October 22, 2025

The Honorable Dr. Mehmed Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Russell Vought
Director, Office of Management & Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

Re: Urgent Opposition to Proposed Inclusion of Ostomy and Urological Supplies in Medicare Competitive Bidding; File Code CMS-1828-P

Dear Administrator Oz and Director Vought,

Imagine how difficult it would be to function in society, if you could not contain the flow of urine and/or fecal matter from your body; how it would affect the way you live and work in your community and the quality of your life.

United Ostomy Associations of America, Inc. (UOAA), a national nonprofit representing thousands of individuals living with an ostomy or continent diversion, strongly opposes the Centers for Medicare and Medicaid Services' (CMS) proposal [CMS-1828-P] to redefine **ostomy and urological supplies, including intermittent catheters** as "medical equipment items" to justify inclusion in the expansion of the DMEPOS Competitive Bidding Program (CBP). As the voice and leading organization advocating for people living with an ostomy, we know first-hand how important access to ostomy and urological supplies are for this patient population.

Under the Social Security Act, ostomy and urological supplies are rightly categorized and defined as **prosthetic devices** (§1861(s)(8)) as they are restoring the lost organ functions of biological waste storage and elimination —and as such, were specifically **excluded from CBP** by Congress under §1847(a)(2)(A). CMS lacks the legal authority to redefine these as "medical equipment items" and doing so would contradict both statute and Congressional intent.

For those who depend on these products—many of whom are managing lifelong or complex medical conditions—access to the **right product, at the right time, matched to the individual's needs** is not optional. It is essential. Ostomy supplies and intermittent urinary catheters are **not generic commodities** like a crutch or knee brace, but highly specialized tools critical to daily function, infection prevention, and

maintaining dignity and independence. As such prosthetics are not an appropriate product for the competitive bidding process.

Many ostomy products are similar, but they are not the same. Each manufacturer has a different chemical composition of their product adhesives and pouch fabric material as well as specific features of the pouching system. Products used with pouching systems, called accessories, also vary greatly and can be just as important as the pouch itself. A successful "pouching prosthetic system" is a combination of pouch type and accessories to achieve proper fit that is well-sealed. *Not every DME provider/supplier has every type of product. Restricting beneficiaries to particular suppliers will create a barrier to access of the products they need as well as innovative technologies with proven[1,2] improved patient outcomes.*

From our perspective, this proposal also marks **a troubling step away** from 1) **protecting patient safety -** On September 17, 2025, World Patient Safety Day, Dr. Oz, you posted on social media "Patients come first at @CMSGov. We're committed to delivering exceptional care and fiercely protecting patient safety." This proposal is not putting patients first. It will increase patient harm and not protect beneficiaries. And 2) **patient-centered, outcome-focused care -** The goal of CMS should be to foster quality, safety, and innovation—not to inadvertently incentivize low-cost, low-quality options that place patients at greater risk of complications like urinary tract infections, peristomal skin damage, and avoidable hospitalizations. Readmission rates following ostomy surgery are already one of the highest conditions[3,4,5]. One study reported one in five patients being readmitted with a stoma-related complication within 30 days of creation of an ileostomy[6]. Additionally, ill-fitting products lead to peristomal skin complications (PSCs), which also accounts for a high admission rate[4,7] and 80% reported incidence[8]. 72% of ostomates will have a peristomal skin condition within 12 months of surgery[9]. *In many cases PSCs are a preventable readmission with the right products.*

As noted by Duke surgical resident, Dr. Diego Schaps, MD, MPH "The long-term success of every ostomy I make depends on patients having access to a wide range of appliances that fit their bodies. The danger of treating ostomy supplies as uniform is clear. Poorly fitting appliances are not just uncomfortable or embarrassing when they cause leaks. They allow stool or urine to sit directly on the skin, causing painful breakdown, infections, and sometimes hospitalizations. Anybody who has seen an infant with a horrible diaper rash can imagine this. The costs of treating these complications – from antibiotics to emergency department visits to further procedures – would quickly outweigh any "savings" CMS might achieve by narrowing the supply[10]."

In 2013, the Centers for Medicare & Medicaid Services established the Hospital Readmission Reduction Program (HRRP), a cost-containment strategy that financially penalizes hospitals with higher-than-expected 30-day readmission. **Including ostomy and urological supplies in the CBP will only lead to an increase in hospital readmissions and ED visits; which is contradictory to the goal of the HRRP which aims to improve patient health outcomes and quality of care.**

Lastly, ostomy supplies are prescribed by health care professionals to address a Medicare beneficiary's tailored clinical needs. They require a health care professional's ongoing services for selection, fitting,

training on use, adjustment, and to address health care conditions and clinical complexities that arise. Including these supplies in the CBP would be **ignoring the decision-making relationship** between the patient and health care professional and **disrupting prescribed treatment**. Imagine if you needed a prosthetic leg and your doctor prescribed the proper size and fit for your body and your DME provider gave you an off-the-shelf leg that they had in stock which did not fit your leg. "Persons with ostomies deserve to be treated as fully dignified people who are living with a prosthetic digestive system, NOT as financial burdens to insurance companies." Ostomate A.S.

For these reasons we urge CMS to **reconsider and stop the inclusion of ostomy and urological supplies from the Competitive Bidding Program** to ensure patient safety, uphold the law, and protect access to medically necessary prosthetics.

We would appreciate the opportunity to engage further with the CMS and OMB representatives assigned to this proposal. I can be reached at the contact information below or our Advocacy Manager, Jeanine Gleba can be reached at advocacy@ostomy.org.

Thank you for your attention to this pressing matter.
Sincerely,

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United Ostomy Association of America (UOAA)
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207-985-9700

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