



# HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

*Delivered Electronically*

June 10, 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 – Delay of Opening of 2021 Bid Window and Bona Fide Bid Guidance**

Dear Mr. Keane,

We are writing in response to recent developments pertaining to the Round 2021 bid cycle for the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). The Healthcare Nutrition Council (HNC) represents manufacturers of enteral nutrition formulas, parenteral nutrition solutions, supplies and equipment. HNC represents a large portion of the enteral nutrition (EN) industry. Our mission is to improve health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. Our organization aims to promote nutritional screening, diagnosis, assessment, appropriate and timely clinical nutrition interventions, as well as patient access to specialized nutrition support products and services throughout the continuum of care.

We want to acknowledge and thank CMS for delaying the opening of the bid window until July 16, 2019. This additional time will allow bidders to better understand the intricacies of the new bid program, especially the changes associated with lead item bidding. HNC also commends CMS for the recently announced webcast series to assist bidders and stakeholders with understanding the key components of the Round 2021 bidding process.

While the additional time and education will be helpful to bidders, HNC continues to have concerns about CMS' bona fide bid evaluation process. Since previous HCPCS code fee schedules and bid cycles did not rely on proportionality between lead and non-lead items, (as detailed in our enclosed April 5, 2019 letter), there is a strong potential for access issues, particularly to a limited set of specialty formulas (B4153 and B4154). It is therefore essential that CMS have in place a stringent process to conduct bona fide bid reviews.

In CMS' most recent fact sheet on the DMEPOS Competitive Bid website, CMS repeats that a bona fide bid must pass "scrutiny as a rational and feasible bid for furnishing the lead item and all non-lead items in the product category." While this is a valid overarching principle, CMS has not detailed more specific criteria that will be used to trigger a bona fide bid review, or what more specific thresholds it will use to approve a bid. HNC urges CMS to establish and publish clear guidelines on the standards it will use to determine which bids will be subject to bona fide reviews, as well as the thresholds that will be used to approve a bid subject to such a review. To mitigate risk to access for enteral nutrition formulas, HNC recommends that CMS conduct bona fide bid reviews of all winning bids for EN products, scrutinizing



# HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

any lead item bids lower than the 2018 single payment amount (SPA), and any bids that significantly degrade reimbursement for enteral nutrition formulas.

Thank you again for your commitment to DMEPOS CBP and your work to ensure beneficiaries have access to critical nutritional products. If you have any questions, please me.

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)