September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

The National Home Infusion Association (NHIA) submits the following comments on the Centers for Medicare and Medicaid Services' (CMS') proposed End Stage Renal Disease (ESRD) and Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) CY 2020 Proposed Rule (CMS-1713-P).

The National Home Infusion Association (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. Home infusion therapy frequently requires the use of an external infusion pump (EIP), which is an item of durable medical equipment (DME). As such, the majority of NHIA members are enrolled in the Medicare program as suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS).

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).

Many infusion drugs require an external infusion pump (EIP) for administration. These pumps can be ambulatory (i.e., worn by the patient) for the continuous or intermittent infusion of medication, or stationary for brief, once-daily infusions. Drugs requiring an EIP cannot be administered without this important equipment. As such, a patient cannot begin home infusion therapy until they have received an EIP from their supplier.

With that in mind, NHIA has serious concerns about CMS' proposal to create a Master List of items of DME – including external infusion pumps (E0781) -- that are potentially subject to prior authorization and/or the face-to-face encounter and written order prior to delivery requirements. Modifying existing policy could potentially delay patients' access to care.

To begin, we believe that it is inappropriate to include infusion pumps on the master list, as they are not the most therapeutically relevant item of home infusion DME. Typically, when a physician orders home infusion therapy, the order is first and foremost about the *drug* that is being supplied. The pump is secondary, as some infused drugs require a pump and others do not. The initial verbal or written order would likely be for the drug, while ancillary equipment and supplies would come later in the detailed written order.

Irrespective of whether the policy focuses on the pump or the drug, requiring a face-to-face encounter or written order prior to delivery (WOPD) could inhibit patient access to home infusion and would create an unnecessary administrative burden for providers.

Currently, home infusion therapy suppliers can deliver equipment and supplies based on a physician's verbal order. By requiring home infusion therapy suppliers to obtain a WOPD, however, CMS is potentially adding several layers of bureaucracy between the patient and their provider. The following example illustrates how this policy could interfere with patient care and result in higher costs for the Medicare program.

> A 72-year old patient is prescribed intravenous pain relief following abdominal surgery. He cannot be discharged from the hospital until an electronic infusion pump is ordered and delivered to his home. Because the supplier must obtain a written order before they can deliver the pump, the patient's discharge from the hospital is delayed by one day, increasing the risk of acquiring a surgical site infection that extends his inpatient stay by several days, requires additional medication, and impairs his recovery.

We recommend that CMS remove the external infusion pump (E0781) from the Master List, eliminating the future potential for requiring a physician to provide a written order prior to delivery for the infusion pump, which is one of many components required to start a beneficiary on home infusion therapy.

CMS is also proposing to change the timeframe in which contract suppliers are required to notify CMS about a change of ownership (CHOW) from 60 days before the effective CHOW date, to 10 days after the effective date of the CHOW. NHIA is supportive of this proposal.

We also note that the current Medicare gap fill methodology is out-of-date, insufficient, and significantly flawed. NHIA opposes CMS' proposal to codify the flawed gap-filling pricing policies in federal regulation. Instead, we urge CMS to implement a transparent process that involves all stakeholders, including industry experts.

While not part of the proposed rule, NHIA would also like to take this opportunity to recommend that CMS modify policy to allow for improvements in transitions of care from the institutional setting to the home for DME infused drugs.

Patients on continuous IV medication, pain management and inotropic drug therapies need these drug therapies as they leave the institutional environment and travel home. Hospitals and SNFs typically do not allow their equipment to leave their facilities and often the equipment they use is not ambulatory/portable (e.g., may be pole-mounted or require an outlet to power).

We request that the policy be modified to allow for delivery of equipment ***and*** supplies to a facility up to two days prior to discharge to allow for a smooth transition home. We understand that the supplies are not to be used in the facility, but rather at time of discharge in order to allow for a smooth transition home with the home infusion provider that has the specialized equipment, supplies, and support services to safely manage the beneficiaries care outside of a healthcare facility.

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

In closing, we thank you for the opportunity to share our comments. Please contact me at connie.sullivan@nhia.org if you have any questions.

Sincerely,

Connie Sullivan, BS Pharm.
President and CEO