

[[DATE]]

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

Dear Administrator Oz:

We write to express our concern regarding the Centers for Medicare & Medicaid Services' (CMS) decision—announced in the November 28, 2025, final DMEPOS rule—to proceed with inclusion of ostomy, tracheostomy, and urological supplies in Medicare's Competitive Bidding Program with implementation planned for as early as spring 2026.

We respectfully urge you to halt this implementation or, at a minimum, significantly delay the new proposed bidding protocols for these prosthetic products to allow for a thorough review of the serious concerns outlined below.

Ostomy, tracheostomy, and urological supplies are not interchangeable, off-the-shelf commodity items easily sent by mail without the need for clinical fitting and support. These are highly individualized prosthetics used by hundreds of thousands of beneficiaries. These are products that allow patients with Spina Bifida, paralysis, colorectal cancer, bladder cancer, and other serious chronic conditions to: avoid life-threatening infections and hospitalizations; participate in employment; maintain continence and dignity; and breathe safely and effectively.

Wound, ostomy, and continence clinicians across the country emphasize that these products cannot be managed with a "one-size-fits-all" assumption. The precise fit and clinical appropriateness of these devices are matters of life and death.

Compounding these concerns, the implementation timeline outlined in the final rule places the beginning of the bidding process in spring 2026. This abbreviated timeline is particularly alarming to clinicians and patient advocates given that these specific items have never been subject to national competitive bidding.

We also remain concerned that re-classifying these supplies will not offer significant cost savings and will undermine President Trump's commitment to lower healthcare costs. Ostomy, tracheostomy, and urological supplies represent a relatively small portion of overall Medicare spending. These products are both absolutely essential to patients and already considered low cost.

Clinicians, patients, and patient advocates agree that traditional procurement methods offer a better opportunity to ensure the best clinical fit. Reportedly, when patients receive poorly fitted or inappropriate prosthetics through a low-bid type program: leaks become inevitable and frequent, causing skin breakdown and serious dermatologic infections; urological complications

increase, including urinary tract infections and kidney infections that can become life threatening; and patients will land in emergency departments and hospitals.

Given the specialized nature of these products, we believe otherwise preventable hospitalizations and complications will generate enormous costs in Medicare Part A—far exceeding any savings realized through proposed, uncertain Part B reductions.

Aside from the medical and patient benefits, we appreciate the Administration's strong commitment to American manufacturing and supply chain security. As you may know, the ostomy and urological prosthetic industries operate manufacturing, distribution, and quality control businesses across the United States in towns and cities that include Stuarts Draft, Virginia; York, Pennsylvania; Brasleton, Woodstock and Covington, Georgia; Pensacola and Stuart, Florida; Mt. Juliet, Tennessee; Brookshire, Texas; Libertyville, Illinois; Minneapolis, Minnesota; and Camarillo, California.

These facilities employ thousands of American workers in skilled manufacturing, clinical support, distribution, and logistics roles. Outsourcing these products offshore undermines President Trump's America First agenda and creates the exact supply chain vulnerability that the Administration has rightfully strived to avoid.

In light of our deep concern for patient health and our commitment to protect the best medical options for securing properly fitting ostomy, tracheostomy, and urological supplies, we respectfully request that CMS withdraw the November 28 final rules—or significantly modify the policy to fully and compassionately accommodate the needs of those who rely on these uniquely situated products.

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cc: Chris Klomp, CMS Medicare Center