug	$ 16.57
Per Diem (Nursing and Pharmacy Professional Services)	$ 141.12
DME	$ 29.36
Total	**$187.05**

Based on the final rule, however, home infusion suppliers would be reimbursed significantly less for professional services compared to published rates. Assuming a once-weekly nursing visit, CMS proposes to reimburse the following:

Service	Average Rate Per Day
Drug	$ 16.57
Per Diem (Nursing and Pharmacy Professional Services)	$ 20.16
DME	$ 29.36
Total	**$66.09**

As illustrated here, payment under the final rule represents a dramatic and unsustainable reduction from other payers' reimbursement for home infusion services.

The Costs of Maintaining Accreditation Standards

The final rule requires that home infusion suppliers be accredited by a recognized accreditation organization. To become accredited, a home infusion supplier must be in compliance with all federal and state regulations, including United States Pharmacopeia (USP) Chapter <797> and the Food and Drug Administration guidance documents on sterile compounding. Additionally, accreditation requirements necessitate a significant investment in clinical training for both pharmacists and nurses to ensure compliance with standards for conducting patient assessments, care planning, clinical monitoring, and patient training; as well as a robust quality improvement program. Home infusion pharmacies operate under a case management model similar to what is used in home health. Home infusion providers collect quality and outcome data related to adverse events, response to therapy, and hospitalization rates among other elements; and regularly assess patient satisfaction with services. Simply put, the proposed reimbursement is insufficient to cover these costs to provide a comprehensive, coordinated service and could create safety concerns.

Underpayment for Patients with Immune Disease

Immunoglobulin (Ig) is used to provide passive immunity for patients with a variety of diseases and has become a necessary therapy for several conditions, most notably, primary immunodeficiency (PID). By utilizing the subcutaneous route of administration, patients with PID are frequently able to infuse their medications independently at home, without the presence of a nurse. The transition from intravenous to subcutaneous infusions for Ig has provided patients with greater flexibility with regard to scheduling and has improved outcomes[1].

If CMS does not act, patients will be more likely to receive IV formulations of Ig in a clinic setting, which reduces efficacy, increases cost, and lessens patient quality of life. Home administration of Ig requires a pharmaceutical care plan designed and managed by the pharmacist for the safe and effective delivery of this complex therapy. The patient's weight must be obtained and validated prior to each delivery, and orders must be re-assessed for formulation selection and dosing appropriateness. The care plan for Ig

[1] Abolhassani, H., Sadaghiani, M., Aghamohammadi, A., et al. Home-Based Subcutaneous Immunoglobulin Versus Hospital-Based Intravenous Immunoglobulin in Treatment of Primary Antibody Deficiencies: Systematic Review and Meta Analysis. Hassan Abolhassani & Mohammad Salehi Sadaghiani & Asghar Aghamohammadi & Hans D. Ochs & Nima Rezaei. J Clin Immunol (2012) 32:1180–1192

therapies must document the clinical improvement of the disease, monitor for infection and impact on energy levels, and be updated to ensure that the patient is receiving the desired effects of the medication. Additionally, the pharmacist is on-call to troubleshoot administration-related issues and respond to questions about side effects and/or adverse events.

Because the final rule only provides reimbursement for nursing visits, none of these pharmacy-based services would be supported. Moreover, Ig infusion can sometimes take several days, so it is unrealistic to expect that these patients would be able to receive subcutaneous infusions in an out-patient setting, thus the assumption that patients will be forced to rely on IV infusions of Ig provided in an office-based setting is a reasonable one.

Erroneous Budget Estimate

The Congressional Budget Office (CBO) estimated that the *21st Century Cures Act* would save the federal government approximately $660 million over ten 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 $55 million in 2019 -- approximately the same amount that CMS estimates it will cost to cover home infusion therapy professional services in 2019.

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. Using 2016 utilization data, however, NHIA estimates that the actual annualized change in reimbursement caused by moving from AWP to ASP based payment was $263,396,459.44 (see Attachment A). In other words, CMS is proposing to fill a $263 million hole with a $58 million reimbursement. This represents a 78 percent rate cut for home infusion suppliers and is simply unsustainable and will result in a utilization shift.

Furthermore, the shift in policy to continue to allow for home health agencies to provide nursing to home infusion patients under the home health benefits obstructs the home infusion supplier from accessing the "in home" trigger for reimbursement of all professional services that "are built into the payment for the day the professional services are furnished in the home"

Recommendations

CMS' final rule is wholly inadequate to cover home infusion services and would cause home infusion suppliers to discontinue providing services to Medicare beneficiaries, forcing patients to receive their infusions in costlier settings. In lieu of the narrowly defined infusion drug administration calendar day proposed in the final rule, NHIA strongly urges **CMS to issue sub regulatory guidance that:**

- Clarifies that home infusion services are reimbursed on any day a patient receives a professional service, including those provided remotely by the pharmacist, to enable the safe administration of part B eligible parenteral drugs and biologics administered through catheters and/or needles in home;

- Establishes a billing mechanism that distinguishes between professional services provided in the home by the nurse and the remote pharmacy services (e.g., drug preparation, plan of care development, clinical assessments, and care coordination, etc.).

These changes would allow home infusion and home care providers to collaborate to serve patients with a home care episode without interfering with the provision of either benefit, provide CMS with the data necessary to construct a permanent payment rate that reflects the complexity and duration of services necessary to delivery home infusion therapy, incentivize the delivery of safe, effective and high-quality care, and inform future policy discussions as new and emerging medications become available.

NHIA remains committed to working with CMS, members of Congress, and other stakeholders to ensure that Medicare beneficiaries can access home infusion services. Please feel free to contact me at connie.sullivan@nhia.org, or Sharon Pearce, Vice President of Government Affairs at Sharon.pearce@nhia.org or (703)838-2661. We thank you for your consideration and look forward to working with you to modify this rule.

Sincerely,

Connie Sullivan, BS, Pharm.
President and Chief Executive Officer
National Home Infusion Association

Attachment 1

HCPCS Code	Short Description	HCPCS Code Dosage	**Q4 2017** DME Fee Schedule (ASP +6%)	**Q4 2016** DME Infusion Limit (95% of the 2003 AWP)	Medicare DME FFS Utilization 2016 Units	Annualized change in reimbursement moving from AWP to **Q4 2017** ASP based payment. **(Red is Negative)**
J0133	Acyclovir	5 MG	0.072	0.470	507,757	(202,087.29)
J0285	Amphotericin B	50 MG	32.783	10.280	-	-
J0287	Amphotericin b lipid complex	10 MG	13.859	21.850	7,242	(57,870.82)
J0288	Amphotericin b cholesteryl Sul	10 MG	TBD*	15.200	-	-
J0289	Amphotericin b liposome inj	10 MG	21.515	35.800	43,256	(617,911.96)
J0895	Deferoxamine mesylate inj	500 MG	8.035	15.630	121,630	(923,779.85)
J1170	Hydromorphone injection	4 MG	2.046	1.490	979,279	544,479.12
J1250	Inj dobutamine HCL/250 mg	250 MG	5.600	4.740	164,628	141,580.08
J1265	Dopamine injection	40 MG	0.635	0.620	41,410	621.15
J1325	Epoprostenol injection	0.5 MG	15.566	12.640	1,585,362	4,638,769.21
J1455	Foscarnet sodium	1000 MG	75.172	13.070	17,003	1,055,920.31
J1559 JB	IG Hizentra	100 MG	9.813	14.364	13,830,133	(62,940,935.28)
J1561 JB	IG Gamunex/ Gammaked	500 MG	38.944	46.170	616,790	(4,456,924.54)
J1569 JB	IG Gammagard liquid	500MG	39.783	52.497	1,203,983	(15,307,439.86)
J1570	Ganciclovir sodium injection	500 MG	68.489	35.250	10,778	358,249.94
J1575 JB	IG Hyqvia	100 MG	13.136	17.372	1,838,918	(7,789,656.65)
J1817	***Insulin for insulin pump use	50 UNITS	9.968	2.800	8,247,311	59,116,725.25
J2175	Meperidine hydrochl /100 MG	100 MG	5.101	0.560	-	-
J2260	*Milrinone lactate	5MG	1.944	51.580	3,181,525	(157,918,174.90)
J2270	Morphine sulfate injection	10 MG	1.416	0.710	134,507	94,961.94
J2278	Ziconotide	1 Microgram	7.419	6.935	-	-
J3010	Fentanyl citrate injection	0.1 MG	0.499	0.700	42,004	(8,442.80)
J3285	Treprostinil	1 MG	61.237	61.750	2,904,877	(1,490,201.90)
J7340	***Carbidopa 5 MG/ Levodopa 20 MG	100 MG	213.950	230.099	2,007,063	(32,412,060.39)
J7799 JB	**CUVITRU	1 ML	35.616	35.616	6,361	-
J9000	Doxorubicin hcl	10 MG	2.978	12.540	1,430	(13,673.66)
J9039	Blinatumomab	1 Microgram	103.429	103.530	20,295	(2,049.79)
J9040	Bleomycin sulfate injection	15 UNITS	37.181	289.370	-	-
J9065	Inj cladribine per 1 MG	1 MG	20.662	61.720	529	(21,719.68)
J9100	Cytarabine hcl 100 MG inj	100 MG	0.816	8.190	-	-
J9190	Fluorouracil injection	500 MG	1.624	2.070	590,025	(263,151.15)
J9200	Floxuridine injection	500 MG	72.674	136.800	636	(40,784.14)
J9360	Vinblastine sulfate inj	1 MG	3.477	4.100	-	-
J9370	Vincristine sulfate 1 MG inj	1 MG	4.981	33.980	224	(6,495.78)
				Estimated annualized reduction:		**(218,522,053.44)**
J1817	Insulin for insulin pump use	50 UNITS	9.968	2.800	6,271,918	44,957,108.22
				Annualized backing out Insulin:		(263,479,161.66)

Notes:

-2% Sequestration is not taken into account in this spreadsheet

**Rate for Cuvitru (NOC code J7799) based on communication from CGS,this is not in the Drug Fee Schedule.

*** Home Infusion Services payment does not apply (J1817 is statutorily excluded, J7340 in administered via enteral route)