

M E M O R A N D U M

To: ITEM Coalition Members

From: Peter Thomas, ITEM Coalition Coordinator
Michael Barnett, ITEM Coalition Coordinator
Leela Baggett, ITEM Coalition Low Vision Subgroup Coordinator

Date: January 13, 2026

Re: **ITEM Coalition 2025 Year in Review**

EXECUTIVE SUMMARY

We write to provide you with an update on the activities of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition in 2025. As we continue our work in 2026, we want to summarize the efforts made on behalf of the ITEM Coalition and its member organizations over the past twelve months.

The ITEM Coalition's strength as a representative coalition of organizations concerned with access to and coverage of assistive devices, technologies, and related services by Medicare, Medicaid, and other public and private payers for people with disabilities, chronic conditions, injuries, illnesses, and all other consumers is evident through its active and productive portfolio of advocacy efforts. This past year was no exception, as the ITEM Coalition engaged with policymakers and federal agencies to advance its targeted agenda of policy priorities.

This memorandum summarizes the ITEM Coalition's work across a number of key priorities in 2025 that were developed and affirmed in a vote by the ITEM Coalition membership early last year. Further information on the ITEM Coalition's activities, as well as our advocacy archives, can be found on the ITEM Coalition's website at www.itemcoalition.org. We encourage ITEM Coalition members and funders to review this memo and consider any suggestions for continued or new policy priorities in 2026.

We will discuss the work we performed last year and discuss our priorities for this year at the upcoming all-member meeting, scheduled for **Wednesday, January 28th, from 12-2pm ET**. **The Annual Meeting will be held in-person at Powers Law offices (1250 Connecticut Ave., NW, Eighth Floor, Washington, DC 20036) with a hybrid virtual option available via Zoom**. The meeting is open to all ITEM Coalition members, and all ITEM Coalition non-voting funders have been invited as guests. Lunch will be served. If you have any questions about the Annual Meeting, please contact Angelica Nina at Angelica.Nina@PowersLaw.com.

2025 ADVOCACY HIGHLIGHTS

In 2025, the ITEM Coalition engaged with Congress, the Trump Administration, and external stakeholders on a wide variety of key priorities for the Coalition. Significant additional advocacy efforts surrounded each of these initiatives, including outreach to Congressional offices and agency officials, grassroots advocacy, and partnerships with other community stakeholders. These efforts advanced the ITEM Coalition's stated [2025 policy priorities](#) involving increased access to assistive devices, technologies, and related services. Our advocacy efforts are summarized below.

1. Seat Elevation and Standing Systems in Power Wheelchairs

In 2023, the ITEM Coalition secured a major victory when the Centers for Medicare and Medicaid Services (CMS) published a landmark final national coverage determination (NCD) concluding that seat elevation systems in power wheelchairs fall within the benefit category of durable medical equipment (DME) and are, therefore, covered under the Medicare program when reasonable and necessary. In 2020, the ITEM Coalition convened a large team of consumer, provider, and clinical experts to develop and submit a complete and formal [Request for Reconsideration of the NCD for Mobility Assistive Equipment \(MAE\)](#) requesting the following:

- 1) A Benefit Category Determination (BCD) that both power seat elevation and power standing systems are “primarily medical in nature” and thus qualify under the Medicare DME benefit category; and
- 2) Affirmative coverage of these systems when reasonable and necessary for beneficiaries with a medical or functional need to perform or assist in participating in mobility-related activities of daily living (MRADLs), the standard for coverage of DME in the home.

The request was deemed “complete” by CMS in November 2020, but the agency delayed opening the request for public comment. After two years of extensive ITEM Coalition advocacy, CMS opened on August 15, 2022, a National Coverage Analysis (NCA) for Power Seat Elevation Systems but did not open the related review of the medical evidence supporting coverage of power standing systems. Although the ITEM Coalition was seriously disappointed both with the decision to split the review of the two systems and the lack of a timeline for opening the standing systems NCA, the ITEM Coalition began a comprehensive campaign to demonstrate public support for coverage of power seat elevation, holding advocacy on standing systems to another day.

On May 16, 2023, CMS published a final NCD governing power seat elevation. Under the final NCD, Medicare covers seat elevation in Groups 2, 3 and 5 Complex Rehabilitative Technology (CRT) power wheelchairs when a patient needs seat elevation to transfer from one surface to another—with or without caregiver assistance, assistive devices, or lift equipment—or to improve one’s reach in order to perform MRADLs. In addition, under the final NCD, Medicare covers seat elevation systems in non-CRT power wheelchairs when determined by Medicare

contractors to be reasonable and necessary. The final NCD was considerably improved from the preliminary decision, but after extensive public input cited by CMS, the agency settled on a very comprehensive coverage policy for seat elevation, a huge win for the coalition's multiple stakeholder organizations.

Since that decision and throughout 2025, the ITEM Coalition has continued to urge CMS to proceed expeditiously with the opening of a separate NCA for power standing systems to ensure that Medicare beneficiaries can access these necessary systems. In June, the ITEM Coalition submitted a formal [letter](#) requesting a meeting with CMS Administrator, Mehmet Oz, to discuss the status of the long-pending NCA for standing systems in Group 3 power wheelchairs. We urged CMS in our letter to proceed expeditiously with opening this NCA for public comment without further delay, suggesting that the agency should do so to coincide with the 35th Anniversary of the Americans with Disabilities Act ("ADA"), which fell on July 26th. The letter was supported by 36 ITEM Coalition member organizations. Unfortunately, July 26th came and went without action on the standing systems NCD.

Further, in July the ITEM Coalition submitted a [comment letter](#) focused on standing systems in response to the Department of Health and Human Services' ("HHS") Request for Information on Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again. In our letter, we implored the new HHS Secretary, Robert F. Kennedy, Jr., to work with the new CMS leadership to finally open the pending NCA for power standing systems as soon as possible. The letter was supported by 34 ITEM Coalition member organizations.

In August, the ITEM Coalition held an in-person meeting at the HHS building with CMS Deputy Administrator, Kimberly Brandt, to discuss the status of our pending NCA for standing systems after five years of waiting. Participants in the meeting included two power standing system consumers, two clinicians, representatives from the United Spinal Association and the Christopher & Dana Reeve Foundation, as well as both suppliers and manufacturers of the power standing function. Overall, the meeting with Kim Brandt went very well and we were informed that the reason for the significant delay in opening the ITEM Coalition's NCA was simply due to lack of bandwidth and technical staff at CMS to take this on at the time. Kim suggested that we meet with CMS' Chief Medical Officer, Dora Hughes, and her staff as a next step, which has been requested and working to be scheduled in January. She also confirmed that she had hiring authority and was planning on increasing technical staff at the Coverage and Analysis Group within the Center for Clinical Standards and Quality at CMS.

In 2026, the ITEM Coalition will continue to advocate strongly for timely action on standing systems and engage with CMS and Congress to ensure that this priority moves forward in 2026.

2. Coverage Expansion for Anti-Obesity Medications

In late November 2024, the CMS issued a proposed rule to expand coverage for anti-obesity medications ("AOMs") under both the Medicare Part D and Medicaid programs. Once the proposed rule was released, an ITEM Coalition member, the National Association for the Advancement of Orthotics and Prosthetics (NAAOP www.naaop.org) approached the ITEM

Coalition to seek support for its efforts to educate the disability community on the impact of this proposal and support it as a method of reducing chronic illness and limb loss among individuals with mobility impairments.

The ITEM Coalition quickly recognized the impact that AOMs can have in helping people with disabilities maintain a healthy weight and, consequently, reduce the likelihood and severity of chronic conditions. In January 2025, the ITEM Coalition, through NAAOP, embarked on a major campaign to educate other stakeholder organizations on the value of expanded AOM coverage for the disability community. Separate funding was secured for this initiative.

The ITEM Coalition submitted [comments](#) in response to the proposed rule ahead of the January 27, 2025, comment deadline, and worked with other stakeholder groups to offer education on the link between disability and obesity. These efforts resulted in numerous letters from other individual organizations, including NAAOP and the Amputee Coalition, being submitted in response to the proposed rule. ITEM Coalition submitted its own letter of support, attracting 33 members to sign-on. Unfortunately, the Trump Administration “froze” the proposed rule upon taking control of the White House, delaying issuance of the final rule.

In late March 2025, prior to the eventual release of the final rule, the ITEM Coalition met with the White House Office of Information and Regulatory Affairs (“OIRA”), which is an office within the Office of Management and Budget (“OMB”), to discuss the intersection between disability and obesity and the significant and positive impact that expanded AOM coverage would have on the disability community. While the meeting with OIRA was positive overall, in early April 2025, the Trump Administration ultimately declined to finalize the proposed AOM coverage expansion stating that the issue may be revisited in future rulemaking. The ITEM Coalition issued a [press release](#) expressing our tempered disappointment with the Trump Administration’s decision on April 9th.

In late May 2025, NAAOP sponsored an educational [webinar](#) entitled, “*The Intersection Between Disability and Obesity*.” The webinar explored the complex relationship between disability and obesity, including the clinical, social, and policy considerations around expanded coverage of AOMs under the Medicare and Medicaid programs and the potential impact AOMs can have on reducing chronic illness and, in particular, limb loss, especially in the mobility-impaired community.

Soon after the coverage decision was announced, the ITEM Coalition sent a disability community sign-on letter with nearly 50 national organizations in support, to the new CMS Administrator, Dr. Mehmet Oz, expressing disappointment with the decision and requesting a meeting with CMS to discuss the disability community perspective on this issue. Due to scheduling conflicts, the meeting request was delegated to Alec Aramanda, Principal Deputy Director of the Center for Medicare. The meeting was ultimately held on June 24th.

During the June 24th meeting with CMS, Alec Aramanda suggested that the ITEM Coalition develop a proposal for CMS to consider that was smaller in scale compared to the full Medicare and Medicaid coverage expansion that the Biden Administration proposed in

November 2024. The ITEM Coalition, at the request of NAAOP, then drafted a more targeted proposal that included expanded coverage of AOMs under the Medicare and Medicaid programs for individuals with a Body Mass Index (“BMI”) of 30 or greater and who are at high risk of lower limb loss, have lost a lower limb, or primarily use wheeled mobility to perform Mobility Related Activities of Daily Living (“MRADLs”). The proposal also included clinical research demonstrating the increased risk of developing obesity for both lower limb amputees and individuals with mobility disabilities, as well as the associated benefits that would come from expanded coverage for both patient populations and the Medicare and Medicaid programs. This proposal was submitted to CMS in August 2025.

In October, the ITEM Coalition, circulated a [sign-on letter](#) of support to Congressional leadership and the leadership on the Congressional Committees of jurisdiction to reiterate the disability community’s continued support for expanded access to AOMs under the Medicare program. The letter was also submitted to the offices of each individual Member of the House of Representatives who sits on the House Energy & Commerce and Ways and Means Committees, as well as to the offices of each Senator sitting on the Senate Finance Committee. These committees have jurisdiction over the Medicare program.

In November 2025, the ITEM Coalition was pleased when the Trump Administration, in a stunning reversal of opinion, announced its landmark decision to expand access to AOMs under the Medicare and Medicaid programs by granting coverage through a specific coverage model and also significantly reducing the out-of-pocket cost for consumers purchasing these medications. This announcement was warmly welcomed by the disability community and was received as a tremendous victory for patient access to these potentially life-changing medications. ITEM released a [Press Release](#) on November 6th, hailing the decision as a major win for the disability community. While final details of the policy’s implementation are forthcoming, this coverage expansion decision represents a major step forward in the fight against obesity, chronic illness in the disability population, and unnecessary limb loss.

3. Complex Rehabilitation Technology (“CRT”) and Wheeled Mobility

Wheelchair Repairs and Maintenance Policies Position Statement

Timely and consistent access to wheelchair repairs and maintenance has created unnecessary barriers for people with disabilities who rely on wheelchairs to be mobile, functional, employed, live independently, and participate in their communities. To address these barriers, the ITEM Coalition finalized a set of [Proposed Solutions](#) to improved repairs and maintenance of complex manual and power wheelchairs in January 2025. The proposed solutions are designed to address the problems that individuals with mobility disabilities experience in obtaining timely repairs and maintenance of complex manual and power wheelchairs (commonly referred to as “complex rehabilitative technology” or “CRT”). 41 ITEM Coalition member organizations signed-on in support of the proposed solutions. We also circulated a [Press Release](#) in February to coincide with the release of the ITEM Coalition’s proposed solutions. The ITEM Coalition then worked throughout 2025 on legislative language at the federal level with key Congressional champions.

DOT Final Rule on Airline Accessibility for Wheelchair Users

In 2024, the ITEM Coalition [responded](#) to the Department of Transportation’s (“DOT’s”) proposed rule on airline accessibility for air travelers who use wheelchairs. Ensuring that transportation, including air travel, is safe and accessible for individuals with disabilities continues to be a priority for the ITEM Coalition and our comments thanked the DOT for their continued and dedicated work in this space.

In December 2024, the DOT issued a final rule finalizing a majority of the provisions as proposed; however, in 2025, the Trump Administration delayed implementation of the final rule early in the year, and that delay has been extended multiple times—the latest being to March 9, 2026. The ITEM Coalition expects this issue to ultimately be addressed in 2026 and we will increase our advocacy on an as-needed basis.

Mobility Means Freedom Tax Credit Act

In April 2025, the ITEM Coalition submitted a [letter](#) of support for H.R. 2320, the Mobility Means Freedom Tax Credit Act of 2025. This bill, sponsored by Rep. Steve Cohen (D-TN), would provide individuals with a 50% tax credit for the purchase of manual or powered wheelchairs, scooters, walkers, gait trainers, crutches, canes, artificial legs or arms, leg, arm, back or neck braces, and includes any features of or enhancements to such devices. While H.R. 2320 was ultimately not addressed in the first session of the 119th Congress, we expect additional action on this bill in 2026.

4. Low Vision Aids and Devices

The ITEM Coalition has also maintained our dedicated efforts within the ITEM Coalition’s Low Vision Subgroup to advance Medicare coverage of low vision aids. Current CMS policy holds that all devices that use one or more lens to aid vision or provide magnification of images for impaired vision are excluded from coverage due to language in the Medicare statute prohibiting coverage of eyeglasses. In 2025, the Low Vision Subgroup focused on both Congressional and Administration advocacy to address the “Low Vision Aid Exclusion.”

In 2026, the ITEM Coalition Low Vision Subgroup will continue to advocate before the Trump Administration and Congress to advance Medicare coverage of devices for individuals with vision impairments.

5. Accessible Websites and Software Applications

In June 2025, the ITEM Coalition submitted a [letter](#) to U.S. Representative Pete Sessions (R-TX) in support of H.R. 3417, the *Websites and Software Applications Accessibility Act of 2025*, which would require that websites and applications used by covered entities (employment entities, public entities, public accommodation, or testing entities) to communicate or interact with applicants, employees, participants, customers, or other members of the public be readily accessible to and useable by individuals with disabilities.

6. DMEPOS Coverage and Access Initiatives

Return of the DMEPOS Competitive Bidding Program

In July, CMS issued the CY 2026 Home Health and DMEPOS Competitive Bidding Program (“CBP”) proposed rule. In this rule, CMS announced the return of the DMEPOS CBP, which had been on a hiatus since January 1, 2024. CMS also proposed to expand the list of items covered under the CBP in a future round to include ostomy, tracheostomy, and urological supplies, as well as moving forward with another round of competitive bidding for off-the-shelf (“OTS”) orthoses. From June through August, the ITEM Coalition and a wide variety of stakeholders worked extensively to educate Congress and the Administration on the impact of this problematic proposal and to build opposition to demonstrate to CMS the dangers associated with competitive bidding these extremely personal and intimate items.

In August, the ITEM Coalition hosted a webinar with over 200 registered attendees who participated on the dangers of competitive bidding. In late August, ITEM submitted a [comment letter](#) in response to the proposed expansion of the CBP to include ostomy, tracheostomy, and urological supplies. ITEM also submitted separate, broader [comments](#) opposing the inclusion of OTS orthotics in a future round of competitive bidding and addressing other provisions in the proposed rule, including changes to the accreditation process and prior authorization. The ITEM Coalition also worked to build support for a patient-disability community sign-on letter to the Office of Management and Budget (“OMB”) and two separate Congressional sign-on letters expressing opposition to the proposed expansion of the CBP during this same period.

In September, the ITEM Coalition participated in an in-person meeting with OMB staff at the White House to express our concerns and to impress on the Administration the negative impact on patient access, choice, and quality that the proposed expansion would have on the disability community, if finalized. That same month, the ITEM Coalition also held a meeting with CMS Deputy Administrator for the Center for Medicare, Alec Aramanda, to discuss the issue. Throughout October and November, the ITEM Coalition continued to educate and build opposition to the proposed CBP expansion and worked to reiterate the disability community’s concerns with the Congress, CMS, and the Trump Administration.

In late November, CMS finalized the DMEPOS competitive bidding proposals, essentially as proposed, seemingly ignoring over 18,000 stakeholder comments that were submitted in opposition to the proposed rule. The ITEM Coalition issued a [press statement](#) in December expressing our deep disappointment with a final rule that exposes Medicare patients to the lowest bidder for ostomy and urological supplies, as well as certain orthotic braces, under the Medicare program. To make matters worse, CMS accelerated the timeline and some of the changes go into effect as early as 2026.

The ITEM Coalition anticipates a significant amount of work in this area in 2026 as we continue our efforts to encourage the Congress and the Administration to mitigate the impact of this finalized policy. Legislation is expected to be introduced to exclude these items from the

program, appropriations efforts have been initiated to further delay implementation, and a significant amount of additional advocacy will be needed to encourage the Administration to either withdraw the policy or delay it for additional analysis to be done on the related impact.

Ensuring Continued DME Access

In April, the ITEM Coalition submitted a [letter](#) to U.S. Representatives Mariannette Miller-Meeks (R-IA), Paul Tonko (D-NY), Randy Feenstra (R-IA), and Jimmy Panetta (D-CA) expressing our support for H.R. 2005, the *DMEPOS Relief Act of 2025*. This important bill 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.

In May, the ITEM Coalition submitted a [letter](#) to Congressional leadership underscoring the critical need to protect Medicaid beneficiaries’ access to DMEPOS as Congress considered significant Medicaid budget cuts in the One Big Beautiful Bill Act (“OBBA”) that was being negotiated during that time. The letter urged Congressional leadership to recognize that any reductions in Medicaid reimbursement or coverage for DMEPOS would result in serious—and entirely avoidable—consequences. Such cuts would not only undermine the health and dignity of Medicaid beneficiaries but also contradict the program’s goals of promoting access to quality, cost-effective healthcare services.

In October, the ITEM Coalition submitted a [comment letter](#) to the DME Medicare Administrative Contractor (“DME MAC”) Medical Directors in strong support of a proposed Local Coverage Determination (“LCD”) for urological supplies. The LCD proposed to expand Medicare coverage of sterile intermittent catheter kits for individuals with a spinal cord injury (“SCI”) regardless of the level of injury. In November, the DME MACs finalized the proposed LCD essentially as proposed, marking a major win for the SCI and disability communities. In a related victory, the ITEM Coalition engaged in and supported an initiative to establish separate billing codes for hydrophilic catheters, which reduce the incidence of urinary tract infections. After decades of advocacy efforts by urological stakeholders, CMS finally established three new billing codes to reflect the benefits of these catheters. The new codes went into effect on January 1, 2026.

Tariff Treatment for DME

In October, the ITEM Coalition submitted [comments](#) to the U.S. Department of Commerce in response to its Section 232 national security investigation into medical equipment and devices. Our comments strongly urged the Commerce Department not to impose sudden or significant tariffs, quotas, or other trade restrictions on these important medical products and devices which are vital to the health, rehabilitation, and independence of millions of Americans with

disabilities, illnesses, and injuries. We stressed that such measures would undermine patient access to essential medical technologies, disrupt the stability of supply chains, and impose severe cost burdens on manufacturers and suppliers, having the effect of compromising their ability to maintain high quality manufacturing facilities in the United States.

7. Orthotics & Prosthetics (“O&P) Initiatives

Medicare O&P Patient-Centered Care Act

In 2025, the ITEM Coalition worked to generate support for S.2329/H.R.4475, the [Medicare Orthotic and Prosthetic Patient-Centered Care Act](#), legislation focused on ensuring maximum function and independence for Medicare beneficiaries who use orthotic braces and prosthetic limbs while limiting waste, fraud, and abuse in the O&P benefit. This legislation would accomplish the following:

- Exempt certified and/or licensed orthotists and prosthetists from the requirement to have a competitive bidding contract in order to provide off-the-shelf (OTS) orthoses to their patients, but to receive reimbursement at the competitive bidding rates applicable to that geographic area.
- Prohibit the practice of “drop shipping” all prosthetic limbs and custom-fabricated or custom-fitted orthoses to patients homes without providing clinical care.
- Promote timely access to replacements of custom-fitted and custom-fabricated orthoses irrespective of the reasonable useful lifetime of the device as long as the ordering physician determines that there has been a change in the patient’s condition and another device is medically necessary.

While the legislation was not included in a year-end package before the end of the first session of the 119th Congress, we expect continued activity in the realm of O&P in 2026.

Exoskeletal and Other Mobility Assistive Technologies

In December 2025, Representatives Mike Bost, Jack Bergman, Joe Neguse, and Josh Gottheimer reintroduced H.R. 6835, the *Veterans Supporting Trauma Access to New Devices (“STAND”) Act*. This bill, which the ITEM Coalition supported in the 118th Congress, would direct the Secretary of Veterans Affairs to offer annual preventative health evaluations to veterans with spinal cord injuries or disorders and increase access to state-of-the-art assistive mobility technologies, such as Exoskeletal systems and other neuromodulation technologies, which allow paralyzed veterans the ability to improve function and walk again.

The ITEM Coalition plans to submit a letter of support for this important bill in January 2026 and work with the Senate to have a Senate companion bill introduced early in the second session of the 119th Congress.

Veterans SPORT Act

In March 2025, the ITEM Coalition submitted a [letter](#) to Rep. Mariannette Miller-Meeks, Chairwoman of the House Veterans' Affairs Health Subcommittee, in support of H.R. 1971, the *Veterans Supporting Prosthetics Opportunities and Recreational Therapy ("SPORT" Act*, which would provide more consistent coverage under the Department of Veterans Affairs ("VA") benefit for activity-specific prosthetic limbs that veterans with limb loss use to participate in physical activities in order to remain fit and healthy. Specifically, this bill would recognize prosthetic devices for sports and recreational use as medically necessary under the VA benefit. We will work with Rep. Miller-Meeks and Congress to ensure action on this bill in the second session of the 119th Congress.

8. Additional Medicare Issues

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

In February 2025, the ITEM Coalition submitted a [nomination letter](#) for Mary Ann Clark, MHA, to be appointed to the Medicare Evidence Development & Coverage Advisory Committee ("MEDCAC") as an industry representative. Our letter noted our strong belief that Ms. Clark's research and analytical skills combined with her passion for demonstrating improvement in patient outcomes by the highest quality of evidence possible made her a particularly strong candidate for the Committee's consideration. Unfortunately, Ms. Clark was not appointed to the Committee in 2025.

Continued Funding for the National Limb Loss and Paralysis Resource Centers

In July, the ITEM Coalition submitted a [letter](#) to Congressional leadership expressing our strong support for the continued funding of the National Limb Loss Resource Center ("NLLRC") and the Paralysis Resource Center ("PRC"), programs administered by the Administration for Community Living ("ACL"). These centers, which were proposed to be eliminated under the President's FY 2026 budget request, fulfill critical needs by providing free, comprehensive information, peer support, and navigational assistance that empower Americans living with limb loss, limb difference, or paralysis to live independently and fully participate in their communities. Our letter urged Congressional leadership to not move forward with the proposal to eliminate funding for these critical programs and to appropriate continued, sustained, and robust funding for both centers.

Transitional Coverage for Emerging Technology

The ITEM Coalition also continues to advocate for the development of an expedited coverage pathway for innovative medical technology. The ITEM Coalition had previously supported the Medicare Coverage of Innovative Technology ("MCIT") rule finalized in the last days of the first Trump Administration, which was then withdrawn by the Biden Administration in late 2021. This rule would have established a new coverage pathway to allow temporary, nationwide coverage for medical devices designated as "breakthrough" by the Food & Drug Administration ("FDA").

In 2024, CMS finalized a new Medicare coverage pathway designed to achieve more timely and predictable access to breakthrough technologies for Medicare beneficiaries. The Transitional Coverage for Emerging Technologies (“TCET”) pathway uses current national coverage determination (“NCD”) and coverage with evidence development (“CED”) processes to expedite Medicare coverage of certain “breakthrough devices,” deemed as such by the FDA. However, there are widespread concerns that this approach will be ineffective in speeding access of breakthrough technologies to Medicare beneficiaries. With President Trump’s return as President, it remains to be seen what will happen to TCET in his second Administration and whether the since-repealed MCIT pathway will be re-visited.

In August 2025, the ITEM Coalition sent a [letter](#) to CMS encouraging the agency to initiate future rulemaking as soon as possible to create and establish a more timely and predictable pathway for Medicare coverage of FDA-designated breakthrough medical technologies. The ITEM Coalition urged CMS to move forward with a more robust and streamlined coverage pathway—similar to the MCIT framework—providing time-limited Medicare coverage for FDA-designated breakthrough technologies upon a determination that they are safe and effective. This type of policy, as proposed in S. 1717, the *Ensuring Patient Access to Critical Breakthrough Products Act of 2025*, currently before the 119th Congress, would ensure Medicare beneficiaries have timely access to cutting-edge, life-enhancing medical devices and technologies. We expect increased activity on this bill in the second session of the 119th Congress.

9. New Coalition Members

The ITEM Coalition added two new members in 2025. Our new member organizations include:

- [**United Ostomy Associations of America**](#)
- [**CurePSP**](#)

These additions bring the total number of active ITEM Coalition members to 102 organizations, a historic achievement for ITEM. We look forward to continuing to expand in 2026 and to furthering our goal of increasing access to assistive technologies and devices for people with disabilities, injuries, illnesses, and chronic conditions. We invite all ITEM Coalition members to join us, in person or virtually, for our 2026 Annual Meeting where we will discuss our 2025 accomplishments and our policy priorities for the coming year.

The 2026 ITEM Coalition Annual Meeting will be held on Wednesday, January 28th, from 12-2pm ET. All current ITEM Coalition members and funders should have received a calendar invite with the dial-in information. If you have any questions regarding the meeting or to RSVP, please contact Angelica.Nina@PowersLaw.com.