



Submitted via Regulations.gov

December 30, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: HNC and ASPEN Comments on Docket Number CMS-2020-0128 titled "Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) (CMS-1738-P)"

Dear Administrator Verma,

The Healthcare Nutrition Council (HNC) and the American Society for Parenteral and Enteral Nutrition (ASPEN) are providing comments on the proposed rule from the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* November 4, 2020 titled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS);" as well as CMS' October 27, 2020 announcement regarding the DMEPOS Competitive Bidding Program (CBP). HNC is an association representing manufacturers¹ of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), parenteral nutrition (PN) solutions, supplies, and equipment. 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. HNC 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. ASPEN is dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism. Founded in 1976, ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With more than 6,000 members from around the world, ASPEN is a community of dietitians, nurses, pharmacists, physicians, scientists, students, and other health professionals from every facet of nutrition support clinical practice, research, and education.

We would first like to thank CMS for not awarding bids for the enteral nutrition product category for Round 2021 of the CBP during this public health emergency (PHE). The decision aligned with our concerns that the 2021 bid award might limit patient access due to COVID-19 PHE-related market changes that HNC outlined and submitted to CMS in the enclosed letter from June 18, 2020. Now that CMS has announced that it will be forgoing awarded competitive bids for most categories in 2021, we are providing several recommendations stemming from concerns for beneficiary access. These concerns relate to the fact that CMS will now be keeping competitive bidding area (CBA) DMEPOS rates based on older pricing methodology that has been in place for six years, and based on an outdated and flawed methodology.

Our key recommendations are outlined below, followed by a more detailed rationale.

¹ HNC members are Abbott Nutrition, B. Braun Medical Inc., Nestle Healthcare Nutrition, and Nutricia North America.



Summary of key recommendations

- I. Rates in former CBAs should be based on a 90-10 blended payment formula. The 90 percent should be based on the current payment rates in former CBAs, and the 10 percent should be based on the 2015 unadjusted fee schedule amounts.
- II. Rates in non-rural, non-CBAs should be based on a 75-25 blended payment formula. The 75 percent portion should be based on the current rates in former CBA. The 25 percent portion of the blended payment formula should be based on the unadjusted fee schedule.
- III. CMS should eliminate its proposed limit on the number of times an applicant can re-submit applications for new or revised Level II HCPCS codes, provided that the applicant includes new data/information to support the request.
- IV. CMS should add to its HCPCS code panel representatives of state Medicaid programs, and/or a representative from the National Association of Medicaid Directors, and representatives of commercial payers. CMS should also rely on the outside clinical experts, for example, those it has established through the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).
- V. We recommend that CMS establish a separate public notice and comment process for its gap-filling and comparability analyses after a final HCPCS code decision, to allow for both public input and for CMS to publicize the information it uses in making these payment determinations.

Background and rationale for our recommendations

We are aware that the bid process was amended to correct identified flaws in order to allow rates to better reflect the market and to maintain patient access. Given that each round of bidding had the prior rate as a bid ceiling, it required that bidders bid lower than the current rate they had at the time of the bid. Therefore, the most recent bid has the lowest rates. These rates triggered the change of the bidding methodology for Round 2021. CMS has abandoned the payment methodology which established the current rates and replaced it with a methodology that more closely resembles standard auction bid methodology. This resulted in a change from the median bid to clearing price bid and raised the bid ceiling from the current bid to the 2015 fee schedule which was considerably higher than the existing fee schedule. Based on these identified bid parameters requiring changes, we recommend that CMS base payment rates in former CBAs on a 90-10 blended payment formula. The 90 percent should be based on the current payment rates in former CBAs, and the 10 percent should be based on the 2015 unadjusted fee schedule amounts.

The current COVID-19 PHE has created unprecedented strains on the health care system, including our members and the entire DMEPOS community. We commend CMS for its decision to not move forward with the enteral nutrition category and all the prior existing 13 product categories in Round 2021 of the CBP. Please see the enclosed HNC letter to CMS from June 18, 2020 highlighting considerations for access and pricing due to the PHE. The letter shares our concerns around costs and availability of enteral nutrition supplies. A reported 22% of enteral supplies having increased acquisition costs, and 29% of those reported a 20% cost increase during the PHE.² In some areas, enteral nutrition feeding pumps and

² Dobson, A. & DaVanzo, J. Impact of COVID-19 Supply Chain Disruptions and increased Costs on DME Suppliers: A Survey of Companies. Retrieved from: https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmcusercontent.com%2F3c0f3755f13930464597f245a%2Ffiles%2F4488d35f-7a76-4954-80de-0620b4394d3a%2FDobson_DaVanzo_COVID_19_Impact_Report_05_12_20.pdf&data=02%7C01%7Cpamela.pacht%40us.net



supply kit utilization has increased between 10 and 100 times typical utilization.³ The increase in utilization is in part due to COVID-19 patients who are ventilated are relying on nutrition support if they are not able to eat by mouth. If these patients do not have access to nutrition support, they are at risk of nutrient deficiencies and developing malnutrition. Malnourished individuals experience increased morbidity, complications and mortality, longer hospitalizations, more readmissions and institutionalizations, and need for ongoing services than patients who are not malnourished.^{4,5} Providing enteral nutrition early to critically ill hospitalized patients can significantly improve patient survival and reduce total costs of care by about \$14,000 per patient.⁶

Additionally, we request that CMS provide transparency about the lead item bid for the enteral nutrition product category, based upon the bids that were submitted for Round 2021. CMS stated that its decision not to award the category was because the payment amounts did not achieve expected savings and due to the COVID-19 PHE. We would like to review the bid outcome against the fee schedule. If the goal of the restructured bid methodology is to allow the bid program to reflect market changes to maintain a viable program that ensures patient access, then we would like to better understand that. Even if future bids do not provide savings, our understanding is that CMS does have the authority to implement the program, despite the lack of savings. We urge CMS to ensure that future bid programs will be flexible to reflect market changes for enteral nutrition and all product categories.

HNC and ASPEN commend the agency's proposal for permanently keeping the current 50:50 blend for rural rates and fully support CMS for its decision to maintain these higher fee schedules in sparsely populated areas to better assure beneficiary access by permanently keeping the current 50:50 blend.

We recommend that single payment amounts (SPAs) for non-rural, non-CBA areas that CMS utilizes a 75:25 blend. This would include 75 percent of the 2016 rates plus the annual Consumer Price Index for All Urban Consumers (CPI-U) recommended in the former CBAs and 25 percent based on the unadjusted fee schedule. This is recommended based on the same rationale as the request for former CBAs: flawed methodology that is six years old and has been replaced with new CMS bid/fee schedule methodology applied in the bidding process for Round 2021.

HNC and ASPEN appreciate the opportunity to comment on this CMS proposed rule, as well as CMS' October 27, 2020 announcement regarding the DMEPOS CBP. If you have any questions, please contact Berit Dockter, Healthcare Nutrition Council, at bdockter@healthcarenutrition.org or 202-207-1112.

Respectfully,

Robert Rankin
Executive Director, HNC

Jay M. Mirtallo
Clinical Practice Specialist, ASPEN

Enclosed: HNC Letter to CMS re Round 2021 Competitive Bidding Program for Enteral Nutrition Must be Cancelled and Rebid or Delayed (June 18, 2020)

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³ Based on HNC member sales information

⁴ Weiss AJ; Fingar KR; Barrett ML; Elixhauser A; Steiner CA; Guenter P; and Brown MH. Characteristics of Hospital Stays Involving Malnutrition, 2013: Statistical Brief #210. HCUP Statistical Briefs. 2016. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK396064/>.

⁵ *Ibid.*

⁶ Doig, G. S., Simpson, F., and Early PN Trial Investigators Group. Early parenteral nutrition in critically ill patients with short-term relative contraindications to early enteral nutrition: a full economic analysis of a multicenter randomized controlled trial based on US costs. *Clinicoeconomics and Outcomes Research: Ceor*. 2013; 5:369-379.



HEALTHCARE NUTRITION COUNCIL

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SUBMITTED ELECTRONICALLY

June 18, 2020

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Round 2021 Competitive Bidding Program for Enteral Nutrition Must be Cancelled and Rebid or Delayed

Dear Administrator Verma:

The Healthcare Nutrition Council (HNC)¹ is writing to request that the Centers for Medicare and Medicaid Services (CMS) delay the Round 2021 Competitive Bidding Program (CBP) for enteral nutrition (EN). Over the last several months, since the inception of the COVID-19 public health emergency (PHE), we have seen significant increased utilization of EN products and expect shortages very shortly of these items for home care patients. In addition, the EN market has changed dramatically during the COVID-19 PHE, undermining the validity of the EN bids for Round 2021. Due to anticipated shortages and the dramatically changed market, we strongly urge CMS to cancel and rebid, or delay the Round 2021 Competitive Bidding Program for EN, until the market has stabilized after the pandemic has ended.

HNC is writing to express our concerns with the timing of Bid Round 2021 of the Durable Medical Equipment Prosthetics Orthotics & Supplies (DMEPOS) Competitive Bidding Program (CBP). Attached to this letter is a memorandum that details serious concerns with CMS maintaining the current implementation schedule for the Round 2021 CBP, focusing on the EN product category in light of the COVID-19 PHE.

The current COVID-19 PHE has and will continue to significantly alter EN availability and usage, with particularly pronounced negative impacts on the EN product category's lead item. In addition, we predict that the negative impacts on EN will escalate over the next 12 months and be prevalent across the country. The effects of the COVID-19 PHE, combined with the timing of Round 2021, has the potential to decimate beneficiary access to EN.

We urge CMS to consider the following points, not anticipated during the Round 2021 bidding process that have dramatically altered the market dynamics and subsequently the Round 2021 bids:

¹ HNC is an association representing manufacturers of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), parenteral nutrition (PN) formulas, supplies and equipment. 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. HNC members are Abbott Nutrition, B. Braun Medical Inc., Nestle Healthcare Nutrition, and Nutricia North America.



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- The delivery, cost, and overall structure of the industry has changed drastically since the closure of the bid window. Suppliers have been forced to rethink their entire operations and cost structure to meet the demands and restraints caused by COVID-19.
- Suppliers will require different supplies and in different quantities than they did pre-COVID. This new status quo was not incorporated into their bids.
- Current suppliers who would not be serving bid areas starting in January 2021 will begin winding down their inventories well ahead of January.
- Likewise, suppliers who may be currently engaged in delivering crucial supplies, like PPE, may become obligated to put efforts towards meeting their new winning bid obligations rather than the immediately needed supplies.
- Due to the increased strain on the health care supply network, a transition of this magnitude during or in the months following a public health emergency could cause extreme disruptions to needed products and services.
- Patient profiles and needs have shifted drastically since the closure of the bid window. A whole new class of patients will continue to have unique and previously unforeseen needs that were not accounted for in submitted bids.

We therefore urge CMS to cancel and rebid Round 2021 at a future date when the PHE resolves or significantly improves. At a minimum, only if CMS is unable to cancel and rebid the Round 2021 contracts, CMS should delay the implementation of Round 2021 Competitive Bidding Program until the market has returned to a stable state.

We welcome the opportunity to discuss these issues further with you.

Sincerely,

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

Robert Rankin
Executive Director
Healthcare Nutrition Council

Enclosed: Memorandum on the need to rebid or delay Bid Round 2021

CC: Demetrios Kouzoukas
Jason Bennett
Jeanette Kranacs
Joel Kaiser
Cynthia Hake
Michael Keane
Joe Bryson

MEMORANDUM

To: CMS and Key Policymakers

From: Healthcare Nutrition Council

Re: The Need to Rebid or Delay Competitive Bidding Program Round 2021

The Centers for Medicare and Medicaid Services (CMS) closed the bidding for Bid Round 2021 of the Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) in late 2019. In early 2020, the health care system was disrupted in a magnitude not before seen by the COVID-19 Public Health Emergency (PHE). The resulting landscape and associated consequences for providers, suppliers, payers and regulators could not have been reasonably foreseen. For these reasons, and as detailed further below, it is critical that CMS cancel and rebid Round 2021 for the DMEPOS CBP. Continuing with bids submitted in a pre-COVID-19 world would be doing a disservice to Medicare beneficiaries and risking detrimental disruptions in service for life-saving care.

The PHE Has Caused Increased Utilization of Enteral Nutrition and May Create Shortages for Home Care Patients

During this PHE, COVID-19 patients who are admitted to hospitals and placed on mechanical ventilators are also often being placed on enteral tube feedings with enteral feeding pumps. This is because patients on non-invasive ventilation (NIV), or continuous positive airway pressure (CPAP), frequently fail to meet nutritional requirements orally.² Both items, the mechanical ventilators and the enteral nutrition (EN) feeding pumps are often connected upon hospital admission to limit exposure for the frontline medical workers treating critically ill COVID-19 patients.³ Continuous EN feeding via feeding pump, and not via bolus, is the recommended method per the American Society for Parenteral and Enteral Nutrition (ASPEN) the Society of Critical Care Medicine (SCCM), and the European Society for Clinical Nutrition and Metabolism (ESPEN) to decrease patient interaction and exposure.⁴ Due to this, there is a shortage of enteral feeding pumps and feeding pump supply kits nationally.⁵

As the virus spreads to an increasing population across the country, and as patients transition from facility care to home care, the shortage of enteral feeding pumps and the supply sets will also impact home care and long term care patients. In addition, the uncertainty created by bid awards for Round 2021 will lead DMEPOS suppliers to be cautious about stocking inventory as the year progresses due to the possibility of not being awarded future business for Medicare beneficiaries.

² Poor nutrition is associated with a longer length of hospital stay and increased mortality in COPD patients undergoing NIV. (See Route of Nutrition Support in Patients Requiring NIV & CPAP During the COVID-19 Response.) Retrieved from: <https://www.bapen.org.uk/pdfs/covid-19/nutrition-in-niv-21-04-20.pdf>.

³ Martindale, R. et al. Nutrition Therapy in the Patient with COVID-19 Disease requiring ICU Care. Retrieved from: https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/Nutrition%20Therapy%20COVID-19_SCCM-ASPEN.pdf.

⁴ *Id.*

⁵ *Id.*



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The Enteral Nutrition Market Has Changed Dramatically During the PHE Undermining the Validity of the Enteral Nutrition Bids for Round 2021

In the EN product category for the Round 2021 CBP, the feeding pump supply set (HCPCS code B4035) was the lead item used to set payment levels for all other items in the EN product category. However, historic and unanticipated changes in utilization of this lead item and non-lead items has fundamentally changed the market for these products, which will likely make them either unavailable or cost-prohibitive.

If DMEPOS supplier contractors cannot access a sufficient supply of B4035 (the feeding pump supply set), they will need to instead provide beneficiaries with a different item, such as a gravity supply set (B4036) or syringe fed feeding supply kit (B4034). If suppliers have no choice but to utilize either a gravity feeding supply set (B4036) or a syringe supply kit (B4034) in lieu of the feeding pump supply set (HCPCS code B4035), the market basket spend that was used to calculate the bona fide bid for Round 2021 will be completely altered. At the time of bid submission, the bulk of the enteral product category feedings utilized the enteral pump kit and an enteral pump, both of which may be unavailable or in short supply with a surge in COVID-19 cases and concomitant ICU utilization of the EN feeding pumps and pump feeding sets.

Additionally, the supply and demand market dynamics have been changed by COVID-19. When Round 2021 bids were submitted, there was a very different market; supply and demand were steady and predictable. During this PHE, and as different localities go through their single or multiple surges of cases, there will likely continue to be increased costs associated with purchasing these items. This market dynamic change could not have been predicted nor anticipated when the bids were submitted for Round 2021. Due to continued supply and demand shifts, the acquisition costs could have dramatic increases, aligned with what we have seen for PPE, sanitizers, and other items with increasing demand during the COVID-19 PHE.

Current costs and availability of products are no longer predictable and bear no relationship to 2019 costs and availability used for Round 2021 bids. In a recent industry survey, 27% of EN DME suppliers reported supply chain interruptions, and 62% reported a 60-day delay in receiving products. Costs were also impacted with a reported 22% of enteral supplies having increased acquisition costs, and 29% of those reported a 20% cost increase.⁶ Importing and rush ordering supplies adds to increasing cost of goods and acquisition costs during this PHE. When this happens, the bona fide bids submitted in 2019 will no longer be bona fide, given these significantly changed market factors.

EN manufacturers saw a dramatic increase in EN pumps utilized in New York and Louisiana hospitals as the number of ICU patients increased. There has been a demonstrated shortage of EN feeding pumps and the pump supply kits, including the feeding tubing that connects the feeding pump to the patient from a safe distance to decrease exposure.⁷ There remains a

⁶ Dobson, A. & DaVanzo, J. Impact of COVID-19 Supply Chain Disruptions and increased Costs on DME Suppliers: A Survey of Companies. Retrieved from: https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmcusercontent.com%2F3c0f3755f13930464597f245a%2Ffiles%2F4488d35f-7a76-4954-80de-0620b4394d3a%2FDobson_DaVanzo_COVID_19_Impact_Report_05_12_20.pdf&data=02%7C01%7Cpamela.pacht%40us.net%7C2377d0412faf47c8b78b08d7fb346117%7C12a3af23a7694654847f958f3d479f4a%7C0%7C0%7C637254075474115610&sdata=R6FV1KISKSLIRk5UPq%2FH2VlzDtJU3tk10%2FRRRApMsgc%3D&reserved=0.

⁷ Information provided on multiple webinars, web-sites and conference calls on EN impacts from COVID-19.

national shortage of the pump sets from some manufacturers prior to PHE, which has been exacerbated during the increased use. Depending upon the hospital, utilization has increased between 10 and 100 times typical utilization.⁸

Mike Cusack, Executive Director of the Global Enteral Device Supplier Association (GEDSA) has received anecdotal reports from GEDSA members that demand for EN feeding pumps and tubing supplies have dramatically increased, up to 6-times the pre-COVID-19 utilization. If other localities see the same kind of increases, there is likely to be a national stock out of the supplies. The manufacturers of these feeding pumps and the pump kit tubing are unlikely to be able to manufacture enough feeding pumps and pump set tubing to accommodate the dramatic rise in demand in acute care hospitals. The shortage will then be felt in long-term care and home care once the acute care hospitals have utilized the current supplies. The negative impacts will be most pronounced in larger metropolitan areas, where COVID-19 has been more pervasive; the same metropolitan areas included in the Round 2021 CBP.

GEDSA and affiliated organizations have recognized the likelihood of a national and global shortage of enteral feeding pumps and supplies during spikes of COVID-19. As a result, they have posted multiple documents to provide clinical and other advice on how to best deal with those shortages to ensure the best possible patient care.⁹ The professional nutrition and medical nutrition societies: American Society of Parenteral and Enteral Nutrition (ASPEN) and the Academy of Nutrition and Dietetics (AND) websites have posted alternative provisions for feeding patients without utilizing enteral feeding pumps in light of the current national shortages driven by the COVID-19 crisis.¹⁰

Because these mechanically ventilated patients require tube feedings to maintain life, HNC members who are EN formula manufacturers have seen hospital demand shifts increase in certain geographic locations, including cities disproportionately impacted by COVID-19 such as New Orleans and New York. Managing the increased hospital demand requires additional manufacturing ability to meet these dramatically increased patient needs. We understand that the U.S. Food and Drug Administration (FDA) is assessing the availability of these supplies in the U.S. In March and April of 2020, there were significant shortages in select areas of the country. However, additional waves in different portions of the country could overwhelm supply chains.

In response to the COVID-19 pandemic, CMS is now allowing Medicare beneficiaries to obtain amounts of EN products in excess of the usual 30-day limitation. While we appreciate CMS' responsiveness to COVID-19 issues and need for patient care, we are concerned that this will lead to some unnecessary hoarding of supplies, exacerbating anticipated access issues for home care patients.

⁸ Based on HNC member sales information

⁹ See e.g., <https://www.bapen.org.uk/resources-and-education/education-and-guidance/covid-19>.

¹⁰ See organization webpages (www.nutritioncare.org; www.eatright.org; and https://www.nutritioncare.org/Guidelines_and_Clinical_Resources/Resources_for_Clinicians_Caring_for_Patients_with_Coronavirus/#EN).



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Due to Anticipated Shortages and the Dramatically Changed Market, CMS Should Cancel & Rebid or Delay Round 2021 Competitive Bidding Program for Enteral Nutrition

In Round 2021 of the CBP, the lead item (B4035) will drive the payment levels for all other items in the EN product category. If that lead item becomes unavailable or in short supply due to unprecedented high demand from the COVID-19 PHE, EN contractors will not be able to access and provide EN and related pumps and supplies to Medicare beneficiaries. At the same time, the CBP will reduce the number of entities who can provide EN in bid areas, 100 of the largest metropolitan areas; the same areas most impacted by COVID-19.

Based on the facts described above, we urge CMS to cancel Round 2021 of the Competitive Bidding Program for EN. The bids submitted in 2019 are no longer valid due to the COVID-19 health care and resulting economic landscape. If CMS is unwilling to cancel Round 2021 and rebid once the market has stabilized, CMS should at minimum seriously consider a delay in the inclusion of EN in the Round 2021 CBP for at least a year after the PHE, when the EN market has hopefully returned to a stable state similar to the market dynamics pre-COVID-19 PHE.
