August 29, 2025
The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Muscular Dystrophy Association Comments CY 2026 Home Health Prospective Payment System Proposed Rule: Medicare Competitive Bidding of Ostomy and Urological Supplies (CMS-1828-P)

Dear Administrator Oz:
In service to the neuromuscular disease community, the Muscular Dystrophy Association (MDA) writes in opposition to the Calendar Year ("CY") 2026 Home Health Prospective Payment System and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program ("CBP") proposed rule (hereinafter referred to as "Proposed Rule") wherein we express concern with the inclusion of ostomy, urological, and tracheostomy supplies in the list of items CMS may subject to DMEPOS Competitive Bidding.

For 75 years, MDA has led the way in accelerating research, advancing care, and advocating for support and inclusion of families living with neuromuscular conditions. MDA's mission is to empower the people we serve to live longer, more independent lives. In support of that mission, MDA advocates for policies to improve the lives of people affected by neuromuscular disease, including policies that strengthen access to Medicare, which provides critical access to care, therapies, equipment, transportation, and home- and community-based services that empower the neuromuscular community to live independently.

Ostomy and tracheostomy supplies are often used by those living with amyotrophic lateral sclerosis (ALS), complex forms of muscular dystrophy, and several other forms of neuromuscular disease (NMD).[1] The increased barriers to access these needed pieces of medical equipment will throw up unnecessary barrier for all those who deserve timely access to care.

We largely echo the comments of our colleagues at the Enhancement of Medicare and Medicaid ("ITEM") Coalition, and we wanted to provide some additional context from the perspective of the NMD community, as well as some additional context in the vein of other value-based purchasing agreements that are distinguishable from this instance.

[1] Monthly Feature: *Resolving Bowel Issues in Patients with DMD.* *https://www.mda.org/sites/default/files/2024/02/MDA-Monthly-Report-Resolving-Bowel-Issues-in-Patients-with-DMD.pdf See also, MDA Guide for Caregivers,* *https://www.mda.org/sites/default/files/2024/01/MDA_Caregiver_Guide.pdf*

I. Limitation to CMS's Legal Authority:

While the Social Security Act does allow for competitive bidding processes, these processes are limited to certain DMEPOS items at section 1847(a)(2). This section limits CPB to three categories in this instance:

> (1) durable medical equipment and medical supplies used in conjunction with DME;
> (2) enteral nutrients, equipment, and supplies; and
> (3) off-the-shelf orthotics. 42 U.S.C. §1395w–3(a)(2).

Prosthetic devices on the other hand are distinct from DME.[2] Prosthetic devices are defined as "a device that replaces all or part of an internal body organ or replaces all or part of the function of a permanently inoperative or malfunctioning internal body organ."[3] Section 1847 clearly encompasses ostomy, tracheostomy, and urological supplies rather than these supplies being characterized as DME. On a similar note, Section 1861 (s)(8) of the act also clearly cabins ostomy bags as DME as well. For this reason, CMS is exceeding its authority by allowing for competitive bidding processes for these devices, and therefore, CMS should reject competitive bidding in this category.

II. Impacts for the NMD Community:

Even if this CBP is found to be legal under the Social Security Act, it is still a poorly conceived program. Ostomy and tracheostomy supplies are incredibly personal to the user of the device. This is especially true for members of the NMD community, many of whom live with a progressive condition. Given the incredibly changeable nature of these conditions, it is important that a community member's medical devices be able to adapt and change as their condition does. Similarly, the adaptable nature of these devices are not just important due to the progressive nature of their disease, but also due to variable physical ability. For example, many of those in the NMD community experience limited hand function and grip strength. Due to this variable functionality even one device of the same type may not work well from person to person requiring modifications or using a device of a different type. It is incredibly important that we allow for as many diverse types of devices to be available to community members as possible.

By implementing a CBP, we are concerned that a CBP will force providers and medical device manufacturers into a position where they need to offer a cheaper one size fits all approach to these devices. As an example of this potential gap, there are currently three HCPS codes for 1,300 different types of intermittent catheters with just three additional coming in 2026.[4] If contractors are forced to move from the potentially over one thousand customizable options to just a few, this will vastly limit needed access to the robust class of devices.

This concern is further underscored by Congress' intent when they laid out the three areas in which a CBP is allowed. Congress deliberately included off the shelf orthotics which are

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[2] 42 U.S.C 1847(a)(2). §1395x(s)(8).
[3] Medicare Benefit Policy Manual ("MBPM"), Pub. 100-02 Ch. 15, § 120; *see also* 42 U.S.C. §1395x(s)(8); 42 C.F.R. §414.202.
[4] https://aahomecare.org/files/galleries/New_HCPCS_codes_for_Intermittent_Catheters_--_society_support.pdf

orthotics which do *not* require customization for effective use. This underscores that devices such as the ones currently contemplated under this rule which require customization should be left out of competitive bidding.

We have similar access concerns as it relates to Remote Item Delivery (RID) CBP Proposals. Under this program CMS would limit obtaining these devices exclusively to contract suppliers, which currently only constitutes **seven** contracts for urological supplies and **eight** contracts for ostomy supplies. This would severely limit access to these supplies for the NMD community. Many in the community have severely limited mobility which limits their ability to receive items in person, and especially for those that live in rural areas, this limitation to such a small number of contractors is likely to result in delays in obtaining needed supplies.

III. Briefly as it relates to Value Based Purchasing Agreements Generally:

As noted throughout CMS's proposal, the broad point of this venture is to reduce waste, fraud, and abuse in government contracting under the auspices of value-based purchasing agreements.[5] From the outset, MDA is broadly supportive of value-based purchasing agreements. As we noted in a Request for Information on gene therapies, value-based purchasing agreements can serve to lower the high cost of therapies for the NMD community. [6] The use case for these agreements however, are often for bespoke therapies which may otherwise be difficult to pay for and obtain insurance coverage. In the current instance, however, CMS' potential use of this modality flattens the options for access to needed devices rather than expands them. As treatments and devices for neuromuscular conditions continue being developed it will become increasingly important to find new and innovative ways to insure the affordable and broadly accessible options for treatment modalities. We would encourage CMS to continue to work with us on value-based purchasing agreements, but to use them to expand access to care rather than limit it.

For the foregoing reasons and more, we encourage CMS to reject inclusion of ostomy, urological, and tracheostomy supplies in the list of items CMS may subject to DMEPOS Competitive Bidding. We would also ask that CMS continue working with us on ways to reduce the cost of needed medical devices, therapies, and other modalities of treatment through use of value-based purchasing agreements rather than using them to reduce access to care. Should you need any further information or have questions about the foregoing, please contact Joel Cartner, MDA's Director of Access Policy at jcartner@mdausa.org.

Sincerely,

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[5] https://www.federalregister.gov/documents/2025/07/02/2025-12347/medicare-and-medicaid-programs-calendar-year-2026-home-health-prospective-payment-system-hh-pps-rate

[6] https://d3dkdvqff0zqx.cloudfront.net/groups/mda/attachments/Senator%20Cassidy%20RFI-%20MDA(1).pdf

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Muscular Dystrophy Association