



March 18, 2020

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Secretary Azar and Administrator Verma:

In light of the rapidly evolving national public health emergency regarding 2019 Novel Coronavirus Disease (COVID-19) the National Home Infusion Association (NHIA) is offering recommendations for protecting the public, increasing the capacity of the health care delivery system, and improving access to home infusion therapies. Specifically, NHIA respectfully urges the Centers of Medicare and Medicaid Services (CMS) to leverage the home site of care whenever possible to free up limited capacity in institutional settings. This would allow acute care professionals to care for those most affected by the virus as well as limit exposure for our vulnerable Medicare population.

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 industry, we write to offer our perspective at this critical time.

Home infusion pharmacies have safely and effectively treated patients in the home for decades. While the demand for these services by commercial payers has been largely focused on the cost-effectiveness of home infusion, this site of care has the additional benefits of freeing up hospital resources to treat those most in need and limiting exposure pathogens. This makes home infusion a powerful tool in the fight against COVID-19.

While commercial insurance plans offer comprehensive coverage of home infusion therapies, Medicare does not – and the coverage that does exist is fractured. Medicare Part B DMEPOS covers a very limited number of home infused drug therapies, including enteral and parenteral nutrition, intravenous immunoglobulin (IVIG) for treatment of primary immune deficiency disease (PIDD), and about 30 drugs covered under the external infusion pump policy. Home infused drugs not covered by the Part B DMEPOS

program, the majority of home infusion-eligible drugs, may be covered by Medicare Part D Prescription Drug Plans; in fact Part D plans are required to have a network of home infusion pharmacies to meet their subscribers' needs. However, there is no home infusion services benefit offered by CMS for the home infusion drugs covered in Part D, which severely limits Medicare beneficiary access to these home infusion drugs.

NHIA requests that CMS provide COVID-19-specific waiver guidance to home infusion providers participating in the Part B DMEPOS program, as well as Medicaid programs, and offer the following recommendations to reduce administrative burdens and increase flexibilities in the delivery of health care with the intent of promoting greater access to care for individuals affected by the COVID-19 national emergency.

- 1) Relax proof of delivery (POD) signature requirements, so that beneficiaries who wish to limit contact can request that deliveries be left at their home, or a pre-determined location, without the need to sign for the delivery.
- 2) Allow home infusion therapy suppliers to bill for remote pharmacy services under the transitional home infusion therapy services benefit and provide reimbursement for each day an applicable drug is infused. This change will reduce interactions and potential exposure to coronavirus between patients and nurses and maximize nursing capacity.
- 3) Delay roll out of the prior authorization, face-to-face, and work order prior to delivery HCPCS lists until after the national health emergency is over. Ensure that when the face-to-face requirement list is rolled out, it provides clear guidance that includes a telehealth option.
- 4) Temporarily waive the LCD qualifying criteria for parenteral and enteral nutritional therapies, allowing suppliers to bill for and obtain payment for these services through the Part B DMEPOS program. This will help to ensure rapid discharge of those in need of specialized nutritional support, free up capacity in institutional settings, and reduce administrative burden on physicians and other hospital-based health care personnel involved in coordinating discharges.
- 5) Temporarily suspend audits and delay supplier response deadline until 180 days after the national emergency has ended for all requests for additional documentation generated on or before January 1, 2020.
- 6) Extend the HIPAA-related waivers that are currently in place for hospitals to all health care providers and suppliers.
- 7) Consider plans to delay the implementation of Round 2021 of Competitive bidding. This public health emergency has the very real potential of change the landscape of providers/suppliers and the geographic areas that they will continue to do business.

- 8) Expand the rule which allows for DME equipment to be delivered to hospitals up to 2 days prior to discharge to include supplies (drugs are considered supplies). Also, expand the term hospital in the rule referenced above to include hospital or other healthcare location. This will streamline the clinical workload and greatly enhance the ability of beneficiaries to transition to the home environment. Note: The Part B DMEPOS program would not be billed for these items unless/until the beneficiary is utilizing these items at home.

Medicare Part D coverage of home infusion therapy is limited to the drug itself and does not cover the services, supplies and equipment needed to safely deliver therapy in the home. This non-covered expense is often borne by the patients, which causes them to choose between receiving care in a skilled nursing facility or traveling daily to a physician's office or hospital outpatient department to receive their infusion – where the out-of-pocket costs are lower. **We recommend that in order to reduce the strain on institutional settings and protect patients, Medicare utilize the Part B DME transitional home infusion therapy service codes (G0068, G0069 and G0070) for Part D infused drugs to pay home infusion pharmacies for each day the drug is infused to beneficiaries in their homes.**

All health care providers are tasked with working together and leveraging core competencies to help ensure we do everything we can to minimize the impact on beneficiaries during this critical time. This is not a time for red tape. We ask that CMS provide clear guidance allowing for comprehensive coverage of home infusion therapies throughout this national emergency.

Respectfully,



Connie Sullivan, BS Pharm
President and CEO