August 29, 2025

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

Re: ITEM Coalition Comments CY 2026 Home Health Prospective Payment System Proposed Rule: Medicare Competitive Bidding of Ostomy and Urological Supplies (CMS-1828-P)

Dear Administrator Oz:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition 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 (hereinafter referred to as "Proposed Rule") that was published in the Federal Register on June 30, 2025. Our comments focus on our serious concerns regarding the proposal to include ostomy, urological, and tracheostomy supplies in the list of items CMS may subject to DMEPOS Competitive Bidding. We strongly oppose this proposal for the reasons discussed in this comment letter.

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 people 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 spinal cord injury, brain injury, stroke, spina bifida, limb loss, multiple sclerosis, paralysis, cerebral palsy, hearing, speech, and visual impairments, and other life-altering conditions. Many of the individuals represented by our collective organizations rely on ostomy and urological supplies to manage their bowel and bladder disfunction caused by disabling conditions.

I. Including Ostomy, Urological, and Tracheostomy Supplies in Medicare Competitive Bidding Pushes the Limits of CMS's Legal Authority

In its proposed rule, CMS seeks to broaden the definition of items subject to the Medicare competitive acquisition program ("competitive bidding") to include ostomy, tracheostomy, and urological supplies. However, pursuant to section 1847(a)(2) of the Social Security Act ("Act"), Congress intentionally limited the scope of the DMEPOS CPB to only three categories of items:

(1) durable medical equipment and medical supplies used in conjunction with DME;
(2) enteral nutrients, equipment, and supplies; and
(3) off-the-shelf orthotics. 42 U.S.C. §1395w–3(a)(2).

The Act does not authorize CMS to competitively bid "prosthetic devices"—a benefit category that is separate and distinct from DME. *Id*. §1395x(s)(8). Medicare defines a "prosthetic device" as a device that replaces all or part of an internal body organ or replaces all or part of the function of a permanently inoperative or malfunctioning internal body organ. Medicare Benefit Policy Manual ("MBPM"), Pub. 100-02 Ch. 15, § 120; *see also* 42 U.S.C. §1395x(s)(8); 42 C.F.R. §414.202.

Ostomy, tracheostomy, and urological supplies fall within the Medicare benefit category of "prosthetic devices," not "DME." Therefore, in its proposed rule, CMS pushes the limits of its legal authority to competitively bid ostomy, tracheostomy, and urological supplies under section 1847(a)(2) of the Act. For this reason alone, CMS should reject competitive bidding for this benefit category.

II. Patient Harm and Access Risks

Congress established the Medicare competitive bidding program to reduce expenditures on certain devices that are largely commodity-based and interchangeable with competing products (e.g., hospital beds, walkers). A national bidding program assumes homogeneity in patient needs, supplier capabilities, and the items themselves that simply does not exist for ostomy and urological supplies. The program was never intended to competitively bid devices that are inextricably linked to clinical care or are customized to serve the needs of individual patients.

Ostomy and urological supplies are some of the most intimate and personal devices a medical beneficiary can utilize. For these devices to be medically necessary, the beneficiary must have an inability to void waste from his or her body due to a disabling condition such as spinal cord injury, cancer, spinal bifida, stroke, and numerous other medical and surgical conditions. Ostomy and urological supplies are not interchangeable or "off-the-shelf" products. Patients often require highly individualized, clinically guided supplies based on their anatomy, underlying condition, skin integrity, physical abilities, and functional limitations. For urological supplies in particular, the primary barrier is often not brand preference, but finding a device that can meet the physical and dexterity challenges a person faces. Individuals with spina bifida, spinal cord injury, or other neuromuscular conditions may have limited hand function, reduced grip strength, or altered sensation. A catheter that works for one person may be unusable for another simply because they cannot physically manipulate or position it safely. These functional limitations must be considered alongside anatomy and medical condition, underscoring why a "one-size-fits-all" approach in competitive bidding is unsafe and unworkable.

Unlike many items of DME, ostomy and urological supplies are consumable, used daily, and are critical to maintaining health, dignity, and independence in this beneficiary population. Proper management of bowel and bladder disfunction allows many individuals to have a high quality of life and remain largely independent. Poor management of ostomy and urological conditions can lead to secondary conditions, skin breakdowns, infections, hospitalization, social isolation, and

self-selection out of community activities. Disruptions in care puts patients at risk of unnecessary harm. The ITEM Coalition believes that if CMS expands competitive bidding to ostomy and urological supplies, several negative results will occur, including:

- Disruption of established relationships between patients and local providers/suppliers;
- Reduction in patient choice of brand name products;
- Use of lowest-cost, one-size-fits-all, products that may not meet the unique needs of individual patients, compromising the quality of care;
- Reduced patient access to care;
- Outright patient harm due to higher rates of complications such as skin breakdown, urinary tract infections, emergency department use, and unnecessary hospitalization.

For individuals who depend on ostomy systems, 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 exposing these individuals to ill-fitted, generic products that are not clinically prescribed and personally fitted for them by their care providers. Significantly reduced reimbursement levels will force a diminution in quality and a limit on brand name access, with suppliers driving patients toward cheaper and less quality products. 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 (UTIs) by 15-months old, and 81% develop UTIs by age 15. Improper catheters increase the risk of kidney damage, sepsis, and surgical interventions. Ostomy patients—more than 750,000 Americans—encounter 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 of whom 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 urinary catheter can trigger autonomic dysreflexia, chronic infections, and kidney failure.

III. Unique Needs of the Disability Community

Medicare beneficiaries with spinal cord injury, multiple sclerosis, stroke, spina bifida, cancer, and other disabling conditions rely on these products for basic bodily function and infection prevention. These communities—all of which are reflective of the ITEM Coalition membership—already face barriers in access to care and appropriate medical technology. Implementing competitive bidding for these items would increase medical costs from preventable complications, undermine the clinical role of physicians and clinicians in guiding product selection, and conflict with CMS's commitment to person-centered care.

Additionally, CMS has not demonstrated that competitive bidding of these items would yield significant Medicare savings without harming beneficiaries. CMS's assertion that the CBP has led to a 10%-20% reduction in fraud, waste, and abuse lacks factual support and appears to be fully speculative. To date, CMS has not presented any concrete data to substantiate this claim. In contrast, anecdotal evidence from our members on previous rounds of competitive bidding for

other items suggests that many beneficiaries were forced to pay out-of-pocket for lower-cost items—such as walkers and nebulizers—because contract suppliers were often unable to deliver these products in a timely manner.

For these reasons, the **ITEM Coalition strongly opposes this proposal, and we urge CMS to exclude ostomy and urological supplies from the DMEPOS Competitive Bidding Program.** Instead, CMS should work collaboratively with the disability and clinical communities to explore alternative options that promote quality, access, and efficiency without compromising patient care.

Remote Item Delivery ("RID") CBP Proposals

CMS is proposing a new Remote Item Delivery ("RID") CBP that stands to further erode clinical care, patient choice, and quality associated with the products and devices that fall under this program. Under the RID program, contract suppliers would be required to furnish RID items to any Medicare beneficiary in a Competitive Bidding Area ("CBA") who requires them. RID items are defined as those that can be delivered to a beneficiary's home—regardless of the delivery method—or picked up at a supplier's storefront. Unlike the existing mail-order CBP, which permits beneficiaries to pick up items at non-contract supplier storefronts, the RID CBP would require beneficiaries to obtain the item exclusively from a contract supplier, whether by delivery or in-person.

However, it remains unclear whether bidders in a RID CBP must maintain physical locations throughout the entire geographic area of the CBA or if storefront access is only incidental, based on where a supplier happens to have a presence. The way the proposed rule is written strongly suggests that less than 10 national suppliers would be selected nationwide to provide the ostomy and urological supply benefit. This all but assures that local suppliers with whom Medicare beneficiaries develop trusted relationships, will be barred from serving Medicare beneficiaries in the future. **The ITEM Coalition strongly urges CMS to reconsider this proposal, but if CMS persists, we respectfully request CMS to clarify whether physical locations throughout the RID CBA will be required to ensure equitable access for beneficiaries who prefer or need in-person pickup.**

The ITEM Coalition also believes that the establishment of a RID CBP is unnecessary, given that existing CBP rules already permit both regional and national mail-order competitions. Introducing a new RID structure is likely to generate confusion and further reduce access for beneficiaries—particularly those who rely on local suppliers. Under the RID model, beneficiaries could be compelled to use distant, mail-order suppliers, as CMS has acknowledged that RID items would typically be shipped from supplier locations hundreds of miles away.

If items such as ostomy and urological supplies are included in a RID CBP, as CMS appears to suggest, the risks to beneficiary access and safety increase significantly. These essential medical supplies are highly time-sensitive, and any delay—due to shipping disruptions, rural delivery limitations, or natural disasters—could lead to serious health consequences. Although CMS has suggested that such disruptions would be rare, delays in delivery are not uncommon and cannot be dismissed. In such cases, CMS proposes that beneficiaries could obtain supplies from non-

contract suppliers after signing an Advance Beneficiary Notice of Noncoverage ("ABN")—a process that unfairly shifts financial liability to beneficiaries for circumstances beyond their control.

Beneficiaries must retain the ability to choose how and where to obtain their medical supplies—whether through mail order or from a local supplier. **The ITEM Coalition strongly disagrees with CMS's assertion that certain medical supplies, such as ostomy and urological products, are appropriate for inclusion in a national or regional RID CBP.** Individuals who require ostomy supplies often need immediate, local access to a wide array of complex and individualized products. Delays of even a single day can present serious risks to beneficiaries' health and well-being.

For these reasons, CMS should not include in any RID CBP medical supplies or equipment for which emergency access is often required. **The ITEM Coalition and other stakeholders strongly oppose implementing a national or broad regional RID CBP for these categories.** If CMS proceeds with this model, we urge the agency to do so on a limited, state-level basis to evaluate feasibility and monitor beneficiary access before broader implementation.

While competitive bidding is often promoted as a cost-containment strategy, it is also intended to reduce fraud and abuse by limiting the number of contracted suppliers that can submit claims in certain competitive bidding areas. But efforts to reduce fraud and abuse should not be pursued at the expense of patient care. As CMS seeks to control spending and improve efficiency in the Medicare program, the proposed modifications to the CBP raise serious concerns about their potential impact on the quality of care, patient access, and the long-term viability of support for individuals with disabilities and older adults, particularly those with ostomy and urological needs.

The ITEM Coalition fully supports robust efforts to prevent fraud, waste, and abuse and agrees that safeguarding the integrity of the Medicare program is essential. However, the proposed rule would significantly disrupt the DMEPOS supplier infrastructure that delivers medically necessary equipment and supplies to Medicare beneficiaries with both chronic and acute conditions. The price of implementing competitive bidding for ostomy and urological supplies far outweighs the benefits for patients. These items are critical to helping individuals maintain their health and bodily functions, safely remain in their homes, and live as independently as possible—the most cost-effective and preferred setting for care.

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Thank you for the opportunity to submit these comments in response to the CY 2026 Home Health and DMEPOS Competitive Bidding Program proposed rule. If you have any questions, please do not hesitate to contact ITEM Coalition co-coordinators Peter Thomas and Michael Barnett at Peter.Thomas@PowersLaw.com or Michael.Barnett@PowersLaw.com or call 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.
ACCSES
AdvaMed
Alexander Graham Bell Association for the Deaf and Hard of Hearing
All Wheels Up
ALS Association*
American Academy of Physical Medicine & Rehabilitation
American Association for Homecare
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Macular Degeneration Foundation
American Occupational Therapy Association
American Physical Therapy Association
Amputee Coalition*
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Center for Medicare Advocacy
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
Clinician Task Force
CureLGMD2i Foundation
Epilepsy Foundation of America
International Registry of Rehabilitation Technology Suppliers
Institute for Matching Person and Technology
Lakeshore Foundation
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Disability Rights Network (NDRN)
NCART
RESNA
Spina Bifida Association*
The Viscardi Center
Unite 2 Fight Paralysis
United Cerebral Palsy
United Ostomy Associates of America
United Spinal Association*

****ITEM Coalition Steering Committee Member***