National Coalition For Assistive & Rehab Technology

Submitted electronically to www.regulations.gov

August 29, 2025

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Re: Comments on Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies, (CMS-1828-P, 90 Fed. Reg. 299108, July 2, 2025)

Dear Administrator Oz:

The National Coalition for Assistive and Rehab Technology (NCART) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on behalf of our members regarding the DMEPOS provisions outlined in the proposed rule, CMS-1828-P, as listed above.

NCART is a nonprofit national association of suppliers and manufacturers of Complex Rehab Technology products and services. We focus on Complex Rehab Technology (CRT) education and advocacy with the emphasis on establishing and protecting appropriate coding, coverage and payment policies to ensure children and adults with significant disabilities (e.g., Amyotrophic Lateral Sclerosis, Cerebral Palsy, Cerebral Vascular Accident, Multiple Sclerosis, Muscular Dystrophy, Parkinson's Disease, Post-Polio Syndrome, Spina Bifida, a Spinal Cord Injury or Traumatic Brain Injury) and complex medical conditions (e.g., Ehlers-Danlos Syndrome, Guillain-Barre Syndrome, Lupus, Multi-limb Amputations, Myositis, Rheumatoid Arthritis, or Scleroderma) have adequate access to the specialized equipment and related supporting services they require. Our supplier members operate over 800 accredited Medicare/Medicaid supplier locations across the country collectively providing products and critical supporting services to individuals in their local communities.

Issue # 1: CMS' Proposal to Revise the Definition of "Item" Related to Medical Supplies, Clarify the Definition of "Medical Equipment Items", and Include Ostomy, Tracheostomy, and Urological Supplies in the Competitive Bidding Program (CBP).

Ostomy, tracheostomy, and urological suppliers are neither "durable medical equipment" nor are they "supplies used in conjunction with durable medical equipment," they are deemed prosthetic devices as they are personal in use by individuals with disabilities and complex medical conditions for the replacement of non-functioning internal body organs.

Ostomy surgery is a life-saving procedure, undergone by this patient population, which allows bodily waste to pass through a surgically created opening in the abdomen into a prosthetic "pouch." Ostomy supplies are specifically selected to meet the individual's unique stoma, skin, and body type – it is not a commodity type of product that can or should be competitively bid.

A tracheostomy is a surgical procedure that creates an opening in the trachea to provide a direct airway to the lungs to supply oxygen, either from a mechanical ventilator or oxygen tank, for individuals with neuromuscular diseases, injuries, or chronic conditions who cannot breathe, clear their airway, or both. Following the procedure the surgeon inserts a tracheotomy tube into the hole and attaches a corresponding faceplate to the tube to keep it from slipping into the hole. There are two parts to the tracheostomy tube – the outer cannula, which may be cuffed for use with a mechanical ventilator or uncuffed, and an inner cannula that acts as a liner that is removable to clear mucus build up, which is specifically selected for the individual based on the patient's anatomical size, procedural needs, tube characteristics, and the patient's ability to manage airway clearance and speech. As such, these items, and the supplies used in conjunction with them are unique to the individual and should not be bid.

Lastly, individuals with disabilities and complex medical conditions often present with a neurogenic bladder due to neurological damage that impairs the bladder's ability to store and empty urine properly. This can lead to urinary incontinence, urinary retention, or both. Treatment is tailored to the individual with a focus on preventing complications such as kidney damage and urinary tract infections, which can cause a life-threatening situation for this patient population. The array of urological products available on the market contain unique features designed to address the different types of incontinence, clinical needs, size, and materials. These items, and the supplies used with them, are also unique to the individual user for their health and wellbeing and are not conducive to inclusion in Medicare's CBP.

NCART strongly opposes any revision to the definition of "item" related to medical supplies or a clarification to the definition of "medical equipment items" that would allow prosthetic devices such as ostomy, tracheostomy, and/or urological products and supplies to be included in Medicare's CBP.

Issue # 2: CMS' Proposal to Change the Number of Contracts Awarded for the DMEPOS CBP and Reduce the Minimum Number of Contractors/Winners from Five (5) to Two (2) per Competition

In past rounds of the DMEPOS CBP CMS has based the number of contracts needed in an area on the estimated capacity necessary to ensure projected demand is met and beneficiary access to medically necessary equipment is not compromised. Many of our members make manual and power wheelchairs available to their customer base, in alignment with the algorithmic approach to mobility assistive equipment (MAE) and are highly concerned about access to these medically necessary wheelchairs and the options, accessories, seating and positioning components used with them.

By contracting with fewer suppliers, the ability to service patients who require MAE will be severely compromised, leaving beneficiaries with mobility impairments bed-bound and at heightened risk for a preventable adverse occurrence and/or poor health outcomes for a number of reasons including, but not limited to the following:

- A lack of access to a local supplier, especially when an adjustment, modification, or repair of their MAE is necessary for the safe use and/or operation of the device.
- A reduction in the array of MAE available to meet beneficiary needs, especially if a particular brand, size, or configuration is deemed medically necessary to meet the individual's medical, physical, functional, and environmental needs and is not carried by either contract winner.
    - For example, there are currently 662 active products that have been verified by Medicare's contractor for the Pricing, Data Analysis, and Coding (PDAC) of HCPCS Level II DMEPOS codes as meeting the definition of a K0004 manual wheelchair listed on the Product Classification List (PCL).

- Typically, a K0004 manual wheelchair can be configured to fit and function for the unique needs of the individual user such as, but not limited to its size (seat width, depth and height; back height and angle, etc.) and available options and accessories used with it that allow the beneficiary to engage in frequent activities in the home.
- As a result, it would be virtually impossible for only 2 suppliers to support beneficiary access to this medically necessary mobility assistive equipment to meet their needs, thereby significantly limiting beneficiary choice or more importantly limiting access to a medically necessary product.

– Should a contract supplier go out of business or be unable to furnish products within the category for any reason, beneficiary access to medically necessary equipment will be severely threatened.

NCART opposes any reduction in the number of contract winners in a competitive bid area (CBA), strongly encourages CMS to re-evaluate the impact this proposal will have on beneficiary access to medically necessary products and services, and at a minimum maintain the current requirement for five contract suppliers per product category for each CBA.

Issue # 3: CMS' Proposal to Eliminate Supplier-Reported Capacity in Determining the Number of Contracts to Award

While historical data from previous rounds of the CBP are important to consider when determining the number of contracts to award, supplier-reported capacity is equally, if not more important to consider in future rounds. During the hiatus from the CBP the landscape of the DMEPOS industry has changed due to mergers and acquisitions, closing of businesses, supplier changes in product mix and focus, changes in personnel necessary to deliver products and services that were once provided, as well as the impact contracts with other payors have on capacity to service Medicare beneficiaries. All of this must be considered and would only be available to CMS through information submitted by suppliers on their current capacity to provide the products and services they are bidding during the bidding process.

NCART opposes this proposed change and strongly urges CMS to consider supplier-reported capacity, current Medicare utilization information, and historical capacity in the CBA when determining the appropriate number of contractors for each product category in each separate CBA.

Issue # 4: CMS' Proposal to Change the Payment Methodology to the 75th Percentile of Winning Bids in Determining Payment Amounts for the CBP

CMS has acknowledged that its previously implemented "median price" methodology used to establish the SPAs resulted in suppliers being paid less than they bid for an item, was unsustainable, could have led to beneficiary access issues, and was abandoned in subsequent rounds. The proposal to change the pricing methodology to the 75th percentile of winning bids would implement a similar pricing methodology, which will result in the same or similar access to care issues, and should be rejected in favor of a much more sustainable pricing methodology for the overall health of the CBP.

We have long held that a pricing methodology that utilizes the maximum bid for the item by suppliers within the winning range for the product category is not only fair but is also in line with the goals of the CBP and should be considered as an alternative to this proposal.

NCART urges CMS to use the clearing price to establish the SPAs for all future rounds of the CBP.

Issue # 5: CMS' Proposal to Adjust the SPAs During the Second and Third Contract Year Equal to the CPI-U Adjustment for the 12-month Period Ending 6 Months Prior to the Beginning of the Second and Third Year.

In support of contracted suppliers and beneficiary access to medically necessary products included in the CBP it is important to include CPI-U updates during each of the contracted years to keep pace with the rising costs of goods and operational expenses required to provide DMEPOS items included in the CBP.

NCART fully supports this proposed change and thanks CMS for acknowledging the need to adjust payment amounts to account for inflation.

Issue # 6: CMS' Proposal to Apply Previous Rounds of CB Pricing to the Ceiling Price for New Rounds of Bidding

CMS' proposal to base the bid ceiling on SPAs established in previous rounds of bidding could result in rates that are not only unsustainable but would be driven down further in subsequent rounds. This will create significant access to care concerns for individuals with diagnoses such as, but not limited to Guillain-Barre Syndrome, Ehlers-Danlos Syndrome, Lupus, Multi-limb Amputations, Myositis, Rheumatoid Arthritis, or Scleroderma who do not meet the restrictive coverage criteria for a Group 3 Complex Rehab power wheelchair because they do not have a neurological condition, myopathy, or congenital skeletal deformity. As a result, this patient population would only qualify for Group 2 Complex Rehab power wheelchairs, which were included in the Round 1 rebid, but have been excluded from the CBP since 2013.

The provision of CRT is labor intensive. It is not simply assessment followed by prescription; rather, providing a patient with an appropriate complex rehab wheelchair requires a full spectrum of services done through an interdisciplinary team approach that collectively provides clinical and technology-related services in the evaluation and recommendation process. The technology-related component of providing CRT requires the skilled, professional services of the CRT supplier's certified Assistive Technology Professional (ATP) who has direct, in-person involvement with the beneficiary throughout the process. These services include, but are not limited to, evaluation of the home environment; transportation assessment; technology assessment; equipment demonstration, trial, and/or simulation; product feature matching to the beneficiary's identified medical, physical, functional, and environmental needs; system assembly and configuration; fitting; adjustments; programming; and product related training and follow-up – all of which are included in the reimbursement rate for the product(s) provided to Medicare's most vulnerable beneficiaries and none of which can be eliminated from the process.

In addition, product and operational costs have risen substantially in the past 13 years. CMS has updated the fee schedule for these items, based on the CPI-U, annually for 12 of the past 13 years as follows:

2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
.8%	1.0%	1.5%	-.4%	.7%	1.1%	2.3%	.9%	.2%	5.1%	8.7%	2.6%	2.4%

NCART strongly urges CMS to continue to exempt these items for any and all future rounds of the DMEPOS CBP.

Issue # 7: CMS' Proposal to Reduce the Requirements for Submission of Financial Documentation as Part of the Bid Process

CMS has an obligation to thoroughly vet of every supplier's financial capability to purchase the products(s) they are bidding and serve the CBA throughout the entire round of the CBP. We appreciate CMS' attempt to simplify the bidding process and ease the burden placed on suppliers to gather all required documentation to support their long-term financial sustainability. However, we firmly believe that no longer requiring suppliers to submit tax returns, income statements, balance sheets, and cash flow documentation severely compromises CMS' duty to fulfil their responsibility to Medicare beneficiaries, select viable contract suppliers, and safeguard the Medicare Trust Fund.

Further, while CMS' proposal to only require a business or personal credit score may simplify the review process it does not provide the Agency with critical information necessary to establish a supplier's financial stability to participate in the CBP. We contend that any supplier bidding to provide products and services in a CBA has the financial documentation in place, or it is readily available to prove it. To that end, we also contend that CMS needs to issue clearer guidance relative to the financial documentation requirements based on the structure of the business (i.e., sole proprietorship, partnership, limited liability company, C or S-corporation) to limit errors, inadvertent omissions, and inaccurate disqualifications.

NCART objects to CMS' proposal to reduce the financial documentation required for bid submission; recommends CMS retain the current requirements for the submission of tax returns, income statements, balance sheets, and cash flow documentation; and issue further guidance to ensure each business type is submitting documentation that will allow the Agency to make informed decisions.

Issue # 8: CMS' Proposal to Expand the List of Situations in which the Agency may Revoke a Supplier's Application and/or Enrollment, Including Retroactive Revocation

Revocation of a supplier's application and/or enrollment in the Medicare program is a serious situation that must be well thought out, communicated, and executed. As such, we contend situations that may warrant consideration for the revocation of a supplier's application or enrollment in the program are not typically "black and white," can result from errors, inadvertent omissions, misunderstandings and/or the inaccurate interpretation of policies, procedures or information that must be considered such as, but not limited to:

- Identified exceptions that would allow for additional documentation to be submitted prior to revocation.
- A clear definition of "false or misleading," especially as it relates to a supplier's intent to provide false or misleading information.
- The ability for the supplier to address/correct any identified issue in a timely manner.
- Unambiguous parameters that outline when one (1) supplier location is subject to revocation versus a revocation of all supplier locations on the same day.

In addition, there must be clear criteria for when retroactive revocations are warranted or allowed, and it must be limited to situations where harm to the program outweighs harm to the supplier and any potential harm to Medicare beneficiaries.

NCART recommends CMS hold off on making any changes to their policies or procedures related to the revocation of a supplier's enrollment in the Medicare program; work with stakeholders to identify the issues that need to be addressed; and create well established parameters that minimize the risk of harm to Medicare suppliers and beneficiaries while protecting the benefit.

Issue # 9: CMS' Proposal to Require DMEPOS Suppliers to Surveyed and Reaccredited at Least Once every Twelve (12) Months

CMS currently requires DMEPOS suppliers to undergo a survey and reaccreditation every three (3) years, which has been sufficient to ensure compliance with the required standards based on the product categories the supplier makes available to Medicare beneficiaries. Increasing this requirement to an annual process is overly burdensome, extremely cost prohibitive, and will not meet the intended objective of protecting Medicare beneficiaries or the Medicare Trust Fund.

The role and responsibility of a CMS approved accrediting organization (AO) is to assess the supplier's operations against the requirements outlined in the Medicare DMEPOS Quality Standards and confirm their compliance with the DMEPOS Supplier Standards. Surveyors are looking at the square footage of a supplier's location; corroborating the posted hours of operation; confirming there is a working phone and checking to see that protected health information is secure. They may also track the workflow of the typically beneficiary experience through the provision process; verify that policies and procedures for intake, assessment and product-specific services are written and followed appropriately; examine beneficiary records, human resource files, maintenance records and liability insurance coverage; and inspect for safety and sanitation to ensure conditions of participation are met. They are not inspecting a supplier location for violations in connection with the Federal Anti-kickback Statute; False Claims Act; Physician Self-Referral (Stark) Law; Exclusion Statute or compliance with any of the requirements for billing the Medicare Program as it is not their role or responsibility to do so.

However, it appears this proposal is designed to significantly expand the role and responsibility of the AO and their surveyors to include law enforcement activities currently reserved for the Department of Justice, the Federal Bureau of Investigation, and the Office of the Inspector General. If fraud, waste, and abuse are suspected it needs to be addressed directly with the entity subject to the suspicious activities, not with a broad brush approach, such as annual reaccreditation, designed to try and "catch it" as there are much better alternative methods CMS could utilize for this purpose.

NCART strongly urges CMS to reject this proposal in its entirety; work with stakeholders to identity the issues to further address concerns with fraud, waste, and abuse; and create workable solutions that further protect Medicare beneficiaries and the Medicare Trust Fund.

NCART appreciates the opportunity to comment on this proposed rule on behalf of our members. If you have any questions, need additional information or would like to discuss our position further please contact me at wgrau@ncart.us.

Sincerely,

Wayne Grau

Wayne Grau
Executive Director – NCART