August 11, 2025

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

Re: Concerns Regarding Proposed Inclusion of Ostomy and Urological Supplies in Competitive Bidding; File Code CMS-1828-P

Dear Administrator Oz,

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.

Ostomy and urological products provide the ability to contain and control urine and fecal matter and allow people to function. These products (prosthetics) are unique to each individual and replace surgically removed or dysfunctional body systems. Prosthetics are not an appropriate product for the competitive bidding process.

United Ostomy Associations of America, Inc. (UOAA), established in 2005, is a 501(c)(3) national nonprofit organization that represents thousands of individuals across the country living with an ostomy or continent diversion. 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. There are estimated to be 725,000 to 1 million people living with an ostomy or continent diversion in the United States.

People living with an ostomy have undergone surgery to remove their bladder or part of their bowel due to a disease process or trauma. This impairs their ability to store and eliminate bodily

waste. They have a surgically-created opening (stoma) on their abdomen for the elimination of waste and a 'pouching prosthetic system' is continuously worn over the stoma to contain the waste.

We are writing to express serious concern over the Centers for Medicare and Medicaid Services' (CMS) proposed rule CMS-1828-P, which includes redefining **ostomy and urological supplies, including intermittent catheters** as "medical equipment items" to justify inclusion in the expansion of the DMEPOS Competitive Bidding Program (CBP).

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). This statutory language is legally binding. CMS does not have the legal authority to redefine ostomy and urological supplies as "medical equipment items". Any attempt to reinterpret this distinction contradicts both the letter and the spirit of the law. For CMS to include ostomy and/or urological supplies in the competitive bidding program, Congress would have to pass a law adding legal authority for CMS to include these items in the program.

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**, but highly specialized tools critical to daily function, infection prevention, and maintaining dignity and independence.

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.

If this proposal moves forward, it will likely result in **deep reimbursement cuts**, threatening the availability of clinically appropriate products, drastically reducing the number of specialized suppliers available and limiting advancements in technology. These cuts would be especially harmful **and in some cases life-threatening** to individuals with **spinal cord injuries, congenital**

disorders, cancer, and other conditions that necessitate consistent and personalized medical support.

The downstream effects of such a policy change will not be limited to Medicare alone. History shows that **Medicaid programs and private insurers often follow CMS's lead**, creating a domino effect that will restrict access to innovative technologies with proven[1,2] improved patient outcomes. **Low-income individuals and those with disabilities**—who already face systemic barriers to care—would be among the first and most severely impacted.

From our perspective, this proposal also marks a troubling step away from **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.

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. Unlike other medical supplies that are currently in the competitive bidding program, ostomy supplies are not used with other durable medical equipment but rather function on their own, replacing a bodily function.

Changes to an individual's prescribed pouching system for *non-medical reasons* such as cost savings could result in their unique combination of ostomy products not achieving the prosthetic's desired function for them. For those individuals allergic to certain products, if restricted to only those suppliers and products under the Competitive Bidding Program, it **increases infection vulnerability and may be life-threatening**. Additionally, if these supplies were included in the competitive bidding program, it would be **ignoring the decision-making relationship** between the patient and health care professional and **disrupting prescribed treatment**. The consequences of this is that many ostomates would be unable to obtain their prescribed prosthetic devices and no longer able to effectively manage their ostomy; whereby jeopardizing their health and well-being and resulting in hospitalization and increased health care costs.

In light of these concerns, we urge CMS to **reconsider and remove ostomy and urological supplies from the Competitive Bidding Program**. We believe such a decision would better reflect the realities of the patient experience and patient care and uphold CMS's mission to improve health outcomes for all beneficiaries.

Please respond with the contact information for the persons who will be delegated to follow up with this pressing matter.

Thank you for your attention to this important matter. We would welcome the opportunity to engage further on behalf of the communities we serve.

Sincerely,

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1. Zamarripa, Cecilia; Craig, Alexandra; Kelly, Matthew T.; Mathews, Carol; Folk, Amy. Pouching System Leakage and Peristomal Skin Complications Following Ostomy Surgery in the Immediate Postoperative Period: A Retrospective Review. J Wound Ostomy Continence Nurs 51(6): p 478-483, November/December 2024.
2. Cecilia Zamarripa, Alexandra Craig, Carol Mathews, Lisa Small and Amy Folk. A Retrospective Chart Review of Ostomy Pouching Systems in New Ileostomy Patients: A Sub-Analysis *Nursing Reports*. 2025, *15*(6), 206; https://doi.org/10.3390/nursrep15060206