

Healthcare Nutrition Council

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April 5, 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

Dear Michael:

Re: Enteral Nutrition Lead Item Pricing and Bona Fide Bidding of Enteral Nutrition Products for the Competitive Bidding Program 2021 – Enteral Nutrition Product Category Recommendations

We appreciate the opportunity to provide CMS with recommendations on CMS' internal bona fide bid analysis process to ensure that enteral nutrition product category bids submitted using the new lead item pricing methodology are appropriate and will ensure beneficiaries have access to medically necessary, enteral nutrition products. The Healthcare Nutrition Council (HNC) represents manufacturers of enteral nutrition formulas, parenteral nutrition solutions, supplies and equipment. HNC represents about 85% of the Enteral Nutrition 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, to promote nutritional screening, diagnosis, assessment, appropriate and timely clinical nutrition interventions, and to promote patient access to specialized nutrition support products and services throughout the continuum of care.

While the HNC supports the overall changes CMS is implementing with the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program (CBP), we are concerned that lead item pricing for the Enteral Nutrition category will cause increased access issues, particularly to a limited set of specialty formulas. We therefore urge CMS to take special precautions to protect access for Medicare beneficiaries requiring enteral nutrition. We are providing CMS with recommendations for (1) enhanced bidder education specific to the enteral nutrition product category, and (2) a more substantive bona fide bid review process for the enteral nutrition category.

The 2021 NCB Lead Item Process for Enteral Nutrition

While HNC understands the need to simplify the bid and evaluation process, we note with concern that the proportions between the lead item and non-lead items, particularly the enteral formula codes, were very different in 2015 than they are now. As a result, if a bidder simply maintains the current rate for the lead item (B4035), reimbursement for enteral formulas will decrease between 15.5% and 40.5%. The scenario below illustrates HNC's concern.

HCPCS Code	CBP 2021 Bid Ceiling (2015 Rates)	Description	Average 2018 SPA	Enteral Nutrition Formula Pricing with Lead Item at 2018 SPA	Nutritional Formula Percentage Change with a No Change (2018 SPA) Lead Item Bid
B4035	11.95	Lead Item: EN Pump kit	5.25	5.25	0.00%
B4149	1.61	Blenderized Formula	1.01	0.71	-29.68%
B4150	0.70	Standard Formula	0.37	0.31	-17.40%
B4152	0.57	Calorically Dense Formula	0.31	0.25	-18.51%
B4153	1.96	Hydrolyzed Protein Formula	1.19	0.86	-27.39%
B4154	1.25	Metabolic Formula	0.65	0.55	-15.50%
B4155	0.97	Modular Nutrients	0.72	0.43	-40.51%

Lead Item pricing may impact access to critical enteral nutrition formulas because historic HCPCS code fee schedule amounts in the enteral nutrition category were not established on any proportional basis. Earlier rounds of Competitive Bidding also did not

consider proportionality as each HCPCS code was bid separately. The resultant change in bid analysis is so significant that HNC is very concerned that bidders will be prone to error, in spite of best efforts of CMS and the industry to educate them.

HNC is particularly concerned about HCPCS codes B4153 and B4154 whose current reimbursement rates do not represent bona fide bids based on current acquisition and indirect costs. Any reduction in reimbursement for these products may be immediately unsustainable and prevent patient access. Within these enteral formula HCPCS categories, there are specialized tube feeding formulations prescribed for higher acuity, medically fragile beneficiaries with nutrition-related diseases and conditions. In each of these scenarios, the most vulnerable nutrition formulas realize significant declines. Potential for bidding confusion portends first time lead item bidding implementation that could negatively impact enteral nutrition formula access.

We respectfully request that CMS establish safeguards to mitigate the risk of access to enteral nutrition including:

- Additional education focused on the Enteral Nutrition product category.
- Established standards to trigger Bona Fide Bid review.

Additional Education Focused on the Enteral Nutrition Product Category

Modifications to the [Lead Item Pricing Calculator](#) would make it easier for bidders to effectively assess Enteral Nutrition bids. We suggest the following enhancements:

- Display the bid ceiling rates in the calculator output
- Display the percentage change versus existing payment rates for non-lead items to illustrate payment changes.
- Add text to the calculator on bona fide bidding to remind bidders to consider all associated indirect costs and profit margin when submitting their bid.
 - Add the bona fide bid definition as additional text to the calculation page above the “Bid Amount for Lead Item” box, readdressing the Bona Fide Bid consideration for the bid calculation
 - For example: “Bona Fide Bids must include all indirect costs and a profit margin. Indirect cost examples include compliance, operations and warehouse, referral and sales support, document management, call center, logistics and delivery and bad debt expense.”
- Establish and publicize guidelines that will trigger a Bona Fide Bid Review.

Establish standards to trigger a Bona Fide Bid review for the enteral category.

It is important that CMS’ bona fide bid analysis and process is effective to ensure appropriate access. HNC believes this process can be enhanced by establishing and communicating clear guidelines on how bona fide bidding rules will be applied to the EN category.

Following are suggestions that could trigger a mandatory bona fide bid analysis:

- The bottom 10% of EN bids for lead and non-lead items should be subject to bona fide bid analyses
- Any lead item bid at or lower than 2018 SPA
- All bids that generate decreases for HCPCS B4153

HNC is committed to protecting beneficiary access to EN through CPB 2021. We believe these recommendations may prevent bidder confusion and EN awards that would ultimately have a negative impact on beneficiary access.

We strongly urge CMS to take additional precautions to protect beneficiaries that require EN by enhancing bidder education for this category and establishing transparent guidelines to trigger bona fide bid analysis. HNC would welcome a follow-up meeting with CMS to discuss EN category concerns and preservation of access to enteral formulas following CBP 2021.

Respectfully submitted,



Madeline Jurch
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Healthcare Nutrition Council

CC: Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare