## September 15, 2025

The Honorable John Thune Majority Leader United States Senate SD-511 Washington, DC 20510

The Honorable Mike Johnson Speaker U.S. House of Representatives 520 Cannon House Office Building Washington, DC 20515 The Honorable Chuck Schumer Minority Leader United States Senate 322 Hart Senate Office Building Washington DC, 20510

The Honorable Hakeem Jeffries Minority Leader U.S. House of Representatives 22267 Rayburn House Office Building Washington, DC 20515

## Re: <u>Urgent Opposition to CMS/OMB Proposal to Include Ostomy, Tracheostomy, and Urological Supplies in Medicare Competitive Bidding</u>

Dear Majority Leader Thune, Minority Leader Schumer, Speaker Johnson, and Minority Leader Jeffries:

The undersigned patient and clinical organizations write to express our profound concern and opposition over the proposal in the Calendar Year ("CY") 2026 Home Health Prospective Payment System proposed rule ("proposed rule") (CMS-1828-P), which proposes to wrongfully add ostomy, tracheostomy, and urological products—including catheters—to the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program. We urge Congressional leadership to engage with the Trump Administration, without delay, to ensure this proposal does not become final policy. Patient lives, disability rights, the integrity of American manufacturing and the proper application of federal law are at imminent risk.

Ostomy, tracheostomy and urological products are not generic commodities. They are legally and clinically recognized as prosthetic devices under Section 1861(s)(8) of the Social Security Act and have been explicitly excluded from competitive bidding by statutory intent. The proposed rule's attempt to include these products threatens to destabilize access to prosthetic products for those who must rely on them daily for survival and quality of life.

For individuals who depend on ostomy systems or urological catheters or tracheostomy devices—following cancer or inflammatory bowel disease ("IBD") surgery or those with spina bifida or spinal cord injury—competitive bidding and restricting product access would risk these individuals being forced to use ill-fitted, generic products that are not clinically prescribed and personally fitted for them by their care providers. These are devices that must be individually customized: a "one-size-fits-all" approach immediately risks profound medical complications.

For example, individuals with spina bifida require lifelong intermittent catheterization. Studies show that 50% develop urinary tract infections by 15 months old, and 81% by age 15. Improper

catheters increase their risk of kidney damage, sepsis, and surgical interventions. Ostomates—more than 750,000 Americans—may ensure peristomal skin complications in 36-80% of cases if their ostomy products are not precisely matched to their body, leading to severe dermatitis, ulceration, and emergency surgeries. Tracheostomy patients, many who are ventilator-dependent, face life-threatening emergencies from device blockages, faulty tubes, and infections. For spinal cord injury patients, the wrong type or size of catheter can trigger autonomic dysreflexia, chronic infections, and kidney failure.

These products are low-cost for patients today, and an effort to competitively bid these products would only further limit US manufacturing, product access, and supply. There is also a risk of a significant spike in hospital emergency room visits for significant infections and emergency procedures, costing Medicare far more than appropriately managed ostomy and urological care.

The undersigned patient and clinical organizations implore Congress to act without delay to engage the Department of Health and Human Services ("HHS") Secretary, Robert F. Kennedy, Jr., the Centers for Medicare and Medicaid Services ("CMS") Administrator, Dr. Mehmet Oz, and the Director of the United States Office of Management and Budget ("OMB"), Russell Vought, who have issued this proposal, and ask for its immediate withdrawal.

For Medicare beneficiaries who awaken every morning dependent on these essential devices—children, adults, veterans, and survivors of devastating and chronic illnesses—the stakes could not be higher. Their lives should not be jeopardized by bureaucratic misinterpretation or a false conclusion of budgetary impact of a harmful proposal that does not examine health care risk to patients. Congress alone has the authority and responsibility to intervene.

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For these reasons, the undersigned patient and clinical organizations respectfully urge Congressional action on this critical issue. Thank you for your consideration of our significant concerns.

Sincerely,

## **The Undersigned Patient and Clinical Organizations**

Access Ready, Inc.
ACCSES
All Wheels Up
ALS Association
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Occupational Therapy Association
American Urological Association
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Brain Injury Association of America

California Colorectal Cancer Coalition

Center for Medicare Advocacy

Center on Aging and DIS-Ability Policy

Cheeky Charity

Christopher & Dana Reeve Foundation

Clinician Task Force

Colon Cancer Coalition

Colon Cancer Prevention Project

Color of Gastrointestinal Illnesses

Colorectal Cancer Alliance

Crohn's & Colitis Foundation

CureLGMD2i Foundation

Digestive Disease National Coalition

Epilepsy Foundation of America

Fight Colorectal Cancer

GI Cancers Alliance & Raymond Foundation

Hitting Cancer Below the Belt

International Registry of Rehab Technology Suppliers

Lakeshore Foundation

Muscular Dystrophy Association

National Association for the Advancement of Orthotics and Prosthetics (NAAOP)

National Disability Rights Network (NDRN)

**NCART** 

PALTOWN Development Foundation

Paralyzed Veterans of America

**RESNA** 

Spina Bifida Association

THE BLUE HAT FOUNDATION, Inc

The Gloria Borges WunderGlo Foundation

The Viscardi Center

United Cerebral Palsy

United Ostomy Associations of America

**United Spinal Association** 

Wound, Ostomy, and Continence Nurses Society (WOCN)