

September 8, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program (CMS-1784-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 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program* (the “Proposed Rule”) issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on August 7, 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 CMS’s request for information regarding drugs and biologicals which are not usually self-administered and the requirement for manufacturers of certain single-dose container or single-use package drugs to provide refunds for discarded amounts.

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

Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Administration Coding:

¹ 88 Fed. Reg. 52262 (August 7, 2023)

1. NHIA recommends that CMS specify that all intravenous (IV) and subcutaneous (SC) drugs administered through an access device (catheter) or via the use of an infusion pump be disqualified from being placed on the self-administered drug (SAD) list, to ensure that Medicare beneficiaries have access to HIT services.
2. NHIA recommends that CMS institute a transparent process for MACs to evaluate the appropriateness of drugs for the SAD list, including a well-publicized opportunity for public comment.
3. NHIA asks that CMS recognize that the administration of complex non-chemotherapeutic biologic agents requires special expertise from physicians, nurses, and pharmacists to ensure proper preparation and prevention of adverse reactions during and post-infusion and allow for billing using CPT codes 96401-96549.
4. NHIA recommends CMS address the lack of coverage for home administration of complex non-chemotherapeutic biologic agents for Medicare beneficiaries with disabilities, transportation challenges, and those living in rural areas without access to facility-based services.

Requiring Manufacturers of Certain Single-Dose Container of Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts;

1. NHIA recommends that CMS not require use of the JZ modifier for drugs provided under the Part B DMEPOS benefit, as the administrative burden far outweighs any benefit that CMS would obtain by mandating use of the modifier.

Request for Information (RFI): Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Administration Coding

CMS explains that drugs that are not usually self-administered are eligible for Medicare coverage under Medicare Part B, while drugs that are usually self-administered are statutorily excluded from coverage and payment. CMS requires Medicare Administrative Carriers (MACs) to publish a description of the process they use to determine which drugs are usually self-administered by the patient and to publish a list of those drugs, including the data and rationale that led to the determination. This list is known as the “self-administered drug (SAD)” list, and is maintained by each MAC. CMS asserts that drugs that are on a SAD list and excluded from coverage under Medicare Part B are almost always covered under Medicare Part D.

CMS is soliciting comments on two specific policy areas. The first is regarding whether CMS's current SAD list guidance to MACs adequately addresses circumstances posed by newly approved drugs or whether it needs to be updated. The second area relates to non-chemotherapeutic complex drug administration payment. CMS states that interested parties have contended that existing coding and billing for non-chemotherapeutic complex drug administration do not accurately reflect the resources used to furnish these infusion services, and that they are similar to complex and clinically intensive Chemotherapy and Other Highly Complex Biological Agent Administration (Chemotherapy Administration). Stakeholders maintain that non-chemotherapeutic complex drug administration services should be billed under CPT codes 96401-96549, rather than codes 96360-96379 (Therapeutic, Prophylactic, and Diagnostic Injections and Infusion services).

CMS also is seeking comment on its policies regarding exclusion of drugs that are usually self-administered by the patient from coverage under Medicare Part B. CMS seeks comment on definitions and processes, such as those for determining which drugs are classified as "not usually self-administered by the patient."

NHIA appreciates CMS examining issues related to the SAD list and requesting input on the process and definitions used to determine whether a drug should be included on the SAD list. NHIA is aware of instances where the MACs have placed subcutaneous infused drugs (e.g., immune globulin) on the SAD list because patients are able to achieve a level of independence with the infusions. However, patients only are able to infuse these drugs independently because of the ongoing support provided by a home infusion provider to supply pumps, catheter supplies, administration supplies, education and training, as well as 24/7 on-call support from pharmacists and nurses. NHIA does not believe these drugs meet the definition of "usually self-administered by the patient," given all of the support that is required by the home infusion provider."

Furthermore, legislation has created a home infusion therapy (HIT) services benefit under Part B to ensure patients using infused drugs at home have access to the supplies and support needed to infuse subcutaneous drugs independently, however if a drug is placed on the SAD list, it becomes statutorily ineligible for HIT services. NHIA believes that drugs eligible for the Part B HIT services benefit should not be included on the SAD list, as these drugs require an access device and pump to be infused. If the drugs are placed on the SAD list, beneficiaries will not have access to these products at home despite the drug being covered under the DMEPOS infusion pump benefit, which also excludes the drug from being covered under Part D.

NHIA Recommendation:

NHIA recommends CMS specify that all intravenous (IV) and subcutaneous (SC) drugs administered through an access device (catheter) or via the use of an infusion pump be

disqualified from being placed on the SAD list, to ensure that Medicare beneficiaries have access to HIT services.

CMS also makes the comment that drugs on the SAD list are covered by Medicare Part D, which is a true statement, however CMS should exercise caution in making assumptions about beneficiary access to SAD-list drugs on this basis due to the need for administration supplies that may not be covered or provided by the Part D pharmacy. For example, some parenteral drugs require reconstitution with sterile water prior to injection. This requires the patient to obtain vials of sterile water for injection, alcohol swabs, syringes and needles, and proper disposal containers. NHIA cautions CMS from overlooking the importance of ancillary supplies and support from pharmacists and nurses in ensuring proper access and use of self-administered drugs.

CMS asks for input on the process for determining which drugs are classified as “not usually self-administered by the patient,” the process for issuing decisions regarding the classification of such drugs, and the process for issuing any changes to those classifications.

NHIA notes that all these processes are burdened by a lack of transparency and consistency. Indeed, CMS notes that each MAC maintains its own version of the SAD list and that “While the lists are often similar between the MACs, they are not identical.”

In addition, there currently is no notice about what drugs the MACs are reviewing or an opportunity for comment into this process. While the MACs post the updated SAD lists to their websites, no notice is sent to stakeholders that updates have been made to the lists.

NHIA Recommendation:

NHIA recommends that CMS institute a transparent process for MACs to evaluate the appropriateness of drugs for the SAD list, including a well-publicized opportunity for public comment.

Regarding CMS’s solicitation of comments concerning existing coding and billing for non-chemotherapeutic complex drug administration, NHIA notes that the administration of complex non-chemotherapeutic biologic agents requires special expertise from physicians, nurses, and pharmacists to ensure proper preparation and prevention of adverse reactions during and post-infusion. Additionally, patients receiving complex biologics require more frequent and extensive assessments prior to each dose. Medicare does not currently pay for the administration of these agents outside of a physician office or hospital outpatient department despite existing coverage under Medicare Part D for the drugs, however these agents are routinely administered at home and in pharmacy-based infusion suites for patients with other plans, including commercial

insurance, Medicare Advantage, and TRICARE. NHIA urges CMS to consider the lack of equitable access to these agents when patients cannot travel to an office-based setting due to disability, lack of transportation, or living in a rural area, hours away from the nearest facility. The ability to receive biologic infusions at home has been shown to improve adherence and outcomes, and improve beneficiaries' quality of life.^{2,3}

NHIA welcomes the opportunity to work with CMS to understand how non-chemotherapy biological agent administrations are accomplished safely in the home and alternate site setting. Several examples of successful programs are available to serve as models for such a program, including the Medicare intravenous immune globulin (IVIG) demonstration and administration of monoclonal antibodies to treat COVID-19. During the public health emergency, NHIA successfully coordinated with HHS and ASPR to make monoclonal antibodies for the treatment of COVID-19 accessible to Medicare beneficiaries. Data collected from this effort demonstrated comparable clinical outcomes to other sites of care with fewer reported adverse events compared to clinical trial.

NHIA Recommendation:

NHIA asks that CMS recognize that the administration of complex non-chemotherapeutic biologic agents requires special expertise from physicians, nurses, and pharmacists to ensure proper preparation and prevention of adverse reactions during and post-infusion and allow for billing using CPT codes 96401-96549.

NHIA also recommends CMS address the lack of coverage for home administration of complex non-chemotherapeutic biologic agents for Medicare beneficiaries with disabilities, transportation challenges, and those living in rural areas without access to facility-based services.

Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds With Respect to Discarded Amounts

CMS is requiring manufacturers to provide a refund for certain discarded amounts from refundable single-dose container or single-use package drugs. Billing suppliers and providers were required to report the JW modifier for drugs with discarded drug amounts from refundable

² Polinski, J. M., Kowal, M. K., Gagnon, M., Brennan, T. A., & Shrank, W. H. (2017). *Home infusion: Safe, clinically effective, patient preferred, and cost saving*. *Healthcare*, 5(1-2), 68-80. doi:10.1016/j.hjdsi.2016.04.004

³ 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>

single use vials or packages under Medicare Part B beginning January 1, 2023. They also are required to report the JZ modifier for all relevant drugs with no discarded amounts beginning no later than July 1, 2023. CMS also finalized policies for exclusions from these requirements, manufacturer refund calculations, and a dispute resolution process.

In the Proposed Rule, CMS proposes to align the refund program with implementation of the Part B and Part D inflationary rebate programs that were established under the Inflation Reduction Act (IRA). This Proposed Rule addresses several implementation issues, including modifications to the JW and JZ modifier policy for Part B drugs from single-use containers that are furnished by a supplier that is not administering the drug.

CMS addressed the applicability of the JW and JZ modifier policy to drugs not administered by the billing supplier in the CY 2023 physician fee schedule final rule and stated that the reporting requirement does not apply to drugs that are self-administered by a patient or caregiver in the home. In the Proposed Rule, however, CMS stated that this policy may result in claims rejections absent a modification and now proposes to require that drugs separately payable under Part B from single-dose containers that are furnished by a supplier who is not administering the drug be billed with the JZ modifier. NHIA is disappointed by the proposed modifications to the JW/JZ policy.

NHIA Recommendation:

Earlier this year, CMS issued a FAQ, which stated that, “Suppliers who dispense drugs and do not actually administer the drug . . . are not expected to report discarded amounts on claims.” NHIA is disappointed that CMS is proposing to modify its prior policy and require the JZ modifier on claims furnished by a supplier who is not administering the drug. NHIA is concerned that CMS’s proposal to require the JZ modifier to be included on all claims for drugs with no discarded amounts will be administratively burdensome and may require substantial investments to update billing software systems. NHIA recommends that CMS instead require its MACs to provide provider and supplier education regarding use of the JW modifier, rather than create an entirely new, unnecessarily burdensome system. Also, NHIA suggests CMS consider requiring the new JZ modifier only for drugs flagged for waste-related refunds.

NHIA also has reviewed the CMS 2021 Discarded Drug Report for all drugs covered in the home under the Part B DMEPOS program. Only one of the 42 DME infused drugs shows waste in excess of the rebate threshold – J9065 – Cladribine. The 2021 DME utilization file does not include data for J9065, indicating that it was not dispensed under the programs, or that utilization was so low that it did not meet the threshold to report. In addition, the 2021 Discarded Drug Report shows all other drugs with less than five percent of waste – four drugs had two-five

percent waste, seven drugs had one to two percent waste, and the rest had less than one percent. For the intravenous immunoglobulin benefit, the 2021 Discarded Drug Report shows less than two tenths of one percent (0.2%) waste for all covered drugs.

NHIA recommends that CMS not require use of the JZ modifier for drugs provided under the Part B DMEPOS benefit, as the administrative burden far outweighs any benefit that CMS would obtain by mandating use of the modifier.

NHIA appreciates the opportunity to provide comments on these important issues and we welcome the opportunity to continue working with CMS to improve the SAD list process and policies and JZ modifier policy. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,



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