August 31, 2026

The Honorable Mehmet Oz
Administrator
Center for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: ITEM Coalition Comments in Response to the Calendar Year 2027 Home Health Prospective Payment System Proposed Rule (CMS-1844-P)

Dear Administrator Oz:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition, we appreciate the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' 2027 Home Health Prospective Payment System Proposed Rule, which includes several proposals that would impact Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") suppliers operating outside of a home health agency.[1] Our comments focus on the proposals included in the proposed rule related to the DMEPOS Competitive Bidding Program ("CBP"), DMEPOS accreditation, and Medicare enrollment and billing privileges.

The ITEM Coalition is a national consumer- and clinician-led coalition comprised of 103 national organizations 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 limb loss and limb difference, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

The ITEM Coalition strongly supports CMS's long-standing efforts to protect the Medicare program and beneficiaries from fraud, waste, and abuse. Program integrity is essential to protecting beneficiaries and ensuring that Medicare resources remain available to meet the medically necessary device-based needs of beneficiaries. However, program integrity policies must be carefully designed so that efforts to exclude fraudulent actors do not inadvertently drive legitimate suppliers out of the Medicare program, reduce beneficiary choice, disrupt established

[1] Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies, 91 Fed. Reg. 41216 (July 6, 2026).

supplier relationships, or create barriers to medically necessary assistive devices and technologies.

The DMEPOS proposals in this rule illustrate the importance of striking that balance. The ITEM Coalition supports several proposals that would reduce unnecessary administrative barriers to access. At the same time, we have significant concerns with the proposed DMEPOS accreditation changes, the proposed collection of country-of-origin information under the DMEPOS CBP, and the proposed expansion of Medicare enrollment and revocation authorities. These proposals, taken together, could impose substantial burdens on legitimate suppliers without demonstrating a corresponding benefit to beneficiaries or the Medicare program.

I. DMEPOS Competitive Bidding Program

The ITEM Coalition continues to strongly oppose the inclusion of ostomy and urological supplies, as well as off-the-shelf ("OTS") orthoses in the next or future rounds of competitive bidding. Ostomy and urological supplies are critical, life-sustaining items used by individuals with significant medical needs, including those with spinal cord injuries, bladder dysfunction, and other chronic conditions. Competitive bidding may appear to offer short-term cost savings, but in practice, we have grave concerns that unnecessary urinary tract infections, stoma infections, and other complications arising from this program will create much higher inpatient and other treatment costs to address these unnecessary secondary conditions. However, our more patient-centered concerns are far more problematic such as restricted access to care, reduced product choice, and delays and disruptions in care for some of the most vulnerable populations. For individuals who rely on these intimate and personal prosthetic devices every day, consistency, quality, and proper fit are not preferences; they are medical necessities.

For OTS orthoses, the CBP poses risks to both beneficiaries and small, community-based suppliers. Competitive bidding often favors large-volume suppliers that prioritize cost efficiency over individualized service, eroding quality of care in a field where proper fit and follow-up are critical to patient outcomes. This is exacerbated with the Remote Item Delivery ("RID") system CMS is planning on implementing. In orthotic care, this shift can lead to poor clinical results, avoidable complications, and reduced patient satisfaction. For vulnerable populations, including individuals with limb loss, 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 orthotic services.

For these reasons, the ITEM Coalition continues to implore CMS to not move forward with implementation of competitive bidding for these specific items unless and until a comprehensive study can be performed to assess the impact on patient access and quality that will occur as a result.

Furthermore, we have serious concerns with the development of the new and untested RID CBP, the imposition of arbitrary limitations on the number of contract suppliers, the flawed payment methodology for identifying single payment amounts, and the establishment of restrictive bid ceilings. Collectively, these policies undermine patient access to care and should be seriously reconsidered by CMS.

We are particularly concerned given the recent announcement that the nationwide RID competition would result in only five suppliers for urological supplies, six suppliers for ostomy supplies, three suppliers for OTS back braces, four suppliers for OTS knee braces, and five suppliers for OTS upper extremity braces. This restriction on the number of contract suppliers risks nationwide disruption of established patient-provider relationships, reduction of beneficiary choice, and timely access to appropriate orthotic care. This directly impacts quality of care as inadequate access to these supplies will almost certainly result in increased risk of infections, skin breakdown, leakage, avoidable emergency department utilization, and hospitalizations. For OTS orthoses, inadequate access may contribute to falls, reduced mobility, and impaired independence. The RID system would also exclude qualified suppliers that currently serve Medicare beneficiaries. In practice, the nationwide scope of the RID system, coupled with the requirement that contract suppliers satisfy all applicable state licensure requirements throughout the competitive bidding area, creates a substantial barrier to participation for small, community-based suppliers.

Finally, we encourage the agency to exempt orthotists and prosthetists from competitive bidding similar to the way CMS treats physicians and therapists under the CBP. Currently, the Medicare statute exempts from competitive acquisition, items and services provided "by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service."[2] The Secretary has defined "practitioner" to include physician assistants, nurse practitioners, clinical nurse specialists, physical therapists in private practice, and occupational therapists in private practice.[3] 42 C.F.R. § 414.404(b). However, the Secretary has not exempted nationally certified and/or state licensed orthotists from the requirement to obtain a supplier contract. Exempting credentialled orthotists from the CBP would allow such practitioners to provide orthotic care at the point of service, improving patient access and quality, *but at the competitively bid rate*, thereby not costing the Medicare program any more than it otherwise would spend under the CBP, again, consistent with the way other practitioners defined by the Secretary are treated.

a. Face-to-Face Encounter for Replacement of DMEPOS Items

The ITEM Coalition strongly supports CMS's proposal to clarify that a new face-to-face encounter is not required when a beneficiary receives a replacement DMEPOS item that falls under the same Healthcare Common Procedure Coding System ("HCPCS") code as the item being replaced.

In this proposed rule, CMS appropriately recognizes that requiring a beneficiary to undergo another face-to-face examination merely to replace an existing item is unnecessary when the beneficiary continues to have a medical need for the same item. CMS explains that the relevant clinical information should have been documented when the beneficiary was initially evaluated and received the initial item, and that a practitioner should issue a replacement order only when the beneficiary continues to have an ongoing medical need. The ITEM Coalition strongly supports this approach.

[2] 42 U.S.C. § 1395w-3(a)(7).
[3] 42 C.F.R. § 414.404(b).

For beneficiaries with disabilities, unnecessary clinical visits can be substantially more burdensome than they are for the general Medicare population. Individuals with significant mobility limitations may require accessible transportation, caregiver assistance, or other accommodations simply to attend an in-person appointment. We believe that requiring an additional visit when there has been no change in the beneficiary's medical condition adds both an administrative barrier and actual travel without improving clinical decision-making.

The proposed clarification in the draft rule is particularly important for beneficiaries who depend upon mobility and assistive technology to function independently. Delays in replacing a medically necessary device can result in loss of mobility, inability to perform mobility-related activities of daily living ("MRADLs"), interruption of employment or education, and increased risk of falls, injury, or institutionalization. For these reasons, the ITEM Coalition urges CMS to finalize this proposal and to ensure that its implementation is clear to practitioners, suppliers, Medicare Administrative Contractors ("MACs"), and beneficiaries.

b. DMEPOS Accreditation

CMS is proposing to require DMEPOS accreditation organizations to notify CMS of suspected fraud, waste, or abuse by a supplier within three calendar days. The ITEM Coalition supports appropriate communication between accrediting organizations and CMS concerning credible evidence of fraud or abuse. However, CMS should ensure that the new reporting requirement does not transform routine accreditation findings, documentation deficiencies, or unresolved compliance questions into immediate fraud referrals.

Accreditation surveys routinely identify deficiencies that can be corrected through education, corrective action, and follow-up. We believe that a requirement triggered by conduct that merely "may have occurred" could create unnecessary investigations and reputational consequences for legitimate suppliers. ***For these reasons, we urge CMS to establish clear standards distinguishing credible evidence of fraud, waste, or abuse from ordinary accreditation deficiencies before imposing a mandatory reporting requirement.***

c. Country-of-Origin Reporting Requirement

The ITEM Coalition does not support CMS's proposal to require DMEPOS CBP contract suppliers to report the country of origin of lead items and to publish that information in the Medicare Supplier Directory. CMS states that the information would allow beneficiaries and interested parties to learn where DMEPOS items originated. ***However, the ITEM Coalition questions whether this information will meaningfully assist beneficiaries in selecting DMEPOS suppliers or supplies.***

For beneficiaries, particularly those who rely on complex assistive technology, the most consequential supplier information concerns whether the supplier can provide the appropriate product, whether the supplier carries the relevant manufacturers and models, whether the supplier has the clinical and technical expertise necessary to furnish and configure the equipment, and whether the supplier can provide timely repairs, maintenance, replacement, and follow-up services. Country of origin does not answer any of these questions.

Therefore, the ITEM Coalition urges CMS not to finalize this proposed requirement in the final rule. If CMS nevertheless proceeds, the Agency should explain how it intends to use this information. The Agency should also ensure that the information is accurate, current, understandable to beneficiaries, and presented in a manner that does not create confusion or imply that country of origin is a proxy for product or supplier quality.

II. Medicare Enrollment and Billing Privileges

The ITEM Coalition supports CMS's efforts to strengthen Medicare program integrity, particularly in light of the recent Department of Justice investigations that have exposed sophisticated criminal schemes targeting vulnerabilities within the Medicare program. However, program integrity measures must be carefully calibrated to target genuine fraud without imposing disproportionate consequences on legitimate providers and suppliers. ***We therefore urge CMS not to expand its enrollment authorities in ways that lack clear standards, transparency, predictability, and appropriate procedural safeguards.*** Enforcement actions should distinguish between intentional or abusive conduct that poses a meaningful threat to the Medicare program and isolated administrative, technical, or inadvertent errors that do not.

a. Proposed Revocation for High-Risk Enrollments

The ITEM Coalition firmly opposes CMS's proposed new authority under 42 C.F.R. § 424.535(a)(24) to revoke a provider's or supplier's Medicare enrollment based on CMS's determination that the enrollment presents a high risk of fraud, waste, or abuse because the provider or supplier is located within a limited geographic area containing an excessive number of providers and suppliers.

We recognize and share CMS's concern that concentrated enrollment can, in certain circumstances, be associated with sophisticated fraud schemes. CMS cites examples involving large numbers of home health agencies and other providers operating in the same buildings or small geographic areas. However, the existence of provider or supplier concentration is not, standing alone, evidence that an individual provider or supplier is engaging in fraud, waste, or abuse. CMS itself acknowledges that many legitimate medical facilities and medical complexes contain large numbers of providers and suppliers and that these circumstances do not necessarily indicate the presence of fraud or other program integrity risks.

The proposed authority nevertheless would permit CMS to revoke an individual supplier's enrollment based substantially on circumstances that the supplier cannot control. CMS specifically states that the providers and suppliers located in the relevant area do not need to be of the same type. Thus, a legitimate DMEPOS supplier could potentially face revocation because of the presence or conduct of unrelated home health agencies, hospices, physicians, laboratories, or other providers operating nearby.

The ITEM Coalition views this approach as fundamentally inconsistent with the principle that an enrollment sanction should be based upon evidence concerning the provider or supplier being sanctioned. A supplier that has complied with Medicare requirements should not lose its billing privileges merely because CMS believes that there are too many providers or suppliers operating in its geographic vicinity.

This proposal is particularly concerning for DMEPOS suppliers because providers and suppliers frequently operate in shared medical office buildings, rehabilitation centers, hospital campuses, and other health care settings. Such co-location may reflect entirely legitimate considerations, including access to clinicians, coordination of care, beneficiary convenience, availability of specialized services, and local real estate markets. The proposal fails to establish a relationship among the providers or demonstrate that any particular supplier presents a program integrity risk.

The proposal is also impermissibly vague. CMS does not define what constitutes an "excessive" number of providers or suppliers within a geographic area, nor does it establish an objective threshold at which geographic concentration becomes sufficient to support revocation. More significantly, CMS expressly proposes not to require itself to consider specified factors before taking revocation action. Instead, CMS states that it needs flexibility to address the unique facts and circumstances of individual cases. But this gives CMS extensive discretion to impose this draconian sanction without basic protections of due process.

We are concerned that such broad discretion would make it difficult for legitimate suppliers to understand what circumstances could place their Medicare enrollment at risk. The absence of objective standards is particularly problematic where the consequence is revocation of Medicare billing privileges and potentially substantial retroactive financial liability.

Further, CMS already has substantial tools available to address suspected fraud associated with provider concentration, including data analytics, site visits, enhanced screening, payment suspension, claims review, enrollment moratoria, and existing revocation authorities. Indeed, CMS has recently demonstrated its ability to use data-driven approaches to identify and address high-risk DMEPOS enrollment. CMS announced a nationwide six-month moratorium covering specified DMEPOS medical supply companies in February 2026, and CMS described that moratorium as part of its broader effort to address suspected fraudulent DMEPOS billing. These tools allow CMS to investigate and address actual indicators of fraud without creating a new authority to revoke the enrollment of an otherwise compliant supplier based upon its location.

For these reasons, the ITEM Coalition urges CMS to withdraw this proposed expansion of revocation authority. If CMS believes additional authority is necessary to address geographically concentrated fraud schemes, CMS should instead develop objective, supplier-specific criteria requiring evidence of an actual connection between the affected supplier and the underlying program integrity concern. At a minimum, geographic concentration alone should never constitute a sufficient basis for revocation.

b. Proposal to Prohibit the Sharing of Office Space

The ITEM Coalition similarly opposes CMS's proposal to deny enrollment to a supplier because its practice location is in the same suite or office as another provider or supplier whose Medicare enrollment has been denied or revoked. ***Again, a supplier's physical proximity to another provider does not establish fraud, common ownership, common control, or any other program integrity violation.***

CMS should investigate the individual supplier and determine whether there is evidence that the supplier itself presents a program integrity risk. It should not impose an enrollment sanction

based merely upon a landlord's leasing decisions or the physical configuration of a medical office building.

Moreover, existing DMEPOS supplier standards already address location and operational requirements, and DMEPOS suppliers are already subject to requirements concerning separate locations and postal addresses. Accordingly, the ITEM Coalition urges CMS not to finalize this new denial authority in the final rule.

c. Expansion of Retroactive Revocation Grounds

The ITEM Coalition does not support CMS's proposal to make virtually all Medicare enrollment revocations retroactive to the date CMS determines that the supplier first became noncompliant.

The consequences of this proposal are potentially devastating for legitimate DMEPOS suppliers. Under current regulations, a supplier may furnish medically necessary equipment and services while it is actively enrolled in Medicare and reasonably believes it is complying with applicable enrollment requirements. If CMS subsequently determines that an enrollment deficiency existed at an earlier point in time, the supplier could face retroactive loss of billing privileges and substantial recoupment liability.

We stress to CMS that this proposal is not merely an accounting issue. For DMEPOS suppliers, reimbursement frequently follows substantial expenditures made before payment is received. Suppliers may have already purchased equipment, ordered customized components, manufactured or configured items, delivered equipment, trained beneficiaries and caregivers, and provided follow-up services***. Retroactive recoupment could therefore leave suppliers financially responsible for the cost of medically necessary equipment and services that beneficiaries already received. This risk is especially significant for small and rural suppliers, which often lack the financial reserves necessary to withstand large retrospective repayment demands.***

For these reasons, the ITEM Coalition urges CMS to retain prospective revocation as the general rule. Retroactive revocation should be reserved for circumstances involving clear fraud, intentional misconduct, or other conduct where retroactive application is demonstrably necessary to protect the Medicare program. At a minimum, where a supplier timely exercises its administrative appeal rights and the revocation is not based on clear fraud, CMS should suspend associated overpayment recovery until the supplier has had a meaningful opportunity to challenge the revocation

d. Revocation for Abuse of Billing Privileges

The ITEM Coalition also opposes CMS's proposal to remove the existing factors used to determine whether a supplier has engaged in a pattern or practice of submitting claims that do not meet Medicare requirements. ***The existing factors provide important structure and predictability.*** CMS proposes to eliminate those factors and instead rely on its broader discretion to determine whether a pattern or practice exists. CMS expressly indicates that it does not intend to establish a minimum number or percentage of claims necessary to constitute such a pattern.

We believe this approach is overly broad and grants CMS too much discretion without sufficient safeguards for legitimate providers.

DMEPOS claims are subject to complex coverage, coding, documentation, medical necessity, and procedural requirements. Claims may be denied for reasons that do not reflect fraudulent intent or abusive billing. The proposed removal of these objective standards could allow a series of ordinary claim errors or disputed coverage determinations to become the basis for inappropriate revocation of a supplier's Medicare enrollment.

The consequences of revocation are far too severe to justify such an open-ended standard. Accordingly, the ITEM Coalition urges CMS to retain the existing factors. If CMS believes additional flexibility is warranted, it should add carefully defined factors rather than eliminate the standards that provide suppliers with notice and predictability.

e. Claims Submissions After Revocation

The ITEM Coalition also has significant concerns with CMS's proposal to reduce the period for submitting claims for items and services furnished before revocation from 60 days to 15 days. According to CMS, this proposed change is necessary because the Agency believes the shorter period would reduce the opportunity for inappropriate billing following supplier revocation. From the ITEM Coalition's perspective, however, a 15-day period is unnecessarily restrictive and could result in legitimate claims becoming inappropriately uncompensated.

DMEPOS claims frequently require the supplier to gather documentation from physicians and other practitioners, verify delivery information, resolve outstanding documentation issues, and ensure that claims are submitted accurately. This is particularly true for complex rehabilitation technology and other customized assistive devices and technologies, including orthotics and prosthetics. ***We believe that a 15-day deadline would leave practitioners insufficient time to identify outstanding claims, obtain missing information, resolve documentation problems, and submit accurate claims following a revocation determination.*** For these reasons, the ITEM Coalition urges CMS to retain the existing 60-day period.

f. Expansion of the Reapplication Bar

The ITEM Coalition does not support CMS's proposal to permit a reapplication bar of up to ten years regardless of the basis for enrollment denial. ***We believe that a ten-year reapplication bar is an extraordinarily severe consequence.*** Under the current framework, this sanction is associated with false or misleading information submitted to obtain Medicare enrollment. CMS is proposing to make it available following virtually any enrollment denial.

This proposal fails to distinguish intentional fraud from inadvertent administrative errors. For instance, a legitimate supplier could potentially face a decade-long exclusion from Medicare for conduct that does not demonstrate fraud, patient harm, or an inability to furnish high-quality DMEPOS. Additionally, the consequences for beneficiaries could be substantial. If a supplier serving a particular community is unable to participate in Medicare for years, beneficiaries may have fewer choices, longer wait times, and greater difficulty obtaining specialized assistive devices and technologies. For these reasons, the ITEM Coalition urges CMS to retain the current

limitation of the reapplication bar to serious misconduct involving false or misleading information. If CMS nevertheless expands the authority, it should establish objective criteria, proportionality requirements, and meaningful procedural protections before a lengthy reapplication bar may be imposed.

g. Extension of Revocation

Under current regulations, when CMS revokes a supplier's Medicare enrollment under one of the grounds specified in 42 C.F.R. § 424.535(a), the Agency may also revoke any or all of the supplier's other Medicare enrollments. CMS proposes to expand this authority to permit revocation of a supplier's other enrollments following a denial of enrollment under any of the grounds specified in 42 C.F.R. § 424.530(a), rather than limiting this authority to circumstances involving an enrollment revocation.

The ITEM Coalition cautions CMS against finalizing this proposal. An enrollment denial may be based on facts or circumstances specific to a particular enrollment or location and may have no relevance to the supplier's other Medicare enrollments. ***Extending the consequences of a single enrollment denial to otherwise compliant enrolled suppliers could result in disproportionate sanctions and unnecessary disruptions in beneficiary access to DMEPOS.***

If CMS proceeds with this proposal, it should establish clear and objective standards governing when it would exercise this discretionary authority, including a requirement that CMS demonstrate a meaningful connection between the basis for the enrollment denial and the supplier's other Medicare enrollments. CMS should also ensure that suppliers receive adequate notice of the basis for any proposed action and have a meaningful opportunity to challenge the decision before other enrollments are revoked.

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

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.
ACCSES
All Wheels Up
Alliance of Wound Care Stakeholders
ALS Association*
American Association for Homecare
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Macular Degeneration Association
American Music Therapy Association

American Occupational Therapy Association (AOTA)
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Blinded Veterans Association
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
Institute for Matching Person and Technology
International Registry of Rehabilitation Technology Suppliers (iNRRTS)
Lakeshore Foundation
Long Island Center for Independent Living, Inc. (LICIL)
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics (NAAOP)
National Association of Rehabilitation Providers and Agencies
National Clinician Task Force
National Disability Rights Network (NDRN)
Paralyzed Veterans of America
RESNA
Rifton Equipment
Spina Bifida Association*
Unite 2 Fight Paralysis
United Cerebral Palsy
United Spinal Association*
The Viscardi Center

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