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

Re: <u>Comments for CY 2026 Home Health Prospective Payment System Proposed Rule: Medicare Competitive Bidding of Ostomy and Urological Supplies (CMS-1828-P)</u>

Dear Administrator Oz:

The undersigned stakeholders of the ostomy, urological and tracheostomy patient communities appreciate the opportunity to submit these comments in response 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 that was published in the Federal Register on June 30, 2025 (CMS-1828-P). Our comments specifically focus on our grave concerns regarding the proposal to include ostomy, urological, and tracheostomy supplies in the list of items CMS may subject to DMEPOS Competitive Bidding Program. We strongly oppose this proposal for the following reasons:

Revising the Definition of Ostomy, Urological, and Tracheostomy Supplies is Overstepping CMS' Statutory Authority

With this proposal CMS intends to redefine ostomy, urological, and tracheostomy supplies as medical equipment items so that they are mandated for inclusion in the Competitive Bidding Program. These prescribed supplies are essential to replacing the lost functions of waste storage and elimination and breathing in order to live and function. They are not easily interchangeable or off-the-shelf items such as a walker or diabetic test strip.

Under the Social Security Act (§1861(s)(8)) these supplies are properly defined as prosthetic devices since they are restoring the function of a lost organ (e.g., colon, bladder) or are improving the functioning of a malformed body member. Additionally, as stated in the Local Coverage Determination (LCD) policies for these supplies (Ostomy A52487, Urological A52521, Tracheostomy A52492) they are all covered under the Prosthetic Device benefit.

Congress deliberately excluded prosthetics from the program §1847(a)(2)(A) to protect these vulnerable patients from harm and this proposal ignores this legislative intent. Furthermore, this statute is legally binding and CMS does not have the legal authority to reclassify these supplies. We strongly oppose this proposed dangerous change, which will limit access to the right products, disrupt healthcare professionals' prescribed treatment plans, and threaten patient safety and outcomes.

Threatening Patient Health, Safety, Dignity and Quality of Life

The undersigned organizations represent people who have had lifesaving surgery after bladder and colon cancer, veterans who sustained injuries during military service, children born with congenital conditions, those with spinal cord injuries requiring catheterization and other medical conditions such as inflammatory bowel disease and other rare diseases. These intimate and personal products are designed to be placed inside the body or play a critical role in how the body functions. To exemplify for many ostomates it takes months of trial and error to find the proper prosthetic pouching system that achieves a precise fit to avoid leakages, odor and severe skin complications. These supplies are highly individualized and require ongoing clinician support and product adjustment to maintain health, dignity and quality of life. Including these products in the CBP creates significant access barriers to medically necessary supplies, impedes a prescribed treatment plan, and puts patients at risk of avoidable complications.

From the perspective of one of the patients we serve:

"For patients like us, access to supplies and proper care isn't optional — **it's survival**. If new proposals make it harder to get what we need, we risk leaks, infections, skin breakdown, and losing the quality of life we fought so hard to regain. I am living proof that with the right tools, education, and support, people with ostomies can not only survive but thrive. I want every patient — new or experienced — to have that chance." George S.

It is incomprehensible that CMS would force our patient communities to use incompatible or poor-quality products because of cheaper pricing models and restricted supplier networks. Lastly, this proposal goes against the current Administration's "Make America Healthy Again" agenda which aims to empower patients to improve their outcomes and their healthcare experience. It is the policy of the Federal Government "to aggressively combat the critical health challenges facing our citizens". Including these supplies in the Competitive Bidding Program would only exacerbate the challenges for millions of Americans who rely on these supplies to survive and live a quality life.

For the above reasons we, the undersigned, strongly oppose any expansion of the Competitive Bidding Program that would include ostomy, urological, and tracheostomy supplies.

Sincerely,

Bladder Cancer Advocacy Network (BCAN)
Concho Valley Ostomy Support Group
Crohn's & Colitis Foundation
Delmarva Ostomy Group
Desert Ostomy Support Group
Elkhart Area Ostomy Support Group
Embracing Ostomy Life
Empower our Youth Foundation
Exeter Hospital
Fight Colorectal Cancer

Fort Wayne's Ostomy Support Group

Frederick (MD) Area Ostomy Support Group UOAA Affiliated Support Group #412

Friends of Ostomates Worldwide USA

Gettysburg/Hanover Area Ostomy Support Group

Girls With Guts

Greater Baltimore Ostomy Association

Lewiston, Idaho, Clarkston, WA Ostomy Support

Lincoln Ostomy Association

National Alliance of Wound Care & Ostomy

Ostomates San Gabriel Valley

Ostomy211 Inc

Ostomy Association of Greater Hartford

Ostomy Association of Metro Denver

Ostomy Association of Orange County

Ostomy Association of Sonoma County

Ostomy Support Group of Northern Virginia, LLC

Peoria Area Ostomy Support Group

Pouches of Love

Salem Health

Santa Barbara Cottage Hospital

Silicon Valley Ostomy Support Group

South Asian IBD Alliance (SAIA)

South Palm Beach County Ostomy Support Group

South Florida Ostomy and Tube Feeding/HPN Support Group

Snohomish County Ostomy

Spina Bifida Association of America

The Ostomy Association of New York, Inc.

The Ostomy and Feeding Supply Bank

Triangle Area Ostomy Association

UOAA Patient Support Group - Jacksonville

United Ostomy Associations of America, Inc. (UOAA)

United Ostomy Association of America Golden Gate Chapter

United Ostomy Association of Greater St. Louis

United Spinal Association

West Central Illinois UOAA

Wound Ostomy and Continence Nursing Certification Board

Wound, Ostomy, and Continence Nurses Society™ (WOCN®)

Youth Rally Committee, Inc.