National Home Infusion Association

August 29, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Polices; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts (CMS-1770-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 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Polices; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts* (the "Proposed Rule") issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on July 29, 2022.[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 alternate site infusion community, we write to share our feedback regarding payment for monoclonal antibodies and requiring manufacturers of certain products to provide refunds with respect to discarded amounts.

Clarification on Policies for COVID-19 Vaccine and Monoclonal Antibody Products

*Payment Based on Termination of Emergency Use Authorization*

[1] 87 Fed. Reg. 45860 (July 29, 2022)

CMS proposes to clarify that payment and coverage for COVID-19 vaccines and monoclonal antibody products will be tied to the March 27, 2020, Emergency Use Authorization (EUA) declaration for drugs and biological products pursuant to the Food, Drug & Cosmetic act, rather than the Public Health Emergency (PHE) declaration under the Public Health Services Act. CMS notes that an EUA for a drug or biological issued under the March 27, 2020, EUA declaration may remain in effect beyond the duration of the PHE declaration. CMS states that its goals for broad and timely access to COVID-19 vaccines and monoclonal antibodies will be better served if its payment policies for these products continue until the EUA declaration is terminated and proposes to make this policy clarification.

*NHIA Recommendation*:

NHIA supports the proposal to link payment for COVID-19 vaccines and monoclonal antibodies to the end of the EUA, rather than the PHE. NHIA agrees that this policy change will support wide-ranging access to these products and maintain preparedness for responding to potential future variants and surges of COVID-19 infections.

*Payment for Vaccines and Monoclonal Antibodies*

CMS states that it will maintain the current payment for the administration of COVID-19 vaccines through the end of the calendar year in which the March 27, 2020, EUA declaration for drugs and biological products ends. Beginning January 1 after the year that the EUA declaration ends, the payment rate for administration of COVID-19 vaccines will align with the payment rate for administration of other Part B preventive vaccines. CMS is proposing to continue to pay the additional payment of $35.50 for in-home administration of COVID-19 vaccines for calendar year 2023.

CMS also proposes to continue to pay for monoclonal antibody products under the Medicare Part B vaccine benefit through the end of the calendar year in which the March 27, 2020, EUA declaration for drugs and biological products ends. Until the end of the calendar year that the EUA declaration for drugs and biological products is terminated, CMS will continue with the current payment rate for administering COVID-19 monoclonal antibody products for treatment of COVID-19 or for post-exposure prophylaxis in a healthcare setting and the payment rates previously outlined for administering a COVID-19 monoclonal antibody product in the home. Beginning January 1 after the year that the EUA declaration ends, CMS would pay physicians and other suppliers for covered COVID-19 monoclonal antibody products for treatment of COVID-19 or for post-exposure prophylaxis as biological products under section 1847A of the Social Security Act, similar to how they are paid for administering other complex biological products. CMS proposes to continue to adjust this payment amount to reflect cost differences for each geographic area, but proposes to not update the rates based on an increase in the Medicare

Economic Index (MEI). CMS proposes to clarify that its policy of covering and paying for monoclonal antibodies under the Medicare Part B vaccine benefit would include monoclonal antibodies used as pre-exposure prophylaxis for the prevention of COVID-19. CMS would pay for the products under the Medicare Part B vaccine benefit after the EUA declaration for drugs and biological products is terminated, if the products have received market authorization from the FDA.

*NHIA Recommendation*:

NHIA supports the proposal to continue to pay the additional payment of $35.50 for administration of COVID-19 vaccines in the home. NHIA also applauds CMS for proposing to continue to pay $750 for home infusion of COVID-19 monoclonal antibodies for treatment or post-exposure prophylaxis. NHIA also supports CMS' clarification that coverage and payment for monoclonal antibodies would include monoclonal antibodies used as pre-exposure prophylaxis for the prevention of COVID-19. In addition, NHIA applauds CMS for continuing to recognize the value to beneficiaries of being able to continue to receive monoclonal antibodies in the home while the EUA declaration for drugs and biologics remains in effect. This coverage has been critical to patients living in rural areas, who either are homebound, lack transportation to a facility or/and have a condition that would put them at high risk for contracting severe COVID-19. NHIA requests CMS clarify the reasoning for a lower payment rate ($550.50) for "injections" of bebtelovimab as the resources needed to provide this therapy in the home are not less than for infused therapies.

NHIA is concerned, however, that patients will not have access to monoclonal antibodies in the home for treatment or post-exposure prophylaxis following the expiration of the EUA. NHIA believes this raises equity issues, particularly for Medicare beneficiaries in rural areas and for those without the means to travel to an infusion center. Continuous access to home infusion should be part of the agency's future pandemic preparedness strategy. NHIA would welcome the opportunity to engage with CMS on a plan to improve access to home infusion for Medicare beneficiaries.

Additionally, NHIA would like to recognize the efforts of CMS in quickly standing up a network of qualified home infusion providers to administer COVID treatments. Many home infusion pharmacies enrolled with the Medicare program through the established "hotlines" to become eligible to provide COVID monoclonal antibodies in the home. Hotline enrollments are set to expire based on the end of the PHE. Just as coverage of COVID treatments has shifted from being based on the PHE to the EUA, NHIA recommends tying hotline enrollment to the expiration of the EUA declaration.

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

National Home Infusion Association

CMS proposed to implement Section 90004 of the Infrastructure Investment and Jobs Act, which requires manufacturers to furnish a refund to CMS for discarded portions of certain drugs from a refundable single-use container or single-use package. The refund amount is the amount of discarded drug above a certain percentage (required to be at least 10 percent) of total charges for the drug per calendar quarter. Exclusions include radiopharmaceutical or imaging agents (according to FDA-approved labeling); certain drugs necessitating filtration prior to dilution and administration (consistent with FDA labeling); and new drugs approved by the FDA on or after November 15, 2021, for which payment has been made under Medicare Part B for fewer than 18 months (for the first six full calendar quarters following the date of the first sale for any NDCs of the drug).

CMS proposes to use the current JW modifier or its successor to determine the quantity of units of a refundable single-dose container or single-use package that were discarded during the relevant quarter in order to calculate the refund amount. CMS proposes that a separate modifier – the JZ modifier – be included on claims for drugs with no discarded amounts. CMS also states that there may be a need to revise existing billing and payment codes or establish new national drug codes (NDC) for the sole purpose of implementing this requirement.

*NHIA Recommendation*:

NHIA is concerned that CMS' proposal to require a separate modifier to be included on all claims for drugs with no discarded amounts would be administratively burdensome, cause confusion when a drug has more than one manufacturer (generic drugs) and may require substantial investments to update billing software systems. NHIA recommends that CMS instead require its Medicare Administrative Contractors (MAC) 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 2020 discarded drug report, which shows a very small percentage (six percent) of single use container drugs exceeding the threshold of ten percent discarded. NHIA recommends that CMS consider limiting revisions to billing and payment codes to those that experience greater than ten percent waste for two or more consecutive quarters and fall above a certain dollar threshold for the total discarded amounts.

NHIA appreciates the opportunity to provide comments on these important issues. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

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