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 on the CY 2026 Home Health Prospective Payment System Proposed Rule (CMS-1828-P); Competitive Bidding of Off-the-Shelf Orthotics, Accreditation Organizations, and Prior Authorization

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 significant concerns regarding the proposal to include off-the-shelf ("OTS") orthotics in the list of items CMS may subject to DMEPOS CBP, the proposed changes to the DMEPOS supplier accreditation process, and the proposed prior authorization exemption pathway for compliant DMEPOS suppliers.

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, limb loss, multiple sclerosis, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, and other life-altering conditions. Many individuals represented by ITEM Coalition member organizations rely on orthotic braces of the neck, back, arms and legs to address health and functional needs resulting from disabling conditions.

The ITEM Coalition opposes Medicare competitive bidding because prior rounds of this program have resulted in reduced patient access to care, reduced choice of brand name products that meet patient needs, and reduced quality of care. Beneficiaries with disabilities should not be subjected to a program that relegates their care to the lowest bidder and drives to the bottom patient access, choice and quality. Competitive bidding should never be used when clinical services are required to effectuate the use of the device in question. In addition, no item or device that must be customized to meet patient needs should be exposed to competitive bidding because the end product suffers in quality as contract suppliers seek to make ends meet with significantly lower reimbursement levels. On principal, we urge CMS to not proceed with future rounds of

competitive bidding and seek other approaches to enhancing program integrity while preserving patient access, choice and quality of care.

I. Proposed CBP Inclusion of Off-the-Shelf Orthoses

CMS applied competitive bidding to 22 OTS orthotic codes describing knee and back braces from 2021 to 2023. While CMS largely achieved its savings goals, beneficiaries lost access to clinical orthotic services as a less costly delivery model was routinely adopted by suppliers. In addition, a sizable percentage of these claims were denied based on medical necessity but not appealed, as contract suppliers did not view the time and expense of appealing low dollar claims as cost-effective. CMS touted these "savings" as a benefit of the program but much of these savings were simply shifted onto patients and contract suppliers.

CMS is now proposing to conduct a future round (or rounds) of competitive bidding of certain items covered by the Medicare program. In authorizing competitive bidding pursuant to the Medicare Prescription Drug, Improvement and Authorization Act of 2003, Congress intentionally limited the scope of competitive bidding to the following three categories:

1. Durable medical equipment and medical supplies used in conjunction with DME;
2. Enteral nutrients, equipment, and supplies; and
3. Off-the-shelf orthotics.[1]

By limiting the scope of competitive bidding to OTS orthoses only, Congress thereby exempted custom-fabricated and custom-fitted orthoses and all limb prostheses. OTS orthotics are defined as orthoses that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual." *Id.*

However, CMS has defined the term "minimal self-adjustment" in regulation in a manner that, from the ITEM Coalition's perspective, improperly expands the statutory provision. Specifically, CMS defined the term as "an adjustment that the beneficiary, *caretaker for the beneficiary, or supplier of the device* can perform and does not require the services of a certified orthotist. . . or an individual who has specialized training." By allowing suppliers or others to perform adjustments to ensure proper fit, function and efficacy of OTS orthoses, CMS has effectively removed the word "self" from the statutory term, "minimal self-adjustment," which contradicts the plain language of Section 1847(a)(2)(C) of the Act. This has the effect of subjecting far more orthoses to competitive bidding than Congress intended. The ITEM Coalition believes that if the fitting or adjustment of an orthosis requires assistance from anyone other than the patient, particularly from the device supplier, it cannot be reasonably considered a self-adjusted, off-the-shelf orthosis and should not be subject to competitive bidding.

CMS's actions on OTS orthoses allows orthoses that often require clinical expertise to properly assess and fit the device to be competitively bid. With reduced reimbursement levels, contract suppliers have moved toward a "drop shipment" delivery model, where orthoses that are not truly OTS are drop shipped to the patient's home with no clinical fitting or training, and minimal

[1] 42 U.S.C. §1395w-3(a)(2)

instruction as to appropriate use. Without the clinical services associated with the delivery of custom-fitted orthoses, beneficiaries are at risk of receiving clinically inappropriate or unnecessary orthoses, putting patients at risk and compromising the integrity of the Medicare orthotic benefit.

Importantly, once a beneficiary receives an OTS orthosis through competitive bidding, they are generally precluded from obtaining another orthosis of the same or similar type for a five-year period under the Medicare program. Current CMS policy requires contractors to deny coverage for any "same or similar" orthosis if a claim is submitted within the designated useful lifetime of the original device. In these cases, the beneficiary is asked to sign an Advance Beneficiary Notice of Noncoverage ("ABN") and assume the full out-of-pocket cost if the initial, competitively bid OTS orthosis proves ineffective. This policy places beneficiaries at risk of being locked into an ill-fitting or ineffective device for a significant period of time, or paying out of pocket for a more appropriate orthosis, creating serious barriers to appropriate and medically necessary orthotic care.

As an alternative to Medicare competitive bidding of OTS orthoses, the ITEM Coalition has endorsed and strongly urges CMS adopt under its own authority provisions from the *Medicare Orthotics and Prosthetics Patient-Centered Care Act* (H.R. 4475/S. 2329), which would reduce the likelihood of waste, fraud, and abuse in the Medicare program while improving orthotic care for patients who need these services. More specifically, the bill would:

- Exempt certified and licensed orthotists and prosthetists from competitive bidding similar to therapists and physicians, costing Medicare no more than they otherwise would pay for OTS orthoses;
- Ban drop shipment of custom-fit and custom-fabricated orthoses and prostheses with an exception for OTS orthoses; and,
- Allow beneficiaries to access additional orthotic care within the reasonable useful lifetime of the device, similar to Medicare rules applicable to prosthetic limbs.

The provisions of this legislation would meaningfully advance O&P patient care while tackling fraud, waste, and abuse. Together, this approach is far superior to another round of competitive bidding for OTS orthotics. We urge CMS to adopt these provisions under its own authority and to convey its support for this legislation to Congressional leadership.

Subjecting OTS orthotics to competitive bidding creates unnecessary interruptions in the continuum of care and removes the clinical care necessary for quality orthotic treatment. It also increases the likelihood that the orthotic brace will be less quality and fit sub-optimally, which can lead to falls, pressure ulcers, joint misalignment, and exacerbation of existing conditions—harms that are both clinically and financially costly to the Medicare program. The **ITEM Coalition strongly opposes this proposal, and we urge CMS to exclude OTS orthotics from any future round of the DMEPOS Competitive Bidding Program.** Instead, CMS should work collaboratively with the disability and clinical communities to explore alternative options that promote access, choice and quality without compromising patient care.

<u>Deterioration of the DMEPOS Supplier Network</u>

Although the DMEPOS CBP has succeeded in reducing Medicare expenditures, independent research has shown that these savings have come at a significant cost—namely, the deterioration of the DMEPOS supplier network, the suppression of medical innovation, and diminished product availability and quality. These savings place great pressure on suppliers to provide cheaper orthotic brands and fewer options for patients in order to make ends meet. Quality of care suffers as patient choice is restricted and, as a result, patient access to quality orthotic care that will have the maximum therapeutic value is significantly reduced. The program's flawed auction design has introduced structural weaknesses that threaten the long-term stability of the providers who serve Medicare beneficiaries and jeopardize access to appropriate orthotic care for Medicare beneficiaries who need it the most.

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 patient access to medically necessary equipment and supplies for Medicare beneficiaries. These items are critical to helping individuals safely remain in their homes, living as independently as possible, and participating in community activities.

Risks to Beneficiaries and Small Providers

Expanding competitive bidding to OTS orthotics poses serious risks to both Medicare beneficiaries and small providers. Competitive bidding often favors large-volume suppliers with limited patient engagement that prioritize cost efficiency over individualized, patient-centered care. As a result, the quality of the care is eroded in a field where proper fit and follow-up are critical to patient outcomes, and long-standing patient-provider relationships are disrupted resulting in reduced quality and continuity of care. In orthotic care, this shift could lead to poor clinical outcomes, avoidable complications, and reduced patient satisfaction.

At the same time, many small community-based orthotic and prosthetic practices—which offer clinical services such as in-person assessment, custom fitting, and ongoing adjustments to ensure proper fit and function—would be placed at a huge competitive disadvantage against mail-order or warehouse-based suppliers, potentially forcing these small providers to no longer see Medicare patients. For vulnerable populations, including individuals with limb loss or limb differences, neuromuscular disorders, or other complex conditions, this would mean fewer local options, longer wait times, and diminished continuity of care, as price rather than patient need would increasingly dictate access to quality orthotic care. **The ITEM Coalition urges CMS to withdraw this proposal from the final rule to protect access to safe, effective, and patient-centered orthotic care.**

Remote Item Delivery ("RID") CBP Proposals

CMS is proposing a new Remote Item Delivery ("RID") CBP, under which contract suppliers would be required to furnish RID items to any Medicare beneficiary in a Competitive Bidding Area ("CBA") who requests 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. Under this proposal, CMS estimates that less than 10 national suppliers would be selected to provide OTS orthoses nationwide.

The ITEM Coalition strongly opposes this proposal. As a result of this policy, the overwhelming majority of beneficiaries would likely receive OTS orthoses exclusively through mail-order or other remote delivery channels. This would severely limit patient access to local clinical practices, many of whom have relationships with their patients. By consolidating contracts and favoring remote delivery, CMS risks dismantling these relationships and further removing clinical care from the orthotic treatment process. Eliminating meaningful access to local suppliers is especially concerning for vulnerable populations, including older adults and individuals with mobility impairments, who may lack the resources or confidence to manage their care through remote channels alone.

Moreover, this policy fails to account for the serious consequences of disruptions in care that are likely to result from a delivery model that relies primarily on remote fulfillment. CMS itself has acknowledged that in situations where a beneficiary loses or is temporarily without competitively bid items that Medicare has already paid for, the supplier of the replacement items would ask the beneficiary to sign an ABN. In doing so, the beneficiary becomes personally liable for the cost of the replacement item if the claim is denied. The only recourse for the beneficiary would be to file an appeal. Shifting both the financial liability and administrative burden onto beneficiaries is wholly inappropriate and inconsistent with CMS's responsibility to protect beneficiary access.

This proposal improperly favors a handful of large, national entities that can compete on razor-thin margins, while effectively shutting out small businesses that provide clinical services to their communities. We are concerned that this proposed concept will accelerate consolidation and reduce competition. Therefore, CMS should not establish the RID CBP and we urge the agency to not finalize this aspect of the proposed rule. If CMS proceeds with this model despite our strong objection, we urge the agency to do so on a limited, state-level basis to evaluate feasibility and monitor beneficiary access before broader implementation.

II. Proposed Changes to DMEPOS Supplier Accreditation Process

CMS is proposing stricter requirements for becoming and remaining a DMEPOS accrediting organization ("AO") in this proposed rule. AO's are private entities that work with CMS to help ensure that Medicare suppliers meet program requirements. These proposed changes include a proposal to restructure the DMEPOS supplier survey and reaccreditation process to require annual reaccreditation and site visits as opposed to the current requirement of every three years for DMEPOS suppliers. The ITEM Coalition opposes this proposal.

Dramatically increasing the frequency of in-person site visits and reaccreditations will be logistically unworkable and potentially destabilizing to the DMEPOS accreditation system that currently safeguards supplier quality and patient access. Rather than improving the accreditation process, requiring annual reaccreditation would create burdensome

administrative hurdles, significantly increase compliance costs, and potentially reduce the number of AOs, all of which ultimately undermine access to critical durable medical equipment, prosthetics, orthotics, and supplies for Medicare beneficiaries. Worse yet, more frequent site inspections and reaccreditations will do little to combat fraud and abuse as AO's are not tasked with reviewing providers' Medicare claims or other information related directly to specific patient care.

CMS does not provide any evidence in the proposed rule that current DMEPOS AOs are failing in their duties or that the current system lacks safeguards against conflicts of interest, quality lapses, or improper supplier accreditation. In fact, the proposed rule does not identify systemic problems or widespread deficiencies among existing AOs; justify why current AO vetting and oversight practices are insufficient; or consider the impact on patient access and supplier burden, especially in rural and underserved areas where supplier options are already limited. The ITEM Coalition believes that AOs play a vital role in ensuring that suppliers meet quality and safety standards. Undermining their capacity through excessive regulation could have the opposite effect of these proposal's intended purpose and runs counter to this Administration's interest in reducing provider burden.

For these reasons, the **ITEM Coalition encourages CMS to withdraw the proposed changes to DMEPOS AO requirements and instead engage in stakeholder dialogue to identify any targeted, evidence-based improvements that might be warranted.** We urge the agency to preserve the effectiveness and integrity of the DMEPOS accreditation system without introducing new regulatory burdens that would ultimately harm DMEPOS suppliers and the patients they serve.

III. Prior Authorization Exemption Pathway for DMEPOS Suppliers

CMS is proposing a new exemption process for certain DMEPOS suppliers who demonstrate high rates of compliance with Medicare rules. Under this proposal, DMEPOS suppliers with a 90% affirmation rate or higher would be exempt from prior authorization requirements, effective until CMS withdraws the exemption if the provider does not continue to meet the compliance threshold.

In many instances, prior authorization can delay or deny care to Medicare beneficiaries but many DMEPOS providers have found prior authorization to be a favorable alternative to a lengthy and expensive administrative appeals process when reimbursements are recouped after care has been provided to the Medicare beneficiary. **The ITEM Coalition supports this proposed prior authorization exemption pathway. However, we urge CMS to clarify that the exemption would be voluntary.** Suppliers that prefer to continue submitting prior authorization requests should retain the ability to do so, with their requests processed by the DME MACs in the ordinary course. We believe this proposed pathway represents a thoughtful and balanced approach that supports program integrity while reducing unnecessary administrative burdens for both suppliers and beneficiaries.

The ITEM Coalition has long heard from its member organizations that the prior authorization process—while important for program safeguards—can result in frustrating

and harmful delays in access to critical medical services in a wide variety of settings, including in the Medicare Advantage program. This proposal takes meaningful steps toward minimizing the negative implications of prior authorization when the supplier has demonstrated a proven track record for compliance. Allowing DMEPOS providers to continue prior authorization even when they achieve the required threshold for an exemption would further advance program integrity goals and minimize provider burden. We commend CMS for advancing this commonsense, performance-based policy that will improve efficiency and access across the DMEPOS benefit.

****

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
Alexander Graham Bell Association for the Deaf and Hard of Hearing
American Academy of Physical Medicine & Rehabilitation
American Association for Homecare
American Congress of Rehabilitation Medicine
American Macular Degeneration Foundation
American Physical Therapy Association
Amputee Coalition*
Association of Rehabilitation Nurses
Center on Aging and DIS-Ability Policy
CureLGMD2i Foundation
Epilepsy Foundation of America
Institute for Matching Person and Technology
International Registry of Rehabilitation Technology Suppliers
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
United Spinal Association*

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