

August 29, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1780-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements; Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements (CMS-1780-P)

Dear Administrator Brooks La-Sure:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed rule: *Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements; Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements* (the “Proposed Rule”) issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on July 10, 2023.¹ NHIA is a trade association representing companies providing infusion therapy to patients in their homes, as well as manufactures and suppliers of infusion and specialty pharmacy products. As the leading voice for the home and alternate infusion community, we write to share our feedback regarding our concerns related to Medicare beneficiaries’ access to the home infusion therapy (HIT) services benefit. While the Proposed Rule is silent on policies related to the home infusion therapy services benefit – other than how the benefit relates to home administration of intravenous immune globulin (IVIG), we believe it is important to continue to advocate for beneficiary access to these critical services.

¹ 88 Fed. Reg. 43654 (July 10, 2023)

We summarize our recommendations below, which are discussed in more detail in this letter.

HIT Services:

1. Combine the Part B DMEPOS infusion disposable supplies for drug administration and catheter care with the HIT services payments and establish a bundled per infusion-day payment that covers both supplies and services. CMS could account for the additional cost of in-person nursing by paying a differential rate for days a nurse visits the home.
2. Continue issuing the annual HIT Monitoring Report.

Permanent IVIG Benefit:

1. NHIA supports CMS' proposals implementing the permanent IVIG items and services benefit. NHIA appreciates that HCPCS Q2052 bundles supplies ("items") and services necessary for IVIG administration in the home.
2. NHIA is concerned that the LUPA based rate calculation for Q2052 undervalues the significant services involved providing IVIG in the home, with one-on-one care for an extended infusion often lasting more than four hours. Home infusion ensures equitable access to IVIG treatments for beneficiaries with disabilities, transportation barriers, and those living in rural areas; thus, NHIA requests increasing the rate to five times the full LUPA rate, ensuring broad provider participation in the benefit and improved beneficiary access.
3. NHIA requests CMS publish an annual report on the benefit, similar to the HIT Monitoring Report.

Access to Home Infusion Therapy Services

NHIA is extremely disappointed that for the second straight year CMS did not address the HIT services benefit in the Proposed Rule, other than discussing the relationship between the HIT services benefit and home administration of IVIG. Despite CMS's omission, NHIA remains committed to advocating on behalf of Medicare beneficiaries for policies to address the severe deficiency in access to Medicare's home infusion therapy services benefit. CMS' own data, released several months ago in the HIT Monitoring Report, demonstrates that the benefit, as

currently implemented, lacks sufficient participation from providers to ensure equitable access to HIT services across the U.S.²

The HIT Monitoring Report summarized utilization trends for the Medicare Part B HIT services benefit from 2020 through Q1 and Q2 of 2022 and represented the second report by CMS illustrating the failure of the Part B HIT services benefit to attract providers.³ The report found that overall utilization remained essentially flat over the 26-month study period, despite growing enrollment in Medicare over the same timeframe. On average, only 1,250 beneficiaries received Part B HIT services per quarter, a small fraction of the patients eligible for the service. In addition, geographic disparities regarding provider participation worsened since the prior year's report. When comparing data maps from the reports issued in 2022 and 2023, the number of states having no services provided to beneficiaries increased from three to six, including large rural states, which is problematic from an equity standpoint. Additionally, the average number of providers billing for HIT services only grew from 55 to 67 between 2019 and Q2 of 2022, a shockingly low number considering there are nearly 1,000 DMEPOS pharmacies; 11,000 home health agencies; and a wide range of other providers in the U.S. capable of participating in the benefit.

The lack of provider participation in the Part B HIT services benefit is directly related to CMS's policies (i.e., lack of payment for professional pharmacy services each day of infusion) and additional requirements for providers to obtain accreditation to bill for services. Establishing equitable access to home infusion services across the United States requires reforming the Medicare HIT services benefit.

As we have previously noted, since the beginning of the temporary HIT services benefit in 2018, CMS has implemented the benefit in a manner that is inconsistent with Congressional intent, only allowing for reimbursement on days when a nurse or other professional is physically present in the patient's home. This interpretation is counter to the CMS requirement that beneficiaries using drugs covered by the DMEPOS infusion pump benefit can administer independently, without the assistance of a clinician. CMS's insistence that the HIT benefit is intended to cover services a beneficiary should need infrequently is perplexing. NHIA has made numerous efforts to explain that it has always been the pharmacy providing continuous, remote support for patients using DMEPOS-infused drugs, often without any need for a visiting nurse aside from an initial teaching visit (e.g., subcutaneous immune globulin) or a periodic (weekly) visit. This

² Centers for Medicare & Medicaid Services HIT Monitoring Report (February 2023), available at: <https://www.cms.gov/files/document/hit-monitoring-report-feb-2023.pdf>

³ Centers for Medicare & Medicaid Services HIT Monitoring Report (January 2022), available at: <https://www.cms.gov/files/document/hit-monitoring-report-january-2022.pdf>

pharmacy-based model has been in effect in the commercial sector for over 40 years, alleviates pressure on nurses who are in short supply, and generates comparable outcomes to other sites of care, while improving access and the quality of life for beneficiaries. As a result of CMS's flawed implementation, full-service infusion pharmacies are not participating in the Medicare HIT program and Medicare beneficiaries are without meaningful access to these essential home-based services. This lack of access results in additional costs to the Medicare program and to beneficiaries, as they must seek care in other higher-cost settings such as skilled facilities and outpatient clinics.

NHIA routinely hears directly from Medicare beneficiaries about the importance of access to HIT services. These patients tell us that HIT is essential to their independence, improves their quality of life, decreases the chances of acquiring hospital-related illnesses, and increases adherence. One patient stated, "With home-based care, I'm more likely to stay on my regimen and I have a better quality of life. I can't understand why Medicare doesn't have better coverage for this much better solution." Additionally, CMS's own study of the IVIG demonstration illustrates the benefits of home infusion for beneficiaries by removing transportation barriers and improving outcomes.⁵

NHIA reminds CMS that no other payors – commercial, Medicare Advantage, the Veterans Administration, TRICARE – require a professional to be physically present in the home to reimburse for a patient's home infusion therapy services. NHIA is disappointed CMS has not modified its approach, despite having the authority to revise the benefit, and has continued implementing the benefit in a manner inconsistent with the language and intent of the *21st Century Cures Act* that all professional services (not just nursing) are paid under the HIT services benefit. All other payors in the U.S. recognize that offering a robust home infusion benefit lowers the overall cost of care by shifting patients from more expensive settings to home. Previous studies by the Government Accountability Office suggest Congress should examine this gap in coverage for Medicare beneficiaries.⁴ CMS should not continue to deny Medicare beneficiaries the same choices that are afforded to patients with commercial insurance and Medicare Advantage. NHIA's recommendation to bundle supplies with services would bring Medicare a step closer to allowing patients to choose between home and facility settings for receiving infusion services as most infusion drugs are covered by the Part D benefit.

NHIA Recommendation:

NHIA is extremely concerned CMS's actions are eroding access to HIT services for Medicare beneficiaries, due to providers opting out of participating in Medicare's HIT services benefit.

⁴ GAO-10-426 Home Infusion Therapy: Differences Between Medicare and Private Insurer's Coverage

NHIA requests that CMS correct the flawed implementation of the current Medicare Part B HIT services benefit, which does not currently recognize the pharmacy professional services. The *21st Century Cures Act* intended for all professional services to be included in the HIT benefit and paid each day the patient infuses medication at home, consistent with the commercial market and other payors. CMS has the authority and flexibility to restructure how home infusion professional services are defined and paid. By recognizing all 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. This also would lead to simplified billing and administrative processes for Medicare beneficiaries, as well as create consistency with the newly created Home Intravenous Immune Globulin Items and Services benefit.

Specifically, NHIA recommends CMS combine the Part B disposable supplies with the HIT services payments and establish a bundled per infusion-day payment. CMS could account for the additional cost of in-person nursing by paying a differential rate for days a nurse visits the home.

Finally, NHIA requests CMS continue to issue the HIT Monitoring Report on an annual basis.

Medicare Home Intravenous Immune Globulin Items and Services

The Proposed Rule includes proposed regulations to implement coverage and payment for items and services related to the administration of IVIG in the home of a patient diagnosed with a primary immune deficiency disease (PID). CMS proposes to make permanent coverage of the same items and services currently covered under CMS's existing IVIG demonstration. In a report to Congress last year, CMS reported Medicare beneficiaries who participated in the IVIG demonstration reported better access to IVIG therapy and being in better health after enrolling in the demonstration.⁵ Importantly, both providers and beneficiaries reported advantages of in-home IVIG therapy, including decreased transportation barriers, a lower risk of infection, higher rates of compliance with treatment, and better monitoring of the infusion due to one-on-one nursing care.

NHIA agrees home infusion offers better access to infused therapies for beneficiaries living in rural areas and with disabilities while improving clinical outcomes and supports CMS's plan to implement the permanent Medicare home IVIG benefit in a manner that ensures continuation of

⁵ Centers for Medicare & Medicaid Services, Updated Interim Report to Congress: Evaluation of the Medicare Patient Immunoglobulin Demonstration Project (August 2022); available at: <https://innovation.cms.gov/data-and-reports/2022/ivig-updatedintrtc>

these gains for Medicare beneficiaries. NHIA is pleased CMS proposed to modify and continue to use the IVIG demonstration HCPCS code Q2052 for the permanent IVIG items and services benefit. This will assist greatly in tracking utilization and measuring trends going forward. Additionally, NHIA is pleased that geographic adjusters do not apply to the permanent IVIG item and services payment and supports CMS's proposal to annually adjust the rate only by the home health payment update percentage. NHIA believes that the application of geographic adjusters could make servicing patients in rural areas more difficult as budget neutral geographic adjustments can result in allowables significantly lower than the "base" rate.

NHIA Recommendation:

NHIA supports CMS's proposals regarding implementation of the permanent IVIG items and services benefit. NHIA requests CMS publish an annual report on the benefit, similar to the HIT Monitoring Report. NHIA appreciates that HCPCS Q2052 bundles all items and services necessary for IVIG administration in the home.

NHIA is concerned the LUPA based rate calculation for Q2052 undervalues the significant services involved in the provision of IVIG in the home, with one-on-one care for extended infusions lasting more than four hours. Home infusion ensures equitable access to IVIG treatments for beneficiaries with disabilities, transportation barriers, and those living in rural areas. NHIA requests increasing the rate to five times the full LUPA rate to ensure beneficiary access to care.

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. NHIA believes that CMS and the HIT industry can work together to fix the Medicare HIT benefit for the benefit of Medicare beneficiaries. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,



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