April 9, 2026

SUBMITTED ELECTRONICALLY

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

RE: ITEM Coalition's Significant Concerns with Medicare Competitive Bidding of Ostomy and Urological Supplies

Dear Administrator Oz:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition, we write to reiterate our significant concerns with the Agency's decision to include ostomy and urological supplies in the next round of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program ("CBP"). Combined with the implementation of a national Remote Item Delivery ("RID") program for distributing these items to Medicare beneficiaries, we believe this policy represents a fundamental shift away from patient-centered, clinically appropriate care for individuals with disabilities and complex medical needs.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, limb loss and limb difference, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

The ITEM Coalition membership seeks to underscore for CMS the far-reaching implications of these policies and the profound impact on patient access to medically necessary care. The Agency's decision to move forward with these policies despite more than 18,000 stakeholder comments in opposition raises substantial concerns. Patients, clinicians, suppliers, manufacturers, and disability organizations consistently warned that these changes would restrict access to care, undermine clinical outcomes, and conflict with the individualized nature of these intimate and personal products. This extensive record of comments reflects well-established clinical realities that we believe were not adequately addressed.

Ostomy and urological supplies are not generic commodities. They are clinically managed prosthetic devices requiring individualized selection, precise fitting, and ongoing clinician

support. With more than 1,300 catheter options and numerous ostomy system configurations, proper product matching is essential to prevent complications, infections, and maintain health and independence. Applying a low-bid acquisition model designed for commoditized items fails to account for these clinical requirements.

The consequences of this approach are predictable. Limiting access to clinically appropriate products will increase the likelihood that beneficiaries are forced to use ill-fitting or suboptimal alternatives, resulting in higher rates of infection, skin breakdown, and avoidable hospitalizations. These outcomes not only harm patients but also increase overall Medicare spending.

The untested, nationwide RID supplier program further exacerbates these risks by accelerating the shift away from local, specialized suppliers who often provide essential hands-on care toward a remote, centralized, mail-order distribution model. Local, community-based suppliers are not simply vendors; they are a critical component of the care continuum when the patient needs them. They typically have long-standing relationships with individual patients who depend on their services for proper fitting, patient education, and rapid response to emergent complications. This clinical support infrastructure cannot be replicated through remote delivery alone. The loss of this localized clinical support, which is all but guaranteed if CMS proceeds with its CBP plan through RID system, will disproportionately impact individuals with disabilities who depend and rely on personalized, clinically based ostomy and urological care.

In addition, the combined effect of competitive bidding and remote delivery will reduce product quality, limit access to trusted options, and ultimately weaken patient outcomes. A low-bid framework inherently incentivizes reduced product choice and lower-cost alternatives that may not meet individual patient needs. For products that are as personal and medically sensitive as ostomy systems and urinary catheters, reduced choice and diminished quality translate into increased health risks and decreased quality of life. These policies also threaten a robust domestic manufacturing and supplier ecosystem, increasing the risk of market consolidation, offshoring, and supply chain instability—ultimately resulting in fewer choices and diminished access.

For these reasons, the ITEM Coalition strongly urges CMS to reconsider these policies and to meaningfully revisit the substantial stakeholder record opposing their implementation. The decision to proceed despite clear, consistent, and evidence-based concerns from patients, clinicians, and suppliers risks causing predictable and avoidable harm to Medicare beneficiaries who depend on these products for daily health and long-term survival. At a minimum, CMS should immediately halt or delay implementation until the Agency conducts a thorough, transparent evaluation of the impact on patient care. Moving forward without such analysis will not only jeopardize patient safety but also undermine the clinical integrity and cost-effectiveness of the Medicare program.

To ensure a more informed and responsible path forward, CMS should establish a formal advisory board—as it has done twice before under the CBP—comprised of patients, clinicians, suppliers, and manufacturers with direct expertise in these product areas. This advisory body should be charged with rigorously assessing the impact of these policies on patient access,

clinical outcomes, supplier capacity, supply chain stability, and with providing concrete recommendations to CMS before any further implementation proceeds.

Absent such action, CMS risks irreparably disrupting access to essential, individualized prosthetic care for some of the most medically vulnerable beneficiaries—consequences that will be difficult to reverse and costly for both patients and the Medicare program. We would like to continue a dialogue with CMS as it considers our position and implementation of the next round of the competitive bidding program.

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Thank you for your consideration of these concerns. Should you have any further questions, please contact Peter Thomas or Michael Barnett, ITEM Coalition coordinators, at Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by phone at 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.
ACCSES
AG Bell Association for the Deaf and Hard of Hearing
All Wheels Up
ALS Association*
American Academy of Physical Medicine & Rehabilitation (AAPM&R)
American Association for Homecare
American Association of People with Disabilities
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Occupational Therapy Association
Amputee Coalition*
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Brain Injury Association of America
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
3DA
Epilepsy Foundation of America
Institute for Matching Person and Technology
International Registry of Rehabilitation Technology Suppliers (iNRRTS)
Lakeshore Foundation
Long Island Center for Independent Living
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics (NAAOP)
National Clinician Task Force

National Disability Rights Network (NDRN)
NCART
Paralyzed Veterans of America
RESNA
Spina Bifida Association*
Team Gleason*
The Viscardi Center
United Cerebral Palsy
United Ostomy Associations of America, Inc.
Unite 2 Fight Paralysis
United Spinal Association*

Member of the ITEM Coalition Steering Committee

CC: Chris Klomp, Director of Medicare and Deputy Administrator of CMS; Senior Advisor to HHS Secretary Robert F. Kennedy, Jr.
Kimberly Brandt, CMS Deputy Administrator and Chief Operating Officer
Don Dempsey, Office of Management and Budget
Theo Merkel, White House Domestic Policy Counsel
James Bailey, Acting Director, CMS Technology Coding and Pricing Group
Jason Bennett, Acting Director, Center for Medicare
Alec Aramanda, Deputy Director, Center for Medicare
John Brooks, CMS Deputy Administrator and Chief Policy and Regulatory Officer
Sam Waters, Policy Advisor to HHS Secretary Robert F. Kennedy