National Home Infusion Association
Providing solutions for the home and specialty infusion therapy community

June 6, 2019

The Honorable Richard Neal
Chairman, Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Chairman, Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member, Ways and Means Committee
1142 Longworth House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
Ranking Member, Energy and Commerce Committee
2322-A Rayburn House Office Building
Washington, DC 20515

RE: Bipartisan Medicare Part D Drug Pricing Legislation

Dear Chairmen Neal and Pallone and Ranking Members Brady and Walden,

The National Home Infusion Association (NHIA) appreciates the opportunity to provide comments to the House Ways and Means and Energy and Commerce Committees ("the Committees") in response to the draft Bipartisan Medicare Part D Drug Pricing Legislation ("Draft Legislation"). NHIA members include a cross section of more than 350 home infusion providers, suppliers, manufacturers, and other infusion industry stakeholders that assist with or provide home infusion.

About Home Infusion Therapy

Home infusion therapy involves the administration of medication through a needle or catheter. It is prescribed when a patient's condition cannot be treated effectively by oral medications. Typically, "infusion therapy" means that a drug is administered intravenously, but the term also may refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes (into the membranes surrounding the spinal cord).

Home infusion therapy requires several important components: the drug; the equipment and supplies (durable and disposable) necessary to infuse it; and a wide array of professional services required to prepare and administer the therapy (e.g., case management, medication preparation and compounding, clinical monitoring for adverse events and efficacy, coordination with the patient's other health care providers, 24/7 patient support, etc.). Professional services are typically delivered by a multi-disciplinary team that includes a physician, a home infusion pharmacist, a nurse, and the patient and his or her caregiver.

Medicare Coverage of Home Infusion Therapy

For more than 30 years, home infusion therapy has been the standard of care and common practice for patients covered by commercial insurance. Unfortunately, there are several gaps with regard to

Medicare coverage of the services and supplies necessary to deliver safe and high-quality infusion services.

Medicare Part B

Historically, the Medicare program covered some infusion drugs and supplies under the Durable Medical Equipment (DME) benefit under part B. Prior to 2017, Medicare reimbursed home infusion providers for the DME (e.g., pumps, tubing, vascular access devices, etc.) at a competitively-bid rate, and drug costs were reimbursed at a rate of 95 percent of the Average Wholesale Price (AWP). Nursing costs were typically covered under the home health benefit. There was no separate payment for the pharmacy or other professional services necessary for the provision of infusion therapy, but because infusion companies were often able to secure the drugs at a lower price than the AWP, they were able to use the savings to offset the costs of professional services. While an imprecise approach, this reimbursement framework allowed Medicare patients to access some infusion therapies in the safety and comfort of their own homes.

In the *21st Century Cures Act*, Congress reformed payment for home infusion services under Part B by transitioning drug reimbursement from the AWP benchmark to one based on the Average Sales Price plus six percent. At the same time, Congress created a new benefit for the professional services (both pharmacy and nursing professional services) associated with Part B covered infusion drugs. This professional services benefit goes into effect in 2021. In the *Bipartisan Budget Agreement of 2018,* Congress also created a transitional payment to allow home infusion providers to bridge from the AWP reimbursement system to the permanent rate in 2021.

As you may know, there have been challenges associated with the implementation of this benefit, and NHIA has been working with its allies on Capitol Hill, including several members of both the Energy and Commerce and Ways and Means Committee, to clarify Congress' intent with regard to the home infusion benefit.

Medicare Part D

Infusion drugs that do not require an item of DME are covered by Medicare part D. The majority of Part D home infusion drugs are infused antibiotics, which are necessary to treat vulnerable beneficiaries with diabetic foot ulcers, cystic fibrosis, post-surgical infections, among other health conditions.

Currently, the Part D program reimburses providers for the drugs and a retail-based dispensing fee, but does not reimburse for equipment, supplies, or professional services. The costs associated with the safe provision of home infusion drugs, notably the professional services needed to prepare medications, develop and administer plans of care, coordinate infusion-related care services, and other related services fall to patients to cover out of their own pockets.

These coverage gaps leave most Medicare beneficiaries without access to a meaningful home infusion benefit for Part D drugs. The patients often must receive their infusions in a costlier, less convenient site of care, such as a skilled nursing facility, physicians' office, or out-patient infusion center. This coverage gap also puts these patients at risk of acquiring health care-acquired infections -- a critical safety issue for vulnerable Medicare beneficiaries.

Recommendations

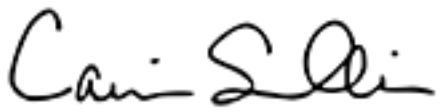
As Congress considers legislative reforms to the Part D program, we urge you to enact legislation that would close the gaps in coverage for home infusion professional services and supplies. These reforms might include additional clarification around the Part B benefit, and expansion of home infusion professional services reimbursement for Medicare Part D enrollees. Closing these gaps would align the Medicare fee-for-service program with other payers, ease the burdens on Medicare beneficiaries, reduce the risk of acquiring health care-acquired infections, and produce savings for the Medicare program.

Additional Comments

NHIA also supports the Committees' efforts to cap beneficiaries' out-of-pocket costs under the Medicare Part D program, in order to ensure that Medicare beneficiaries can continue to access and afford their medications. An annual out-of-pocket cost limit for Medicare beneficiaries under Part D would be consistent with the coverage beneficiaries enjoy under Medicare Parts A and B. More importantly, such a limit would offer necessary catastrophic protection for patients who have conditions that require ongoing prescription medications. Establishment of an out-of-pocket prescription drug limit also would harmonize the Part D benefit with commercial prescription drug benefits. Today, when individuals become eligible for Medicare they often lose the financial security that is offered by commercial plans through an annual cap on out-of-pocket costs. NHIA believes there is no rationale for burdening individuals who incur high annual drug expenditures with unlimited cost sharing simply because they turn 65.

In closing, we thank you again for allowing us to submit our comments on your Draft Legislation. We look forward to working with you to ensure that Medicare beneficiaries can access home infusion services. Please contact me at connie.sullivan@nhia.org, or Sharon Pearce, Vice President of Government Affairs at Sharon.pearce@nhia.org. Thank you for your consideration of our comments.

Sincerely,



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National Home Infusion Association