National Home Infusion Association

1600 Duke Street • Suite 410 • Alexandria, VA 22314 • P: 703.549.3740 • F: 888.206.1532 • info@nhia.org

August 26, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1747-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-Term Care Hospital Quality Reporting Requirements (CMS-1747-P)

Dear Administrator Brooks La-Sure:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed rule: *Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-Term Care Hospital Quality Reporting Requirements* (the "Proposed Rule") issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on July 7, 2021.[1] 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 community, we write to share our feedback regarding implementation of the home infusion therapy (HIT) services benefit. While the Proposed Rule is virtually silent on policies related to the home infusion therapy services benefit, we believe it is important to share our observations and recommendations to date.

[1] 86 Fed. Reg. 35874 (July 7, 2021)

National Home Infusion Association

1600 Duke Street • Suite 410 • Alexandria, VA 22314 • P: 703.549.3740 • F: 888.206.1532 • info@nhia.org

Access to Home Infusion Therapy Services

Over the past years, NHIA and Members of Congress have written to CMS regarding CMS's flawed implementation of the Medicare home infusion therapy services benefit. For calendar years 2019 and 2020, CMS implemented the temporary home infusion therapy services benefit in a faulty manner, only allowing for reimbursement on days when a nurse or other professional was physically present in the patient's home. Indeed, Congress itself wrote to the agency stating, "this physical presence requirement contradicts [the] intent in drafting and enacting this legislation and makes the reimbursement required by the bill inadequate."[2] CMS's damaging approach has consistently failed to account for the extensive pharmacy services necessary to deliver the home infusion therapy services benefit, including designing the therapy, assessing the patient, monitoring for adverse drug reactions, coordinating care, preparing the drug to a final form, and recommending modifications to the plan of care. NHIA reminds CMS that commercial payers recognize that home infusion care centers around the intravenous (IV) drug therapy being provided. Additionally, pharmacists play a key role in ensuring services are provided in a timely and seamless manner by coordinating and executing the plan of care between the patient, physician, and nurse, for which the pharmacy is paid a set fee by commercial plans for each day the medication is infused. Importantly, no other payors – commercial, Medicare Advantage, the Veterans Administration – require a professional to be physically present in the home to reimburse for a patient's home infusion therapy services. NHIA is disappointed that CMS has not modified its approach and has continued with implementing the permanent benefit in a flawed manner, inconsistent with the language and intent of the *21st Century Cures Act*.

NHIA is extremely concerned that the actions CMS has taken over the past years have resulted in providers being forced out of participating in Medicare's home infusion therapy services benefit and a decrease in access to home infusion therapy services for Medicare beneficiaries. Over the past five years, the rate of reimbursement for each component of the Medicare Part B home infusion program has been reduced by competitive bidding, implementation of the Average Sales Price (ASP) methodology for home infusion drugs, and other policies implemented by CMS. These changes have led to reduced overall access and utilization of the home infusion therapy benefit and the unfortunate migration of patients to other, more expensive, settings for their care. Medicare beneficiaries who have historically utilized the Part B home infusion benefit have serious conditions that are among the most likely to be readmitted to the hospital, such as congestive heart failure, immune deficiency, cancer, and invasive fungal and viral infections.

[2] Letter to CMS Administrator Seema Verma, October 8, 2018, U.S. Senators Johnny Isakson, Mark Warner, et. al. Available at: https://www.nhia.org/wp-content/uploads/2020/09/USS_Seema_Verma_Ltr.pdf. *See also*, Letter to CMS Administrator Seema Verma, September 26, 2018, U.S. Representatives Kenny Marchant, Fred Upton, Elliot Engel, Terri Sewell, et. al. Available at: https://www.nhia.org/wp-content/uploads/2020/09/CMS_Proposed-Rule_House_Letter_to_CMS.pdf.

National Home Infusion Association

1600 Duke Street • Suite 410 • Alexandria, VA 22314 • P: 703.549.3740 • F: 888.206.1532 • info@nhia.org

Shifting care back to institutional and office-based settings comes at the expense of undue burden and negative quality of life impacts for the beneficiaries and their families, as well as additional cost to the Medicare program. These impacts will be felt more intensely by beneficiaries living in rural areas. NHIA, in partnership with a major software vendor, collected data about home infusion services in rural areas. Using CMS's definition of "rural" from the competitive bidding program, NHIA found that home infusion providers serve significant numbers of patients living in rural communities, where access to IV care is more limited. Twenty five percent of home infusion pharmacies in the study (n=200) reported that more than 25 percent of the patients they serve live in rural areas.

Between 2014 and 2018, home infusion provider participation in Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) has declined by 52 percent. Beneficiary utilization over this same period has likewise declined by 25 percent despite a growing Medicare-age population. The permanent home infusion therapy services benefit, which began on January 1, is likely to result in further declines in utilization of Part B-covered home infusion due to low provider enrollment. Currently, fewer than 250 individual home infusion pharmacies (less than half of eligible DMEPOS pharmacy suppliers) have enrolled to provide Part B home infusion therapy services under the permanent benefit. While other entities are permitted to enroll in the benefit, they are doing so in such small numbers that their impact on access is negligible. A home health agency has a limited catchment area compared to a home infusion pharmacy that operates under a hub and spoke model to cover a large service area, and therefore cannot serve as many beneficiaries. As the primary coordinator of services, a home infusion pharmacy has an existing network of nursing providers it can rely on to serve patients over a broad geographic area. With so few beneficiaries utilizing home infusion therapy services, the cost-to-benefit ratio for a home health agency is likely too narrow to incentivize the high-level participation needed to ensure beneficiary access everywhere in the U.S.

CMS's problematic policies of requiring a practitioner's physical presence are jeopardizing access to home infusion therapy, which is a safe, effective, and less expensive service compared to other, acute and subacute sites of care. Face-to-face nursing services are critical to the success of home infusion, but without adequate reimbursement for the complimentary pharmacist professional services, CMS has put beneficiary access at risk. NHIA recently conducted a multi-center study of home infusion pharmacist professional activities for 25 patients representing 309 infusion therapy days. Data from 352 individual pharmacist tasks for the 25 patients were categorized and analyzed based on the need for an infusion pump. Our findings show that patients dependent on infusion pumps for continuous administration of IV medications place the highest demands on pharmacist time. Patients utilizing a pump required 2.37 pharmacist tasks per day compared to 1.09 for non-pump patients. Simply put, patients utilizing infusion pumps required more frequent pharmacist support.

National Home Infusion Association

1600 Duke Street • Suite 410 • Alexandria, VA 22314 • P: 703.549.3740 • F: 888.206.1532 • info@nhia.org

NHIA is troubled by the Medicare home infusion therapy services data that it has reviewed to date. In CMS's CY 2019 proposed rule, the agency estimated in Table 66 that nearly 18,000 Medicare beneficiaries would access the transitional home infusion therapy services benefit each year, which would result in more than 300,000 billable service days at a cost of approximately $58.6 million.[3] According to claims data obtained by NHIA through a third party for CY 2018, 2019 and 2020, CMS has essentially paid for services to fewer than 700 Medicare beneficiaries per month with an annual expenditure of approximately $4 million. In CY 2020, there was a slight increase, resulting in expenditures of approximately $5 million. This shortfall indicates that CMS significantly over-estimated the need for in-person nursing support and under-estimated the role pharmacists play in the home infusion care model. The result is that fewer providers continue to provide the benefit and fewer beneficiaries are being served at home. Without a change in course, CMS's policies will continue to threaten the viability of the Medicare Part B home infusion therapy program.

NHIA Recommendation:

NHIA requests that CMS modify the definition of infusion drug administration calendar day to remove the in-person requirement and ensure that home infusion providers are reimbursed for each day the patient receives an infusion medication, consistent with the intent of the *21st Century Cures Act* and with practices in the commercial market. CMS has the authority and flexibility to restructure how home infusion professional services are defined and paid. By recognizing pharmacist services and paying each day of infusion, more full-service home infusion pharmacies will be incentivized to enroll and participate in the program, increasing access for many vulnerable Medicare beneficiaries. Additionally, CMS could account for the additional cost of in-person nursing by paying a differential rate for days a nurse visits the home.

Sterile Drug Quality and Safety

NHIA is concerned that the current policy of limiting payment to in-person nursing services will cause more pharmacies to exit the DMEPOS home infusion benefit. A portion of the revenue previously paid to the DMEPOS pharmacy to support sterile drug preparation functions has been shifted to the HIT services supplier to cover nursing costs. This leaves pharmacies with substantially less funding for maintenance of cleanroom facilities and administrative costs associated with compliance with national sterile compounding standards. Furthermore, neither CMS's HIT nor DMEPOS accreditation standards require that compounded sterile products be prepared consistent with United States Pharmacopeia (USP) standards, which ensure that the

[3] 83 Fed. Reg. 32340, 32507 (July 12, 2018)

National Home Infusion Association

1600 Duke Street • Suite 410 • Alexandria, VA 22314 • P: 703.549.3740 • F: 888.206.1532 • info@nhia.org

drugs are free of contamination. In fact, nothing in CMS's policies require that a drug be provided to a patient in a final, useable form – the current industry standard - when the drug properties permit preparation in a cleanroom environment in advance of delivery to the patient. Relying on federal and state regulations is insufficient for ensuring the safety of compounded sterile medications, due to inconsistent standards and lack of enforcement capacity at the state level.

NHIA believes these gaps in standards and payment policy undermine the expectation that home infusion services ensure the provision of high-quality, sterile drugs in a final useable form, and potentially puts patients at risk for adverse events and infections. In passing the 21st Century Cures Act, Congress intended to protect and fund professional pharmacist services associated with the safe preparation of compounded sterile products. The home infusion industry has a well-established private sector-driven accreditation structure, with companies that offer full-service accreditation programs that evaluate and credential all aspects of the home infusion pharmacy and nursing programs, including sterile compounding, in compliance with state, federal and industry standards. Commercial payers rely on the accreditation programs to validate that a home infusion provider meets or exceeds expected industry standards and complies with state and federal laws. Medicare beneficiaries deserve no less.

NHIA Recommendation:

NHIA believes that consistent with standards of care found within commercial, Medicare Advantage and state Medicaid programs, home infusion therapy services providers should be required to meet accreditation standards to ensure that, when possible, drugs are prepared in a sterile manner to their final, useable form according to USP, state, and federal standards.

Safety and Quality Standards and Accreditation

In addition to our concerns regarding sterile drug quality, NHIA is troubled by the minimal safety and quality standards in the Medicare home infusion therapy services program. Home infusion providers that participate in the commercial market are held to higher standards for ensuring clinical competencies for pharmacists and nurses who care for home infusion patients; equipment safety and maintenance procedures; patient assessments, care planning and care coordination requirements; patient education and safety requirements; and quality assessment and improvement program requirements. The Medicare home infusion therapy benefit relies on physicians to perform functions normally supported by the HIT supplier. CMS stated in a previous rule that the home infusion plan of care must be established and reviewed by the physician in consultation with the DME supplier responsible for furnishing the home infusion drugs. Requiring the physician – who may be a different person than the physician ordering the

National Home Infusion Association

1600 Duke Street • Suite 410 • Alexandria, VA 22314 • P: 703.549.3740 • F: 888.206.1532 • info@nhia.org

DME – to sign the HIT plan of care and coordinate services between the HIT and DME suppliers is creating an unnecessary administrative burden for physicians and HIT suppliers alike. The fragmented system established by CMS does not require the supplier of HIT services to coordinate directly with the DME supplier, which increases the potential for medication errors and adverse events, potentially leading to higher rates of emergency department use and hospital re-admission.

NHIA Recommendation:

NHIA again recommends that home infusion therapy services supplier be required to coordinate directly with the supplier of the equipment, drug and supplies, establishing a primary point of contact for patients and their families, physicians, referral sources, and other entities involved in the home-based care. Additionally, standards for the HIT benefit should be comprehensive and include requirements to ensure staff qualifications and proficiencies are evaluated; care is initiated in a timely manner; patients are periodically assessed for satisfaction; quality outcome data is collected and evaluated; and requirements for maintaining a consolidated medical record of services associated with the IV therapy are provided.

NHIA appreciates the opportunity to provide comments on these important issues and we welcome the opportunity to continue working with CMS to improve the Medicare home infusion therapy benefit for Medicare beneficiaries. We would appreciate the opportunity to meet with you directly to discuss our recommendations and provide additional information about the impacts of CMS's policies on access to home infusion therapy for Medicare beneficiaries. For question or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer