



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via regulations.gov

September 6, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts; CMS-1770-P

Dear Administrator Brooks-LaSure:

The Healthcare Nutrition Council (HNC) is providing comments on the CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts Proposed Rule. HNC is an association representing manufacturers¹ of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access of essential nutrition support therapies across 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 the addition of services to the Medicare telehealth services list on a Category 3 basis and urges CMS to expand availability of telehealth to the maximum extent possible.**

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

- **Strongly supports inclusion of health equity measures for future years in MIPS, and strongly recommends that CMS adopt a diagnosis of malnutrition as a measure to address health equity in MIPS.**

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.^{1,2} 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.^{3,4,5,6}

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,⁷ pressure ulcers,⁸ nosocomial infections,⁹ and death.¹⁰ In addition, malnutrition is a risk factor for other severe clinical events, such as falls¹¹ and worse outcomes after surgery or trauma.¹² 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,¹³ heart failure,¹⁴ cancer,¹⁵ and COPD.¹⁶ 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.¹⁷

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.¹⁸ 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.¹⁹ 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.²⁰ 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.²¹

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.²² However, this figure likely underestimates the total burden of disease-related malnutrition given the diagnosis gap in hospitalized patients.²³ In addition, malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital.²⁴ 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).²⁵ 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.²⁶

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-19.²⁷ 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.²⁸

- **HNC strongly supports the addition of services to the Medicare telehealth services list on a Category 3 basis 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 make several services that are temporarily available as telehealth services for the PHE available through CY 2023 on a Category III basis, allowing more time for the collection of data that could support their eventual inclusion as permanent additions to the Medicare telehealth services list. Additionally, HNC supports CMS’ proposal to extend the duration of time that services are temporarily included on the telehealth services list during the PHE, but are not included on a Category I, II, or III basis, for a period of 151 days following the end of the PHE, in alignment with the Consolidated Appropriations Act, 2022.

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.

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 (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."²⁹

- **HNC strongly supports inclusion of health equity measures for future years in MIPS, and strongly recommends that CMS adopt a diagnosis of malnutrition as a measure to address health equity in MIPS.**

CMS is seeking input to better understand the type and structure of health equity measures that would be appropriate for implementation in the Merit-based Incentive Payment System (MIPS). As CMS notes, belonging to a racial or ethnic minoritized group; being a member of a religious minority; living with a disability; being a member of lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level is often associated with worse health outcomes. One approach being employed to reduce health inequity across CMS is the expansion of efforts to report quality measure results stratified by patient social risk factors and demographic variables.

HNC is pleased that CMS is addressing these important and ongoing issues and is seeking public comment to better understand the type and structure of health equity measures that would be appropriate for implementation in MIPS.

Nutritional status, and by consequence malnutrition, is often influenced by a variety of social determinants of health (SDH). According to the World Health Organization (WHO), SDHs are "the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems."³⁰ In many cases, SDHs will have a drastic impact on the availability and quality of foods, how those foods can be prepared and consumed, and what foods will be commonly



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consumed as staple parts of the diet. As a result, SDHs shape a population's nutritional status and may result in certain populations, such as the elderly, disabled, and the poorest segments of society, becoming malnourished.

Malnutrition is a risk factor for severe clinical events, such as loss of lean body mass and risk of frailty and falls, and possibly worse outcomes after surgery or trauma since proper nutrition is critical for healing and recovery.

Malnutrition also contributes to sarcopenia. The prevalence of sarcopenia in intensive care unit (ICU) patients is documented at 56-71%.³¹ Regardless of hospitalization, it is estimated that 5-13% of adults over age 60 years and approximately 50% of adults over 80 years have sarcopenia.³² Adequate nutrition, and specifically adequate protein intake, can help attenuate the declines in muscle mass and function associated with sarcopenia, and reduce the risk of frailty and falls. Multiple international expert groups recommend increased protein intake for older adults, with a minimum of 1.0 to 1.2 g/kg/d for healthy older adults and even higher levels (1.2-1.5 g/kg/d) for those who are malnourished or at risk of malnutrition due to acute or chronic illness.^{33,34}

For these reasons, HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a measure to address health equity in MIPS, to ensure appropriate identification and nutritional management of malnourished patients, make reporting of health disparities based on social risk factors and race and ethnicity, rurality, sexual orientation and gender identity, religion, and disability more comprehensive, and to address gaps in health equity.

HNC also wants to ensure CMS continues to be aware that malnutrition in food secure individuals can present as either under-nutrition or over-nutrition, and that CMS continues to address the issue of malnutrition for all Medicare beneficiaries.

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,

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

Robert Rankin
Executive Director

- ¹ Tyler R, Barrocas A, Guenter P, Araujo Torres K, Bechtold ML, Chan LN, Collier B, Collins NA, Evans DC, Godamunne K, Hamilton C, Hernandez BJD, Mirtallo JM, Nadeau WJ, Partridge J, Perugini M, Valladares A; ASPEN Value Project Scientific Advisory Council. Value of Nutrition Support Therapy: Impact on Clinical and Economic Outcomes in the United States. *JPEN J Parenter Enteral Nutr.* 2020 Mar;44(3):395-406. doi: 10.1002/jpen.1768. Epub 2020 Jan 29. PMID: 31994761.
- ² Mullin GE, Fan L, Sulo S, Partridge J. The Association between Oral Nutritional Supplements and 30-Day Hospital Readmissions of Malnourished Patients at a US Academic Medical Center. *J Acad Nutr Diet.* 2019 Jul;119(7):1168-1175. doi: 10.1016/j.jand.2019.01.014. Epub 2019 Apr 4. PMID: 30954446.
- ³ Robinson MK, Trujillo EB, Mogensen KM, et al: Improving nutritional screening of hospitalized patients: The role of prealbumin. *JPEN J Parenter Enteral Nutr.* 2003 27:389-395.
- ⁴ Chima CS, Barco K, Dewitt MLA, et al: Relationship of nutritional status to length of stay, hospital costs, discharge status of patients hospitalized in the medicine service. *J Am Diet Assoc* 1997 97:975-978.
- ⁵ Braunschweig C, Gomez S, Sheean PM: Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. *J Am Diet Assoc* 2000 100:1316-1322.
- ⁶ Crogan NL, Pasvogel A: The influence of protein-calorie malnutrition on quality of life in nursing homes. *J Gerontol A Biol Sci Med Sci* 2003 58A(2):159-164.
- ⁷ Callahan CM, Wolinsky FD. Hospitalization for pneumonia among older adults. *J Gerontol.* 1996; 51A:M276-M282.
- ⁸ Mechanick JL. Practical aspects of nutritional support for wound-healing patients. *Am J Surg.* 2004;188:52S-56S.
- ⁹ Schneider SM, Veyres P, Pivrot X, et al. Malnutrition is an independent factor associated with nosocomial infections. *Br J Nutr.* 2004; 92:105-111.
- ¹⁰ Correia MI, Waitzberg DL. The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. *Clin Nutr.* 2003;22:235-239.
- ¹¹ Meijers JMM, Halfens RJG, Neyens JCL, et al. Predicting falls in elderly receiving home care: the role of malnutrition and impaired mobility. *J Nutr Health Aging;* 2012; 16: 654-658.
- ¹² Marik PE and Flemmer M. Immunonutrition in the surgical patient. *Minerva Anesthesiologica.* 2012; 78: 336-342.
- ¹³ Davalos A, Ricart W, Gonzalez-Huix F, et al. Effect of malnutrition after acute stroke on clinical outcome. *Stroke.* 1996;27:1028-1032.
- ¹⁴ Zapatero A, Barba R, Gonzalez N, et al. Influence of obesity and malnutrition on acute heart failure. *Rev Esp Cardiol.* 2012; 65(5): 421-426.
- ¹⁵ Lis CG, Gupta D, Lammersfeld CA, et al. Role of nutritional status in predicting quality of life outcomes in cancer – a systematic review of the epidemiological literature. *Nutr J.* 2012; 11:27: 2-18.
- ¹⁶ A.S.P.E.N. Board of Directors and the Clinical Guidelines Task Force. Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients. *JPEN J Parenter Enteral Nutr.* 2002;26(1suppl):1SA-138SA.
- ¹⁷ Chima CS, Barco K, Dewitt ML, et al. Relationship of nutritional status to length of stay, hospital costs, and discharge status of patients hospitalized in the medicine service. *J Am Diet Assoc.* 1997; 97: 975-978.
- ¹⁸ Alvarez-Hernandez J, Planas Vila M, Leon-Sanz M, et al. Prevalence and costs of malnutrition in hospitalized patients; the PREDyCES® Study. *Nutr Hosp.* 2012; 27(4): 1049-1059.
- ¹⁹ Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. *HCUP Statistical Brief #218.* 2018. 1-18.
- ²⁰ Authors to be included in final report. Draft Comparative Effectiveness Review, Malnutrition in Hospitalized Adults, Prepared for the Agency for Healthcare Research and Quality, June 3, 2021.
- ²¹ Zapatero A, Barba R, Gonzalez N, et al. Influence of obesity and malnutrition on acute heart failure. *Rev Esp Cardiol.* 2012; 65(5): 421-426.
- ²² Snider J, et al: Economic burden of community-based disease-associated malnutrition in the United States. *JPEN J Parenter Enteral Nutr.* 2014;38:55-165.
- ²³ Snider JT, Linthicum MT, Wu Y, et al. Economic burden of community-based disease-associated malnutrition in the United States. *JPEN J Parenter Enteral Nutr.* 2014; 38 (Suppl 2): 77S-85S.
- ²⁴ Braunschweig C, Gomez S, Sheean PM. Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. *J Am Diet Assoc.* 2000;100:1316-1322.
- ²⁵ Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. *HCUP Statistical Brief #218.* 2018. 1-18.
- ²⁶ Thomas DR, Zdrowski CD, Wilson MM, et al. Malnutrition in subacute care. *Am J Clin Nutr.* 2002;75:308-313.
- ²⁷ Deepa Handu, PhD, RDN, LDN, Lisa Moloney, MS, RDN, Mary Rozga, PhD, RDN, and Feon W. Cheng, PhD, MPH, RDN, CHTS-CP. Malnutrition Care During the COVID-19 Pandemic: Considerations for Registered Dietitian Nutritionists. *J Acad Nutr Diet* 2021; 121(5): 979-987.
- ²⁸ Id.
- ²⁹ Brunton, Cory, Mary B. Arensberg, Susan Drawert, Christina Badaracco, Wendy Everett, and Sharon M. McCauley 2021. "Perspectives of Registered Dietitian Nutritionists on Adoption of Telehealth for Nutrition Care during the COVID-19 Pandemic" *Healthcare* 9, no. 2: 235. <https://doi.org/10.3390/healthcare9020235>.



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³⁰World Health Organization. Social Determinants of Health.2019. Retrieved from http://www.who.int/social_determinants/en/

³¹Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.

³² Traylor, Daniel; Stefan Gorissen, and Stuart Phillips. Perspective: Protein Requirements and Optimal Intakes in Aging: Are We Ready to Recommend More Than the Recommended Daily Allowance? *Adv Nutr*. 2018; 9:171-182

³³ Bauer, J; Biolo, G; Cederholm, T; Cesari, M; Cruz-Jentoft, AJ; Morley, JE; Phillips, S; Sieber, C; Stehle, P; Teta, D; Visvanathan, R; Volpi, E; and Boirie, Y. Evidence-Based Recommendations for Optimal Dietary Protein Intake in Older People: A Position Paper From the PROT-AGE Study Group. *J Am Med Dir Assoc*. 2013; 14:543-559.

³⁴ Deutz, NE; Bauer, JM; Barazzoni, R; Biolo, G; Boirie, Y; Bony-Westphal, A; Cederholm, T; Cruz-Jentoft, A; Krznarić, Z; Nair, KS; Singer, P; Teta, D; Tipton, K; and Calder, PC. Protein intake and exercise for optimal muscle function with aging: Recommendations from the ESPEN Expert Group. *Clin Nutr*. 2014; 33(6):929-936.