Congress of the United States

Washington, DC 20515

October 24, 2025

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20510

Dear Administrator Oz:

As Co-Chairs of the House and Senate Diabetes Caucuses, we write to express our concerns about the Centers for Medicare & Medicaid Services' (CMS) proposals regarding the Medicare Competitive Bidding Program included in the Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) proposed rule. Specifically, we are concerned that the agency's proposals will reduce and complicate patient access to continuous glucose monitors (CGMs) and durable insulin pumps.

As you know, diabetes is one of the most common and costliest chronic diseases among Americans.[1] Despite the prevalence and costly nature of this disease, many Medicare beneficiaries have difficulty accessing effective tools to manage their diabetes, such as CGMs and insulin pumps, both of which are part of the American Diabetes Association's and the American Association of Clinical Endocrinology's standards of care for individuals with diabetes.[2] These tools are also cost-effective, as research has shown that their use has yielded billions of dollars of savings to federal health care programs, namely due to reduced hospitalization and utilization of emergency department visits.[3] Federal policies should support access to these technologies.

In the CY 2026 HH PPS proposed rule, CMS proposes a new and untested payment model for CGMs and durable insulin pumps while also proposing to include these devices in the competitive bidding program. We are concerned that by shifting responsibilities for maintenance, education and training from CGM and insulin pump manufacturers to suppliers, CMS' proposal

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[1] National Diabetes Statistics Report, Centers for Disease Control and Prevention (May 15, 2024), https://www.cdc.gov/diabetes/php/data-research/index html;
Estimated federal cost savings from the Special Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/wp-content/uploads/2025/07/White-Paper_Estimated-federal-cost-savings-from-the-Special-Diabetes-Program.pdf.

[2] *Standards of Care in Diabetes – 2025*, 48 Diabetes Care S1 (2025), https://diabetesjournals.org/care/issue/48/Supplement_1; George Grunberger, et. al., *American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus*, 27 Endocrine Practice 505 (2021), https://www.endocrinepractice.org/action/showPdf?pii=S1530-891X%2821%2900165-8; Lawrence Blonde, et. al., *American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update*, 28 Endocrine Practice P923 (2022), https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.

[3] Estimated federal cost savings from the Special Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/wp-content/uploads/2025/07/White-Paper_Estimated-federal-cost-savings-from-the-Special-Diabetes-Program.pdf.

would both decrease patient access and choice to this critical technology and hinder technological innovation.

Under the proposed rule, just a few suppliers nationwide would be responsible for furnishing durable insulin pumps and CGMs to beneficiaries, in addition to the maintenance, software updates, and recalls of these technologies, creating a new and unnecessary layer of bureaucracy. This is in contrast to the current system in which medical providers prescribe insulin pumps and CGMs and manufacturers are directly responsible for support. We also are concerned that these proposed policies will have the unintended consequence of reducing choices for CGM or durable insulin pump beneficiaries. Suppliers would not be required to carry all types and combinations of CGMs and durable insulin pumps under this proposal, which would push beneficiaries closer to a one size fits all model that would not meet their needs. Indeed, these technologies are not universally interchangeable, and each beneficiary uses a specific device based on their clinical needs and physiology after consulting with their medical provider. Previous rounds of competitive bidding have been associated with a decline in technological innovation, including a 25% reduction in new product entries and a 75% decrease in medical device patenting, which raises serious concerns for the diabetes community where ongoing device advancements are essential to patient care.[4]

On top of these concerns, the new tasks suppliers will have to undertake as winning bidders under competitive bidding would further disrupt beneficiary access. As you know, suppliers are generally not legally authorized under Food & Drug Administration regulations to perform tasks such as software updates, or address device malfunctions, recall management and insulin pump refurbishment. Imposing substantial new requirements on suppliers is especially concerning given the importance and technical nature of maintaining and educating beneficiaries on appropriately using devices as sophisticated as CGMs and insulin pumps.

Given these concerns, we urge CMS to not finalize these proposals. As we have stated in past communications to the agency, we believe it is more appropriate for CMS to reform coverage policies for these technologies in alignment with the latest clinical evidence and support streamlined access. We note that there is currently a National Coverage Determination reconsideration request to align Medicare insulin pump coverage with current standards of care and evidence pending at CMS, and we encourage the agency to act expeditiously on that request. Additionally, while we support the overarching goal of the agency's proposal to allow beneficiaries to switch to newer technologies more often than every five years, we believe there are other mechanisms for CMS to effectuate the same goal and stand ready to work with the agency to improve access to insulin pumps and CGMs.

We acknowledge and share CMS's concerns and goals to address fraud and the bad actors who take advantage of the Medicare program. However, we ask the agency to ensure that whatever approach it takes appropriately balances and protects beneficiary access to these life-sustaining technologies.

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[4] i, Y., & Rogers, P. (2024). *The long-run impacts of regulated price cuts: Evidence from Medicare* (NBER Working Paper No. 33083). National Bureau of Economic Research. https://doi.org/10.3386/w33083

Thank you for your attention to this matter and we look forward to working with you to achieve our shared goal of ensuring that all Medicare beneficiaries have access to appropriate high quality diabetes care.

Sincerely,

Jeanne Shaheen
United States Senator

Susan M. Collins
United States Senator

Diana DeGette
Member of Congress

Gus M. Bilirakis
Member of Congress

April 1, 2025

The Honorable Mariannette Miller-Meeks (R-IA)
U.S. House of Representatives
504 Cannon House Office Building
Washington, DC 20515

The Honorable Paul Tonko (D-NY)
U.S. House of Representatives
2269 Rayburn House Office Building
Washington, DC 20515

The Honorable Randy Feenstra (R-IA)
U.S. House of Representatives
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Jimmy Panetta (D-CA)
U.S. House of Representatives
200 Cannon House Office Building
Washington, DC 20515

Re: ITEM Coalition Support for H.R. 2005, the DMEPOS Relief Act of 2025

Dear Representatives Miller-Meeks, Tonko, Feenstra, and Panetta:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition write to express our support for H.R. 2005, the *DMEPOS Relief Act of 2025*, which would provide critically-needed funding relief to many home medical equipment ("HME") providers across the country and ensure continued access to these essential medical supplies for seniors and individuals with disabilities. Specifically, the bill would re-establish the 75/25 blended Medicare reimbursement rate for DMEPOS in non-rural/non-Competitive Bidding Areas through the end of 2025. By addressing outdated Medicare reimbursement rates, this bipartisan bill would help preserve access to assistive devices and technologies for millions of Medicare beneficiaries across the country with disabilities and chronic conditions. The ITEM Coalition typically does not address reimbursement issues and tends to focus on coverage and coding of assistive devices and technologies. However, when reimbursement policies materially impact patient access to care, we feel it is important to weigh-in with our members' concerns.

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.

ITEM Coalition members have had long-standing concerns that the DMEPOS competitive bidding program limits access, choice, and quality of care. In 2018, CMS paused the CBP because of design flaws that caused unsustainable payment rates resulting in access issues for Medicare beneficiaries who need DMEPOS services. CMS used the 2-year pause to redesign the program. Unfortunately, CMS maintained the previously flawed payment rates that were established in 2016 during the pause, which were 50-60% lower than the unadjusted Medicare

fee schedule rates. Congress and CMS have intervened numerous times through the years to provide additional relief, most recently providing a 75/25 blended rate for non-bid, non-rural areas through 2023 (75% Competitive Bid rate/25% unadjusted Medicare fee schedule rates). This 75/25 blended rate was a much-needed lifeline for DMEPOS suppliers and providers and afforded beneficiaries continued access to the level of care and services that they needed.

The 75/25 blended rate expired last year on January 1, 2024, and this expiration led to a 20% fee reduction across the top 25 DME HCPCS codes, creating major barriers for Medicare beneficiaries with disabilities and chronic conditions to manage their medical and functional needs at home. The *DMEPOS Relief Act of 2025*, if enacted into law, would ensure continued beneficiary access to DMEPOS services and devices, provide a much-needed measure of relief and stability for non-rural, non-CBA suppliers, and also have positive impacts on reimbursement levels from other payers who pattern their reimbursement levels off the Medicare fee schedule.

The reason the competitively bid rates are not presently adequate to support access and quality of DMEPOS care to Medicare beneficiaries is because the competitive bidding program is no longer in effect. This means that any supplier or provider who participates in Medicare can provide the DMEPOS benefit. Contracts with a limited number of suppliers in a particular competitive bidding area are no longer necessary, resulting in far less volume of patients being directed to certain suppliers, who, when the competitive bidding program was in effect, were able to discount their prices in exchange for greater volume. Without the increased volume, many suppliers are not able to remain viable at the decreased competitively bid rates. H.R. 2005 would help ameliorate this situation and increase access to patient care.

H.R. 2005 is squarely in line with the goals of the ITEM Coalition to ensure that all people can access the specialized devices and services they need to ensure their health and independent function. For these reasons, we are proud to support this critically important legislation and look forward to working with your office to ensure its enactment into law in order to preserve and protect access to affordable, timely, and quality home medical equipment for Medicare beneficiaries.

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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
All Wheels Up
American Association for Homecare

American Association on Health and Disability
American Cochlear Implant Alliance
American Macular Degeneration Foundation
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Blinded Veterans Association
Center on Aging and DIS-Ability Policy
Clinician Task Force
3DA
Institute for Matching Person and Technology
International Registry of Rehabilitation Technology Suppliers
Lakeshore Foundation
Long Island Center for Independent Living, Inc. (LICIL)
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
NCART
Perkins School for the Blind
Rifton Equipment
RESNA
Spina Bifida Association*
Team Gleason*
United Cerebral Palsy

ITEM Coalition Steering Committee Member

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***

Congress of the United States

Washington, DC 20515

October 24, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave, SW
Washington, DC 20201

Dear Administrator Oz,

As Members of Congress committed to advancing President Trump's America First agenda, we write to express serious concern that the Centers for Medicare and Medicaid Services' proposed rule (CMS-1828-P) to expand and redesign the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program may conflict with the President's directives on deregulation, trade, and domestic industrial strength. We respectfully urge CMS to pause and re-evaluate these provisions to ensure that they fully align with the Administration's goal of rebuilding American manufacturing, protecting Main Street businesses, and fostering innovation.

The President has directed all federal agencies to strengthen American workers and industries and remove unnecessary regulatory burdens that restricts competition. While we share CMS's goal of improving efficiency and protecting taxpayers, the proposed rule—by reviving methodologies deliberately replaced by the first Trump Administration—appears to move in the opposite direction. Pegging reimbursement to the cheapest bids and expanding competitive bidding into highly specialized product categories—including urological, tracheostomy, and ostomy supplies—would give an advantage to cheap foreign-made goods compared to the quality and professional delivery offered by U.S. suppliers and manufacturers in the midst of a manufacturing renaissance. The April 2025 America First Trade Report identifies medical supplies, including DMEPOS, as priority sectors for federal procurement. Weakening these sectors risks undermining the Administration's broader effort to restore industrial strength and supply-chain security.

Past rounds of competitive bidding demonstrated these risks. Previous rounds of competitive bidding led to a forty-nine percent drop in new U.S. market entrants and a ninety percent decline in domestic manufacturer participation. New FDA product submissions fell by a quarter, patent filings by three-quarters, and U.S. research and development investment by more than half, while repair and replacement rates for equipment more than doubled. Extending the program to technologies such as continuous glucose monitors and insulin pumps—fields with only a handful of U.S. manufacturers—would further discourage investment and threaten America's leadership in advanced medical devices. Even strong tariff protections could not offset the disadvantage created by a reimbursement model that rewards the cheapest bid and favors foreign over quality domestic manufacturers.

Small businesses would be particularly harmed as participation consolidates among a few large suppliers, displacing community-based providers that employ local workers and serve seniors and veterans directly. The rule also lacks important small business protections which were included during the first Trump Administration that ensured Main Street would not be harmed in a nationwide bid program. These businesses and skilled workers, once lost, seldom return.

We fully support strong, targeted action to combat fraud, waste, and abuse, but competitive bidding is not a proven anti-fraud tool. CMS can achieve far better results through the use of artificial-intelligence analytics to identify abnormal billing and utilization patterns, expansion of prior authorization for high-risk items, mandatory electronic prescribing, and stricter supplier quality standards. These modern, data-driven measures protect the Medicare program while preserving the healthy competition and local capacity that the President's deregulatory policy is meant to encourage.

For these reasons, we urge CMS to withdraw the proposed expansion and reassess it in light of the President's directives. The guardrails established under the first Trump Administration—including use of the unadjusted 2015 fee schedules as the bid ceiling and payment at the clearing price—helped stabilize the market, maintain supplier viability, and protect

patient access; they should remain in place. CMS should instead consider directing the Center for Medicare and Medicaid Innovation to test an America First demonstration that rewards U.S.-made and allied-sourced products, incorporates modern fraud-prevention technologies, and evaluates outcomes before any nationwide expansion.

We share CMS's commitment to fiscal responsibility and program integrity and would welcome the opportunity to meet with you and discuss reforms that advance Medicare's goals while fully embodying the President's America First, Deregulatory, and Make America Healthy Again principles.

Sincerely,

Dan Meuser
Member of Congress

Mariannette J. Miller-Meeks, M.D.
Member of Congress

Nicholas A. Langworthy
Member of Congress

Claudia Tenney
Member of Congress

Nick LaLota
Member of Congress

Rob Bresnahan, Jr.
Member of Congress

Russ Fulcher
Member of Congress

August Pfluger
Member of Congress

Dan Crenshaw
Member of Congress

Tracey Mann
Member of Congress

Julie Fedorchak
Member of Congress

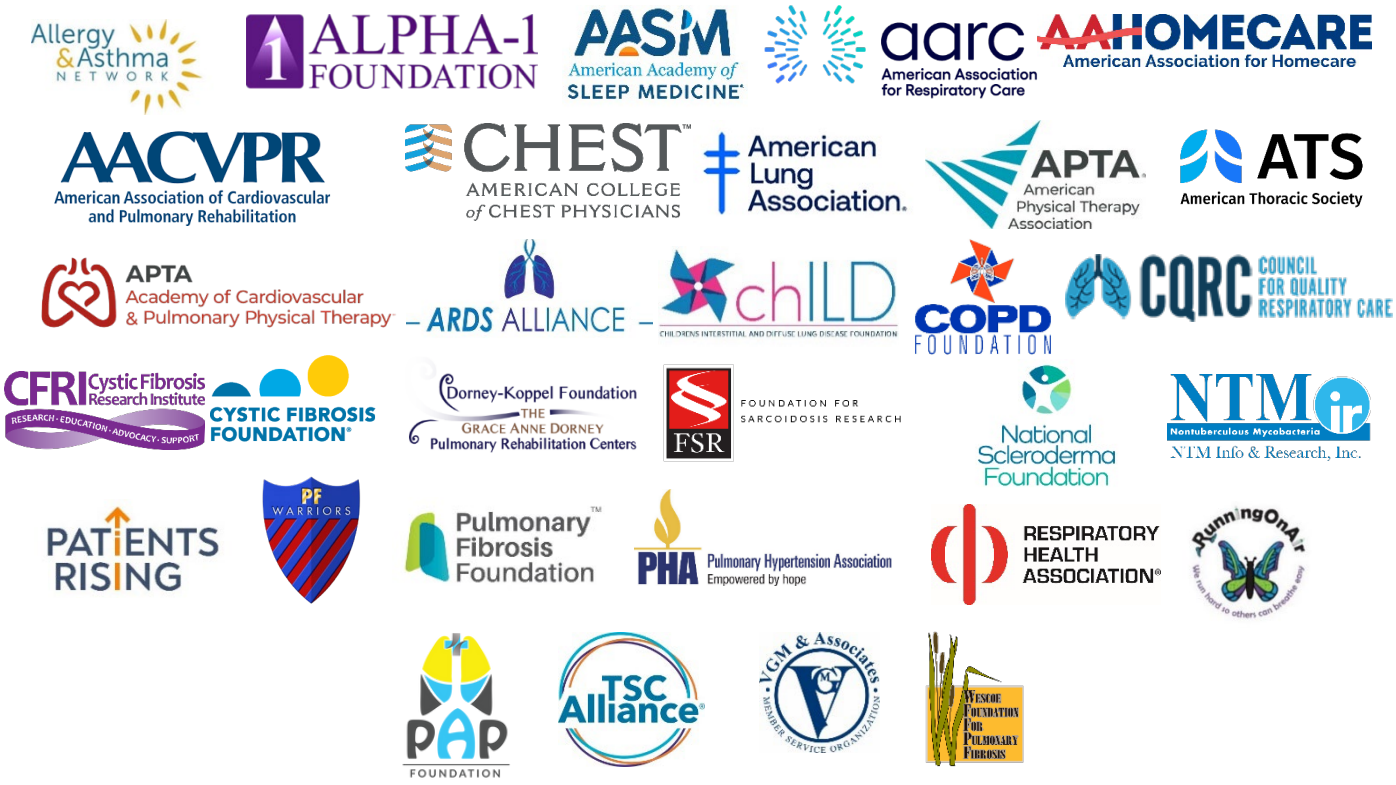
David G. Valadao
Member of Congress

Mike Rogers
Member of Congress

Mike Kelly
Member of Congress

Jefferson Van Drew
Member of Congress

Pat Fallon
Member of Congress



April 15, 2025

Dear Senator/Representative:

We are writing as a group of more than 30 patient, healthcare professional, and industry organizations to request that you cosponsor bipartisan legislation S.1406/H.R. 2902, the Supplemental Oxygen Access Reform (SOAR) Act, sponsored by Senator Bill Cassidy (R-LA), Senator Mark Warner (D-VA), Senator Amy Klobuchar (D-MN), Representative David Valadao (R-CA), Representative Julia Brownley (D-CA) and Representative Adrian Smith (R-NE).

More than 1.5 million people living with chronic lung and heart diseases in the U.S. face significant challenges in accessing supplemental oxygen. The SOAR Act is critical to ensuring these individuals can access the oxygen treatment and services they need to live healthy and more full lives.

Since 2011, supplemental oxygen has been part of Medicare's DMEPOS Competitive Bidding Program, resulting in significant decreases in payments for oxygen equipment and supplies. While this has produced Medicare savings, it has also led to unacceptable barriers for patients who need medically necessary oxygen equipment, supplies, and services.

Supplemental oxygen can be delivered in several forms; however, people with the most significant oxygen needs cannot use small, portable oxygen concentrators (POCs) because they do not provide high flow rates. Instead, these individuals must rely on heavy, bulky tanks of compressed, gaseous oxygen that may provide only a few hours of oxygen at a time.

Liquid oxygen, which offers a continuous, high-liter flow of oxygen and is portable, is a viable alternative. However, due to the inadequate reimbursement rates – suppliers have been unable to continue providing liquid oxygen widely, leaving patients with few viable options. Without access to appropriate supplemental oxygen, patients are at higher risk for worsening health, avoidable emergency room visits, hospitalizations and the devastating prospect of being homebound.

The SOAR Act addresses these challenges by making supplemental oxygen patient-centric, moving away from “home” oxygen to “supplemental oxygen”. The bill would remove all oxygen services and equipment from the competitive bidding reimbursement system and create a new reimbursement system for this benefit based on current payment rates so that people can access the appropriate modality of oxygen. Additionally, the SOAR Act would also ensure patients have access to respiratory therapist services through their oxygen supplier. It would also establish national standardized documentation requirements that rely upon a template rather than prescriber medical records to support claims for supplemental oxygen suppliers to ensure predictable and adequate reimbursement and to protect against fraud and abuse.

The SOAR Act prioritizes patient safety and protects the system from fraud, waste and abuse. The safeguards included in the SOAR Act reinforce its focus on accountability while ensuring that patients receive the care they deserve.

By passing the SOAR Act, Congress can help the more than 1.5 million individuals living with COPD, heart disease, pulmonary hypertension, pulmonary fibrosis, people awaiting lung transplants and other advanced chronic respiratory diseases who rely on supplemental oxygen live independently and healthily. This bill also addresses challenges faced by low-income and rural and medically underserved people who currently struggle to secure adequate care.

Supplemental oxygen is a lifeline for so many people - decreasing mortality, reducing shortness of breath, and increasing exercise capacity. No one should struggle to access the oxygen modality that works best for their medical needs and lifestyle, and no one should suffer the pain and fear of struggling to breathe.

We request that you cosponsor the SOAR Act (S.1406/H.R.2902) and urge the legislation be passed in 2025.

Thank you for your attention to this critical issue.

Sincerely,

Allergy & Asthma Network
Alpha-1 Foundation
American Academy of Sleep Medicine
American Association for Homecare
American Association for Respiratory Care
American Association of Cardiovascular and Pulmonary Rehabilitation
American College of Chest Physicians (CHEST)
American Lung Association
American Physical Therapy Association
American Thoracic Society
APTA Academy of Cardiovascular & Pulmonary Physical Therapy
ARDS Alliance
Children's Interstitial and Diffuse Lung Disease (chILD) Foundation
COPD Foundation
Council for Quality Respiratory Care
Cystic Fibrosis Foundation
Cystic Fibrosis Research Institute
Dorney-Koppel Foundation
Foundation for Sarcoidosis Research
National Scleroderma Foundation
NTM Info & Research, Inc.
Patients Rising
PF Warriors
Pulmonary Fibrosis Foundation
Pulmonary Hypertension Association
Respiratory Health Association
Running On Air
The PAP Foundation
TSC Alliance
VGM Government Relations
Wescoe Foundation for Pulmonary Fibrosis