National Home Infusion Association
Providing solutions for the infusion therapy community

August 16, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1651-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Policy and Fee Schedule Adjustments; Proposed Rule (CMS-1651-P)

Dear Acting Administrator Slavitt:

The National Home Infusion Association (NHIA) submits these comments in response to the proposed rule published in the Federal Register on June 30, 2016 that would modify the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program and fee schedule (CMS-1651-P).

NHIA is a national membership association for companies that provide infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion providers; and hospital-based home infusion companies.

NHIA strongly supports the Centers for Medicare and Medicaid Services' (CMS) proposal to revise bid limits for individual items based on the fee schedule amounts that would have applied before being adjusted based on competitive bidding single payment amounts. Similarly, we support CMS' proposal to implement the statutory requirement that bidding entities satisfy applicable state licensure requirements to be eligible for a contract under the program. We also appreciate and support expanding the appeals process to suppliers who receive a breach of contract notice from CMS.

However, as described in more detail below, we are concerned that the new, adjusted payment rates for DMEPOS may be insufficient to ensure beneficiaries' access to items and services. In addition, CMS' methodology for dealing with price inversions does not necessarily establish realistic, market-based payment rates for all items within a grouping of products. The competitive bidding program has resulted in severely reduced payment rates due to the operation of the bidding process, and we question the appropriateness of CMS' further reducing payment amounts that result from that process simply because those rates are higher for some products than for others.

1. CMS' Proposal to Modify Bid Limits for Individual Items so They Are Based on the Fee Schedule Amounts That Would Have Applied Prior to Being Adjusted Based on Competitive Bidding Information is a Sound Approach That Will Result in More Accurate and Sustainable Payment Rates.

We applaud CMS for proposing to revise the limits on bids for individual items for future competitions so that they are based on the fee schedule amounts that would have applied in the absence of the competitive bidding program. This new policy can help avoid a "race to the bottom," where increasingly artificially low bid limits would result in clearly inadequate payment rates. The new bid limits and resulting single payment amounts (SPAs) should reflect more accurately the cost of furnishing items and services over time.

NHIA agrees that CMS' previous policy on bid limits would have resulted in an unsustainable downward trend, since lower bid limits would have applied to each subsequent round of competitive bidding, regardless of market forces. We commend CMS for recognizing the flaws in this policy, and for proposing a new policy that enables providers' bids and the resulting payment rates to fluctuate with decreases and increases in providers' costs. We agree with CMS that this new policy will improve the viability of the competitive bidding program.

2. The Adjusted Payment Rates for DMEPOS That Became Effective on July 1, 2016 May Be Insufficient, and May Negatively Impact Beneficiaries' Access to Items and Services.

It is premature for CMS to evaluate whether beneficiaries have continued access to quality DMEPOS in non-competitive bidding areas, or to conclude that there are no access issues resulting from competitive bidding payment rates. Payment rates adjusted by competitive bidding information began applying in non-competitive bidding areas on July 1, 2016. Thus, the market is only now beginning to see the impact of the significant payment reductions.

For example, compared with 2015 Medicare payment rates in the contiguous United States, 2016 rates for enteral pumps (rental) were slashed by 50 percent in urban areas and 44 percent in rural areas; 2016 rates for enteral supplies (daily) were cut by 56 percent in urban areas and 51 percent in rural areas; and 2016 rates for enteral nutrients were cut by 44 percent in urban areas and 38 percent in rural areas. As a result of the payment reductions, two of the largest nationwide suppliers of enteral nutrition items, supplies and equipment *recently* left the market. CMS should continue to monitor this trend with concern.

We maintain that the Medicare rate reductions resulting from competitive bidding rates should not apply to products categories, such as external infusion pumps and supplies, that were bid in ten or fewer Competitive Bidding Areas (CBA). The extremely limited market experience, in nine CBAs, is not sufficient to adjust rates nationwide, especially in rural areas.

CMS' preliminary data, and its broad conclusions based on such information has inaccurately characterized a market that, in fact, has changed significantly as a result of these drastic payment cuts. In light of suppliers beginning to leave the DMEPOS market, it is becoming more likely that beneficiaries will experience reduced access to quality DMEPOS. It is vitally important that CMS continue to evaluate the impact of these reduced payments on beneficiaries' access to DMEPOS items and services.

3. CMS Should Ensure That Its Methodology for Addressing Price Inversions Does Not Establish Artificially Low Payment Rates for Medically Necessary DMEPOS Items and Services.

We encourage CMS to ensure that its policy for addressing price inversions does not establish unrealistic or unsustainable payment rates for DMEPOS items within a grouping. Certain DMEPOS items and supplies may be costlier because they are used less frequently or are more difficult to obtain. The methodology for addressing price inversions should recognize that the features of an item do not independently determine the cost of the item. Also, it is somewhat inconsistent for CMS to assert on one hand that the bidding process produces payment amounts that reflect the market, and on the other to undo the results of that process to reduce payment amounts for particular items. The method for establishing SPAs for similar items should consider all market forces, and provide some flexibility for instances where the method produces payment rates that are unworkable.

Please feel free to have your staff contact Bill Noyes, NHIA Vice President of Health Information Policy, at (703) 838-2661 or bill.noyes@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's concerns.

Sincerely,

Tyler J. Wilson
President & CEO
National Home Infusion Association