



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Delivered Electronically

October 23, 2019

Mr. Michael Keane
Director, Division of DMEPOS Competitive Bidding
Chronic Care Policy Group
Centers for Medicare Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21224

Re: DMEPOS Competitive Bidding Program – Review of Bona Fide Bids and Meeting Request

Dear Mr. Keane,

Thank you for your response to the Healthcare Nutrition Council's (HNC)¹ letter from June 10 requesting a meeting to discuss review of bona fide bids for the Round 2021 bid cycle for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). Since our last communication, HNC has witnessed and been informed of an alarming lack of understanding among suppliers of the new bid processes, even as the bid window for 2021 was coming to a close. As a result of this, and as detailed further below, we urge CMS to conduct a bona fide bid review of *all* bids selected for bid round 2021. Further, we value the ability to maintain an ongoing dialogue with CMS and would be happy to meet to discuss our concerns and recommendations in more detail.

We first want to acknowledge and thank CMS for the many steps it has taken to educate suppliers about the fundamental changes made to the CBP for Round 2021. These educational efforts, combined with other changes such as the delay of the bid window, are positive measures that will improve the chances of a sustainable result for Round 2021. HNC stands committed to continuing to work with CMS to ensure continued access to enteral nutrition (EN) products for vulnerable Medicare beneficiaries, as these nutritional therapies play an important role in patient outcomes and moderating costs.

HNC, as one of the four sponsoring organizations, has collaborated with the CBP DME Education Coalition to broaden national education efforts to reach out to bidders addressing EN bid concerns to a broad audience. Despite the ongoing efforts of both CMS and stakeholder educational coalitions, over the last several months, stakeholders continued to observe a significant lack of knowledge among potential bidders about the new bid and pricing methodology, even among relatively experienced and sophisticated suppliers. Therefore, HNC is requesting that 100 percent of all selected bids undergo a comprehensive bona fide bid review.

As HNC detailed in its enclosed April 10th letter to CMS, the EN category is at significant risk for bid errors that might lead to unsustainable reimbursement rates. This is because the proportions between the lead item and non-lead items among EN codes were very different in 2015 than they are now. As a result, if a bidder simply maintains the current rate for some EN lead items, reimbursement for EN formulas will decrease up to 40.5% from current levels.² This is an immediately unsustainable outcome that could result in troubling access issues for life-sustaining nutritional formulas. It is therefore essential CMS conduct a comprehensive review and analysis of each and every bid it intends to accept in the EN category for Round 2021.

¹ HNC represents manufacturers¹ of enteral nutrition (EN) formulas, parenteral nutrition solutions, supplies and equipment. HNC represents a large portion of the enteral nutrition industry, which is one of the categories for the CBP Round 2021. HNC members are Abbott Nutrition, B. Braun Medical Inc., Nestle Healthcare Nutrition, and Nutricia North America.

² HNC Letter to Michael Keane, April 10th, 2019 (enclosed as an attachment).



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

The tenuous situation of the EN category is highlighted by a recent Oley Foundation survey of Medicare healthcare professional providers and patient beneficiaries that resulted in some startling findings. The survey found that a remarkable 54% of providers said they have observed beneficiaries that have difficulty finding a company to provide tube feeding formulas through Medicare suppliers. In addition, nearly 1 in 3 Medicare beneficiaries reported needing to switch suppliers to obtain their formulas. Included in the Oley survey were several testimonials that the current reimbursement rate for EN formulas result in an unsustainable loss for suppliers, and that suppliers have made the difficult choice to stop offering the formulas. All this goes to demonstrate that provision of EN to Medicare beneficiaries is an issue, even at current reimbursement rates.

Currently, CMS states it will only require bids to pass scrutiny as a rational and feasible bid for furnishing the lead item and all non-lead items in the product category. Given ongoing confusion among suppliers, even as the bid window is now closed, this standard is simply not enough for a category so prone to error such as the EN category. To mitigate these risks, HNC recommends that CMS conduct bona fide bid reviews of all winning bids for EN products, scrutinizing any lead item bids lower than the 2018 single payment amount (SPA), and any bids that significantly degrade reimbursement for the non-lead items, EN formulas. This should include extensive dialogue with any suppliers being considered for a winning bid to ensure the supplier understands the obligations and costs to the suppliers for all lead and non-lead items.

CMS has engaged in a worthwhile effort to reform and modernize the CBP. However, with such monumental tasks comes inherent risks that must be addressed. In this case, the change to lead-item pricing is one that poses serious risk of harm to Medicare beneficiaries during the first bidding round, and CMS should take any and all steps to prevent the failure of a supplier and the resulting devastating loss in access to needed supplies.

Thank you again for your commitment to the DMEPOS CBP and your work to ensure beneficiaries have access to critical nutritional products. If you have any questions, please do not hesitate to contact me. We would also be happy to meet with you in-person to discuss our concerns and recommendations in more detail.

Sincerely,

A handwritten signature in black ink that reads "Robert Rankin". The signature is written in a cursive, flowing style.

Robert Rankin
Executive Director

Enclosure: HNC Letter to CMS EN Product Category Recommendations (4-5-19)