Submitted via Email to: regulations.gov

September 13, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements, Proposed Rule; CMS-1751-P

Dear Administrator Brooks-LaSure:

The Healthcare Nutrition Council (HNC) is providing comments on the CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements Proposed rule. HNC is an association representing manufacturers[1] 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. 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.

In line with our mission, we are providing comments on several areas of this year's proposed rule relating to access to nutritional therapies. As detailed further below, HNC:

- **Strongly supports retaining services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023 and urges CMS to expand availability of telehealth to the maximum extent possible.**
- **Opposes removal of National Coverage Determination (NCD) 180.2 for enteral and parenteral nutrition therapy and supports a revision of the current NCD 180.2 to reflect current clinical practice.**

[1] HNC members are Abbott Nutrition, Nestle Healthcare Nutrition, and Nutricia North America.

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- **Strongly supports the proposed MIPS improvement activity, "Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols."**
- **Supports CMS' proposals relating to payment for medical nutrition therapy services and related services and medical nutrition therapy.**

Summary of the importance of addressing malnutrition.

It is widely recognized that nutritional status plays a significant role in health outcomes and healthcare costs. Addressing malnutrition is essential to improving overall healthcare and may ultimately reduce the economic burden incurred when caring for the oldest and sickest Americans. Disease-related malnutrition can manifest in patients across all spectrums of body mass index, ranging from under to overweight individuals, including those presenting with obesity. Malnutrition often is associated with acute and chronic diseases and injury, such as cancer, stroke, infection, trauma, and surgical procedures. Large-scale studies have shown that as many as half of hospitalized patients and 35% to 85% of older long-term care residents are undernourished.[1,2,3,4]

If unaddressed, malnutrition increases the cost of care and likelihood of poor health outcomes, including increased complications, longer hospitalizations, and more readmissions. For example, malnourished patients are more likely to experience complications, such as pneumonia,[5] pressure ulcers,[6] nosocomial infections,[7] and death.[8] In addition, malnutrition is a risk factor for other severe clinical events, such as falls[9] and worse outcomes after surgery or trauma.[10] Falls are especially a concern among individuals considered frail. Malnutrition also has negative impacts on patients with specific chronic diseases and conditions, such as stroke,[11] heart failure,[12] cancer,[13] and COPD.[14] Malnourished patients, as well as patients at risk for malnutrition, have significantly longer hospitalizations than well-nourished patients and patients not at risk for malnutrition.[15]

Additionally, readmission rates, institutionalization, and ongoing healthcare services increase in patients suffering from malnutrition. In particular, disease-related malnutrition is a common reason for patients to be readmitted to hospitals.[16] A study published in *HCUP Statistical Briefs,* developed by the Agency for Healthcare Research and Quality (AHRQ), in 2016 found that malnutrition in U.S. hospitalized patients is associated with a more than 50 percent higher rate of readmission within 30 days, compared to patient stays not associated with malnutrition.[17] In 2021, a draft comparative effectiveness review on malnutrition in hospitalized adults, prepared for AHRQ by the Evidence-based Practice Center, found an association between malnutrition and prolonged hospital stays as well as increased mortality among malnourished patients.[18] Hospitalized patients at risk of malnutrition are also more likely to be discharged to another facility or require ongoing healthcare services after being discharged from the hospital than patients who are not at risk.[19]

Beyond just the effect on utilization and outcomes, malnutrition has an outsized effect on overall cost of care. Malnutrition costs associated with older adults aged 65 years and older who are the most at risk for malnutrition, and largely depending on Medicare, are estimated at $51.3 billion annually.[20] However, this figure likely underestimates the total burden of disease-

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related malnutrition given the diagnosis gap in hospitalized patients.[21] In addition, malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital.[22] Further, the average costs per readmission for patients with malnutrition were found to be 26-34 percent higher ($16,900 to $17,900) compared to those without malnutrition ($13,400).[23] A retrospective health economic study found that providing oral nutritional supplements (ONS) to Medicare patients aged 65+ with any primary diagnosis was associated with a 16% reduction in length of stay and a 15.8% cost savings – an average of $3,079 -- per episode.[24]

Lastly, despite the impact on overall health and the prevalence of malnutrition among hospitalized patients, a patient's nutritional status is often not evaluated or diagnosed in a timely manner. In a recent study conducted by AHRQ using the Healthcare Cost and Utilization Project database, only about 7 percent of hospitalized patients are diagnosed with malnutrition. The extremely low number of those diagnosed with malnutrition represents a screening and diagnosis gap that needs to be addressed. The COVID-19 pandemic has elevated the need to address this gap in care, as recent evidence shows the enormous impact malnutrition has on health outcomes in patients diagnosed with COVID-19.[25] Additionally, outside of a healthcare setting, the economic and social consequences resulting from the pandemic contribute to the risk of food insecurity and malnourishment in the community.[26]

I. **HNC strongly supports retaining services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023 and urges CMS to expand availability of telehealth to the maximum extent possible.**

One of the most important modifications CMS made in response to COVID-19 was to expand the types of providers and types of services permitted to be provided via telehealth during the PHE. CMS also lifted originating site and other telehealth rules that expanded the ability of beneficiaries to quickly access needed services. This greatly benefited patients who are in need of nutrition support and related services due to a chronic condition or as they recover from an acute injury or illness.

HNC supported the creation of a "Category 3" telehealth list in response to CMS's CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies Proposed Rule (CMS-1734-P). It is encouraging to HNC that CMS is now proposing to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023, providing a glide path to evaluate whether the services should be permanently added to the telehealth list following the COVID-19 PHE.

However, in addition to the steps CMS has proposed, HNC urges the agency to expand the availability of telehealth to the maximum extent possible, including expansion of authorized provider types, service types, elimination of any geographic or site restrictions and allowing audio-only when that is the only available option for the telehealth service. It has become apparent that COVID-19 will have a years-long impact on patients and providers, and flexibility will continue to be needed to ensure health care resources are used to the maximum extent possible. In addition, through the experience of COVID-19, providers and suppliers have demonstrated they can provide a wide range of services virtually safely and effectively.

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Therefore, CMS should be confident in the ability of these services to continue to be delivered remotely, when needed, going forward.

If CMS finds it lacks the statutory authority to make the changes fully permanent, it should extend them indefinitely or for the maximum period allowable. In addition, it should seek from Congress the authority to implement further changes as soon as possible. This will ensure that the U.S. health care system is able to continue to effectively respond to COVID-19, and that the system continues to modernize to the fullest extent possible.

Additionally, The Medical Nutrition Therapy Act of 2021 (H.R. 3108/S. 1536), if passed into law, would expand Medicare Part B medical nutrition therapy (MNT) coverage to include prediabetes, obesity, hypertension, dyslipidemia, malnutrition, eating disorders, cancer, gastrointestinal diseases including celiac disease, HIV/AIDS, cardiovascular disease, and conditions related to unintentional weight loss. Access to telehealth services would increase Medicare beneficiaries' access to, and use of, these expanded MNT services. A study published on the perspectives of registered dietitian nutritionists (RDNs) on the adoption of telehealth for nutrition care highlights the fact that the use of telehealth improves clinical outcomes, reduces costs, and is positively received by patients receiving nutrition care. Furthermore, RDNs reported increased use of telehealth care during the pandemic for nutritionally at-risk patients, and "the opportunity for longer assessment time with patients and the ability to 'look in' their home environments to potentially observe their refrigerators and pantries, allowing further examination of their diet and nutrition habits."[27]

Finally, the Biden Administration recognizes the need to expand and improve access to telehealth services in rural and other underserved communities, where patients at risk for food insecurity and/or malnutrition may have limited access to healthcare services. The Administration has announced it is investing over $19 million through the Health Resources and Services Administration to strengthen telehealth services and improve health in these communities,[28] which will help to address health equity in underserved areas.

II. HNC opposes removal of National Coverage Determination (NCD) 180.2 for enteral and parenteral nutrition therapy and supports a revision of the current NCD 180.2 to reflect current clinical practice.

CMS is seeking comments on its proposed removal of NCD 180.2 Enteral Parenteral Nutritional Therapy. HNC agrees with CMS that portions of this NCD are outdated and do not reflect current clinical practice. HNC's comments focus on the enteral nutrition (EN) components, and we support the comments of the American Society for Parenteral and Enteral Nutrition (ASPEN) with regard to the parenteral nutrition (PN) components.

In the Proposed Rule, CMS states that the Agency periodically reviews NCDs and removes outdated NCDs that do not reflect current clinical information. CMS has identified the nutrition related NCD, Enteral and Parenteral Nutritional Therapy (180.2), for removal. HNC has previously commented to CMS that the NCD for enteral nutrition is outdated, however, we recommend that CMS not remove the NCD, but instead begin the process of updating this NCD to reflect current clinical practice.

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HNC is aware that the DME MACs have recently revised and issued an updated LCD for EN (Future LCD 38955). This new LCD is effective on September 5, 2021. We appreciate the improvements in this new EN LCD. This revised EN LCD, however, references the current NCD. Without the NCD language, we are concerned that certain coverage criteria may not be clear.

More specifically, the revised DME MAC EN LCD references language in the current NCD that describes patients with non-functioning structures that normally permit food to reach the digestive tract:

1) New LCD 38955: Home Enteral Nutrition (HEN), Summary of Evidence, paragraph 5

   Coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2. Additionally, benefit category and billing guidance for enteral nutrition are outlined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120 and the Medicare Claims Processing Manual (CMS Pub. 100-4), Chapter 20, Section 30.7. The guidance outlined in these manuals are reflected in the remainder of the LCD.

2) And again, referenced in new LCD 38955: Conclusion, Home Enteral Nutrition

   Based on review of the best available evidence, HEN is appropriate for the management of; and, improves health outcomes for individuals with a diagnosis of maldigestion/malabsorption. Therefore, the Enteral Nutrition LCD will include coverage of EN as reasonable and necessary as nutritional support therapy for the management of Medicare beneficiaries with a diagnosis of maldigestion and malabsorption. As previously noted, coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2.

We therefore urge CMS to update the NCD and not remove it entirely. A revised NCD is important to ensure continued beneficiary access to medically necessary EN therapy.

HNC appreciates CMS' intent to update the Parenteral and Enteral Nutrition (PEN) coverage policy to reflect current practice. We agree there have been many clinical advancements in nutrition science, enteral nutrition products, medical nutrition therapy, and in the delivery of enteral nutrition in the forty years since the creation of NCD 180.2. We also agree that the NCD's coverage criteria should be based on currently available clinical evidence, and any criteria that is not supported by clinical evidence should be reconsidered or removed.

Consistent with the objective to ensure that Medicare coverage of PEN is aligned with current clinical practice, we urge CMS to identify an alternative benefit category outside of the Prosthetic Device Benefit, place PN and EN into that alternative benefit category, and remove the requirement for test of permanence to allow for shorter duration coverage. There are beneficiaries with diseases and conditions that would clearly medically/clinically benefit from shorter duration EN coverage. These conditions include: stroke recovery,[29] short-term inability

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to swallow requiring home enteral nutrition (HEN),[30] post-surgical gastrointestinal (GI) complications with temporary impairment to GI tract requiring HEN,[31] head & neck cancer, short-term swallowing bypass requiring HEN, trauma requiring finite HEN use, and HEN use in burn patients. The example of pancreatitis is presented as evidence in support of specialized nutrition support (SNS) in the LCD 38955.

> *"SNS should be used in patients with acute or chronic pancreatitis to prevent or to treat malnutrition when oral energy intake is anticipated to be inadequate for 5 to 7 days."*
> ASPEN Board of Directors. Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients *J Parenter Enteral Nutr.* 2009;33 (3):255-259.

The National Academy of Sciences recommends the reevaluation of current regulation in the ambulatory care and home health care settings, which excludes coverage for enteral and parenteral nutrition unless the gut is expected to be dysfunctional for at least 90 days, noting, "to avoid the complications of extended semistarvation and possible rehospitalization, reimbursement for enteral or parenteral nutrition in selected Medicare beneficiaries who would otherwise be unable to eat or to assimilate adequate nutrition due to gastrointestinal dysfunction or neurological impairment for longer than 7 days, must be evaluated as a prudent, potentially cost-saving, alternative."[32] Additionally, clinical guidelines from the National Institute for Health and Care Excellence recommend nutrition support should be considered in people who have eaten little or nothing for more than 5 days and/or are likely to eat little or nothing for 5 days or longer.[33]

For the reasons stated above, HNC recommends that CMS not remove the NCD 180.2, but instead update the NCD with current clinical practice and more comprehensive stakeholder feedback. Additionally, HNC urges CMS to identify an alternative benefit category outside of the Prosthetic Device Benefit, place PN and EN into that alternative benefit category, and remove the requirement for test of permanence to allow for shorter duration coverage. It is critical for beneficiaries and suppliers for CMS to engage in a process that ensures Medicare coverage is consistent with current clinical practice, that beneficiaries have access to clinically appropriate nutritional therapies, and confusion is minimized when interpreting the LCD and related policy articles that reference the NCD.

If CMS does remove NCD 180.2, CMS must carefully look at the new existing PN and EN LCDs and update the language to ensure the interpretation and application of the LCDs is accurate and appropriate, maximizes Medicare beneficiaries' coverage, and ensures optimal patient safety and outcomes.

III. HNC strongly supports the proposed MIPS improvement activity, "Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols."

For the 2022 Merit-based Incentive Payment System (MIPS) performance/2024 MIPS payment year and future years, CMS is proposing to add the implementation of food insecurity and nutrition risk identification and treatment protocols as a new improvement activity under the achieving health equity subcategory. HNC strongly supports this new improvement activity and commends CMS' recognition of the need to identify and provide appropriate support to patients with or at risk for food insecurity, and patients with or at risk for poor nutritional status. HNC also wants to ensure CMS continues to be aware that malnutrition in food secure individuals can

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present as either under-nutrition or over-nutrition, and that CMS continues to address the issue of malnutrition for all Medicare beneficiaries.

IV. HNC supports CMS' proposals relating to payment for medical nutrition therapy services and related services and medical nutrition therapy.

HNC commends CMS for proposing actions aimed at increasing utilization of MNT, and supports all proposed changes related to the Part B MNT benefit for the reasons noted by the agency. Additionally, HNC supports the comments of the Academy of Nutrition and Dietetics regarding additional actions CMS should take to ensure the goals of this Medicare benefit are met.

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Malnutrition continues to be a crucial component in reducing hospital-acquired conditions, lowering healthcare costs and improving the health and well-being of vulnerable Medicare beneficiaries. **HNC urges CMS to prioritize policies and initiatives that identify and treat malnutrition, encourage proper nutrition and the development of cost-effective nutrition therapy products, and that ensures access through adequate coverage and payment policies for nutrition therapy products**. HNC stands ready to work with CMS and all stakeholders to develop these policies as one means to improve the public health system. If you have any questions or would like additional information, please contact Justine Coffey, Healthcare Nutrition Council, at jcoffey@healthcarenutrition.org or 202-207-1109.

Sincerely,

Robert Rankin

Robert Rankin
Executive Director

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