

Improving outcomes through awareness and action

August 29, 2025

Dr. Mehmet Oz Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1828-P P.O. Box 8016 Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

Re: 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)

Dear Administrator Oz:

The Healthcare Nutrition Council (HNC) appreciates the opportunity to comment on the 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). HNC is an association representing manufacturers of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access for people that require or benefit from advanced and specialized nutrition.

HNC commends the Agency's continued interest in nutrition, including in this proposed rule's specific request for information on tools and frameworks that promote healthy eating habits, exercise, nutrition, or physical activity for optimal health, well-being, and best care for all. In promoting nutrition for optimal health, we believe it is important to help identify and intervene for malnutrition across the spectrum of healthcare, including when care is delivered in the home. Thus, we offer comments specific to quality care and malnutrition-related conditions, as well as nutrition interventions and medical nutrition therapy (MNT). Additionally, the proposed rule outlines updates to the methodology for competitive bidding of DMEPOS. Our comments address access to nutrition care, including concerns regarding the competitive bidding proposal.



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Support for Quality Measures in Nutrition, Interoperability, and Well-Being

We support CMS's efforts to explore quality measures for inclusion in the HH QRP that assess:

- Nutrition: We encourage the use of validated tools for identifying and tracking malnutrition risk, use of nutrition support therapies, and the impact of nutrition interventions on recovery and rehospitalization.
- Interoperability: Seamless exchange of clinical and nutrition-related data (e.g., nutrition risk assessments, weight trends, feeding regimens) across care settings is critical for safe and timely care and also for patient-centered care.
- Well-being: Nutrition is foundational to well-being. Malnutrition, especially in older adults, affects mental health, physical function, and quality of life. We recommend integrating nutrition risk or status as a core component of any well-being metric.

Supporting the Malnutrition Care Score (MCS)

HNC strongly urges CMS to consider adapting existing malnutrition quality measures – such as the Malnutrition Care Score (MCS, formerly known as the Global Malnutrition Composite Score used in the Inpatient Quality Reporting program) – for inclusion in the Home Health Quality Reporting Program (HH QRP). While the MCS is currently an electronic clinical quality measure (eCQM) implemented for inpatients, it aligns with the standard nutrition care process and could be adapted for home health agencies that predominantly use Outcome and Assessment Information Set (OASIS)-derived process and outcome measures. By promoting comprehensive malnutrition screening, assessment, care planning, and care transitions, the MCS plays a crucial role in supporting the recovery and overall well-being of patients.

As CMS has previously acknowledged, malnutrition care remains a critical gap area that is associated with multiple poor health outcomes, including hospital readmissions and declines in functional status, psychosocial well-being, and quality of life. Tragically, the national deaths related to malnutrition have doubled from 9,300 deaths in 2018 to 20,500 deaths in 2022 according to the U.S. Centers for Disease Control and Prevention (CDC). In one study, 42.5% of patients whose stay in an acute care hospital was equal to or greater than two weeks were diagnosed with malnutrition.² Disease-associated malnutrition (DAM) is malnutrition that occurs from disease-related causes. DAM can manifest in patients across all spectrums of body mass index, ranging from under to overweight individuals. It is often multifactorial and can include inflammatory responses which can increase metabolic demand, decrease appetite, and lead to gastrointestinal problems and difficulty with chewing and swallowing. This can all lead to decreased nutrient intake, which can diminish immune response and wound healing, and increase infection rates.³ Malnutrition affects approximately 20% to 50% of admitted hospital patients. However, this figure likely underestimates the total burden of DAM, given the diagnosis gap in hospitalized patients. In an analysis by the Agency for Healthcare Research and Quality (AHRQ), malnutrition was diagnosed in only about 8% of hospital stays.⁵

Given the underdiagnosis of malnutrition in the hospital, patients are likely transitioning to homecare still malnourished without a plan for nutrition intervention and treatment, leading to increased complications and costs of care, poorer health outcomes, and more readmissions. Malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital.⁶ A study published in *HCUP Statistical Briefs*, developed by AHRQ, found in 2016 that malnutrition in U.S. hospitalized patients is associated with a more than 50%



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higher rate of readmission within 30 days, compared to patient stays not associated with malnutrition. Further, the average costs per readmission for patients with malnutrition were found to be 26-34% higher (\$16,900 to \$17,900) compared to those without malnutrition (\$13,400).⁷

Making the change to fully integrate malnutrition care (screening, assessment, diagnosis, care plans, interventions, and care transitions) for all adults throughout the healthcare system is a prudent investment because malnutrition care is a low-risk and low-cost solution that can help improve the quality of clinical care and decrease costs associated with negative health outcomes. Timely screening and assessment followed by intervention can significantly improve health outcomes for adults, with studies finding:

- About a 20% decrease in avoidable readmissions⁸
- A 50% reduction in pressure ulcer incidence^{9,10}
- Reduced overall complications¹¹
- Decreased mortality¹²
- Improved quality of life¹³

Hospital best practices demonstrate the cost savings by identifying and treating malnutrition. A study by a Chicago Accountable Care Organization (ACO) implemented a nutrition-focused quality improvement program and analyzed the cost savings and patient outcomes. The total cost-savings from reduced 30-day readmissions and hospital stays associated with nutrition intervention was over \$4.8 million; the net savings was over \$3800 per patient treated for malnutrition. The quality improvement program in this study included malnutrition risk screening at admission, prompt initiation of oral nutritional supplementation for at-risk patients, and nutrition support and education for patients both during the hospital stay as well as post discharge.

Concerns on Competitive Bidding Proposal

In addressing the DMEPOS proposed rule for Competitive Bidding, we are commenting on our concerns regarding patient access to enteral nutrition (EN) tube feedings that have historically been included in the DMEPOS Competitive Bidding Program.

Home care patients need access to prescribed and recommended nutrition interventions, including life-sustaining enteral nutrition. Enteral nutrition is provided to patients who require these medically necessary products to sustain their lives, and it is utilized for a variety of medical conditions. These products are essential nutrition interventions to improve clinical outcomes for those who are malnourished or at risk of malnutrition, helping prevent medical complications.

HNC is concerned that the competitive bidding proposal outlined in the proposed rule could significantly impact patient access and lead to unnecessary and avoidable risks for patients. Access to enteral nutrition is critical for individuals with or at risk of malnutrition, and/or those who cannot meet their nutritional needs by mouth or through a normal diet. These therapies require appropriate training and oversight for safe and effective delivery. If unaddressed, malnutrition will only continue to increase the costs of care and likelihood of poor health outcomes, including increased medical complications, longer hospitalizations, and higher readmission rates. As noted above, malnourished patients and patients with nutrition-related or



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metabolic issues are frequently readmitted to the hospital with significant costs compared to those without malnutrition.^{6,7}

While the proposal seeks to reduce costs, as documented above, any potential cost-savings are negated by the potential for destabilizing care for vulnerable populations who require access to life-sustaining products.

It is for these reasons that HNC strongly urges CMS to reconsider changes to the proposed payment rule and the associated methodology to assign bid winners and bid rates. The proposal reduces the number of providers permitted to serve Medicare beneficiaries in bid areas, shutting out many companies, meaning as few as two companies could be awarded a contract for an area's entire product category. A reduction in potential providers also means that it could be even more difficult for patients to find the particular enteral nutrition or products they require. Additionally, if there are only two awarded companies and there is an issue with either company, there may not be a backup, which could have catastrophic ramifications for patients who need these products to live. Further, the proposal permits companies with no experience in a product category or in a geographic area to count towards a bid area's capacity, meaning bidders with a lack of knowledge or infrastructure could be awarded without proven qualification. Such an approach not only impacts patient access, but also quality of care, which could lead to expensive and unnecessary medical complications for patients who rely on life-sustaining products.

We are opposed to the proposed lowering of the number of providers and the proposal to cap bid prices below market costs, which have the potential to impact quality and range of products available, further hampering patient access and safety, and potentially limiting innovations and availability. Patients receiving enteral therapy need access to clinicians and quality products to ensure the success of their therapy. A lack of quality, life-sustaining products specific to a patient's disease or medical condition and their nutrition requirements could result in serious and avoidable medical complications, including physician visits and/or hospital stays as well as poor health outcomes. We have heard from many beneficiaries who are already struggling to get their life-sustaining enteral nutrition supplies as tube feeding remains their only means of nourishment. These patients have been unable to avoid additional costly medical care and complications because the last few rounds of competitive bidding have led to reduced patient access. Specifically, these patients have had to stay in the hospital much longer than necessary as they sought to find an approved provider for their life-sustaining home tube feeding. HNC requests sustainable rates; the proposed bid ceiling is too low even as a 10% increase on already too low single payment amount (SPA) rates using lead item methodology will actually lower current rates on enteral formulas and supplies. Non-lead items will be dramatically reduced based on ratio assignment of rate. As demonstrated in past rounds of competitive bidding, significantly lowering rates for enteral nutrition formulas and supplies will negatively impact beneficiary access to life-sustaining nutrition.

Given that Medicare often sets the benchmark for Medicaid and private insurers, there is the potential for drastic ramifications for millions of Americans beyond the Medicare population who rely on these products, meaning more people may not be able to access the life-sustaining enteral nutrition products they require. HNC urges CMS to not cap bid prices below market costs as is the case in this proposal, and at minimum, maintain the bid ceiling at the unadjusted



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2015 fee schedule and maintain the SPA at maximum bid for the item by the providers in the winning range. The process for providers to ensure that patients receive the life-sustaining care they require via enteral nutrition is a complicated one, including providers navigating cumbersome and time-consuming documentation and billing requirements as well as providers working as experts, educators, and advocates for beneficiaries. 15 The current proposal would add further and unnecessary complexity into this process with the potential for devastating patient outcomes. Because of this multi-faceted process, inexperienced providers and those without verified capacity will not be able to adequately meet beneficiary nutrition and access needs. This will add increased burden and expense of hospital stays to feed patients requiring tube feeding at home rather than lowering the cost of that care at home. Life-sustaining enteral products are not optional. We have seen patients who only require a tube feeding placed back in the hospital when they cannot get their supplies at home. Additionally, if inexperienced providers limit the feeding formula product options due to decreased reimbursement rates, the beneficiaries who have failed on other formulas will become sick again when they cannot access the formulas they require. The feeding of incorrect formulas, specifically those that are not clinically indicated and prescribed, is another reason that enteral nutrition patients end up back in the hospital and in a higher cost, acute care environment.

If CMS is unable to make changes to this proposed DMEPOS Payment Rule, HNC is concerned about continued patient access to life-sustaining nutrition and that there is not enough reimbursement for legitimate hard-working homecare providers to choose to bid when payment rates do not adequately cover the increased cost of goods, fuel, labor, and support to execute complicated life-sustaining product access. Additional specific concerns include:

- There are no capacity checks to ensure that awarded providers can actually meet beneficiary demand
- With the recent history of trucking, rail, and airline issues, having supplies closer to beneficiaries is essential to ensure access to medically necessary and life-sustaining enteral nutrition supplies and products
- Clear pricing is needed using a 75th percentile will eliminate legitimate providers and further decrease beneficiary access

Conclusion

As CMS advances quality measurement and care, nutrition must be recognized as a clinical cornerstone – not an ancillary service. We urge CMS to consider adapting the MCS for inclusion in the HH QRP and to make the MCS eCQM a mandatory quality measure to ensure standardization of nutrition screening, assessment, diagnosis, and care planning. This emphasis on and evaluation of nutrition care will increase the focus on discharge planning and improve the transition of care for patients on ONS, EN, and PN.

Further, we strongly urge CMS to reconsider their proposed rule updates to competitive bidding for DMEPOS given the potential for serious consequences for patient access and health outcomes. Based on our significant concerns about decreased beneficiary access to life-sustaining enteral nutrition via tube feedings as well as the other important provider issues identified, HNC respectfully opposes the proposed rule as written and requests a delay in instituting the Competitive Bidding Program with the current DMEPOS Proposed Rules. HNC is ready to meet with CMS to share recommendations for better meeting beneficiary needs and for



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preserving access to life-sustaining tube feedings in the Medicare Part B program in a way that prioritizes helping patients stay in the lowest cost care settings. We request CMS modify DMEPOS Competitive Bidding Proposed Rule as it is today, and we request changes to the payment methodology so that it does not create rates that are too low for adequate and experienced providers of enteral nutrition.

Thank you for the opportunity to provide comments. We remain committed to partnering with CMS to ensure that all individuals have access to appropriate, skilled, and effective nutrition care and life-saving interventions across the continuum of care. If you have any questions or would like additional information, please do not hesitate to reach out.

Respectfully submitted,

Wa f. Sandys

Carla Saunders
Executive Director

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