September 12, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
P.O. Box 8010
Baltimore, MD 21244-1810

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; CMS-1772-P

Dear Administrator Brooks-LaSure:

The Healthcare Nutrition Council (HNC) is providing comments on the CY 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs and Rural Emergency Hospitals. HNC is an association representing manufacturers\(^1\) 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, along with CMS priorities, we are providing comments on the application of the Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs. As detailed further below, HNC:

- **Strongly recommends** the inclusion of nutrition quality measures to address health equity in the Hospital Outpatient Quality Reporting (OQR) Program and the Rural Emergency Hospital Quality Reporting (REHQR) Program.

- **Strongly recommends** that CMS include nutrition quality measures to address health equity in the Ambulatory Surgery Center Quality Reporting (ASCQR) Program.

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\(^1\) HNC members are Abbott Nutrition, Nestle Healthcare Nutrition, and Nutricia North America.
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.\textsuperscript{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.\textsuperscript{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,\textsuperscript{7} pressure ulcers,\textsuperscript{8} nosocomial infections,\textsuperscript{9} and death.\textsuperscript{10} In addition, malnutrition is a risk factor for other severe clinical events, such as falls\textsuperscript{11} and worse outcomes after surgery or trauma.\textsuperscript{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,\textsuperscript{13} heart failure,\textsuperscript{14} cancer,\textsuperscript{15} and COPD.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{22} However, this figure likely underestimates the total burden of disease-related malnutrition given the diagnosis gap in hospitalized patients.\textsuperscript{23} In addition, malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital.\textsuperscript{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).\textsuperscript{25} A retrospective health economic study found that providing oral nutritional supplements (ONS) to improve nutritional status for 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.\textsuperscript{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.

I. HNC strongly recommends the inclusion of nutrition quality measures to address health equity in the Hospital Outpatient Quality Reporting (OQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program.

CMS is seeking input on the Request for Information (RFI) included in the FY 2023 Hospital Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System proposed rule (87 FR 19415), titled “Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs.” The RFI describes key considerations across all CMS quality programs when advancing the use of measure stratification to address health care disparities and to advance health equity. HNC commends CMS for addressing these important and ongoing issues and seeking input on the ways to address health equity.

It is extremely important to identify and correctly diagnose malnourished patients and provide them with appropriate nutritional management to ensure recovery, particularly during an emergency room visit. Additionally, as CMS notes, significant and persistent inequities in healthcare outcomes exist in the United States and living in a rural area is often associated with worse health outcomes. And the National Quality Forum (NQF) recently included the Global Malnutrition Composite Score in its 2022 Key Rural Measures: An Updated List of Measures to Advance Rural Health Priorities.\textsuperscript{27} The emergency room treats a broad population of patients and is often used as a source of primary care for individuals without insurance. A CDC report found uninsured adults were more likely than adults with private health insurance or a public health plan to visit the emergency room.\textsuperscript{28} As such, screening for malnutrition in emergency room patients would have a positive impact on the health outcomes of the uninsured patient population, which is often impacted by health disparities and malnutrition prevalence. HNC strongly recommends the inclusion of nutrition quality measures in the Hospital OQR and REHQR Programs, and the inclusion of a diagnosis of malnutrition as part of this reporting.

Recent evidence shows the enormous impact malnutrition has on health outcomes in patients diagnosed with COVID-19.\textsuperscript{29} The COVID-19 pandemic has elevated the need to identify malnourished patients and ensure a diagnosis of malnutrition and related interventions are included in the patient’s care plan. Documentation of the diagnosis and interventions should travel with the patient throughout their continuum of care.

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.\textsuperscript{30} Malnutrition is a risk factor for severe clinical events, such as loss of lean body
mass and risk of falls, and possibly worse outcomes after surgery or trauma, since proper nutrition is critical for healing and recovery. Care provided through an emergency room visit should address these socioeconomic consequences by including an assessment of nutritional status and connecting malnourished patients to community services and access to food. At an August 25, 2021 Congressional Briefing titled Older Adult Nutrition Security: Next Steps for Congress (recording available here), Meredith Ponder Whitmire, JD, Policy Director at Defeat Malnutrition Today, discussed the availability of community-based federal nutrition services for older adults, including the Supplemental Nutrition Assistance Program (SNAP), noting the considerable body of evidence that shows SNAP plays a role in improving food security, economic security, health, and dietary intake throughout the lifespan.

Malnutrition is a critical issue, and malnutrition screening in the outpatient setting, in particular the emergency room department, is necessary to ensure at-risk patients are identified and cared for before experiencing worsening, associated outcomes.

II. HNC strongly recommends that CMS include nutrition quality measures to address health equity in the Ambulatory Surgery Center Quality Reporting (ASCQR) Program.

CMS notes there are a wide array of non-clinical drivers of health known to impact patient outcomes, including social risk factors such as socioeconomic status, housing availability, and nutrition, as well as marked inequity in outcomes based on patient demographics such as race and ethnicity, being a member of a minority religious group, geographic location, sexual orientation and gender identity, religion, and disability status.

Nutritional status, and by consequence malnutrition, is often influenced by a variety of social determinants of health (SDoH). According to the World Health Organization (WHO), SDoH 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.” In many cases SDoH 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 consumed as staple parts of the diet. As a result, SDoH 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.

A patient coming to an ASC from the community could be malnourished but may never have been diagnosed with malnutrition. Patients receiving care in an ASC should be screened for malnutrition, and a diagnosis of malnutrition and related interventions should be properly documented in the patient’s care plan and travel with the patient throughout their continuum of care. As noted above, malnutrition is a risk factor for worse outcomes after surgery or trauma, since proper nutrition is critical for healing and recovery. Additionally, HNC recommends that CMS incorporate nutritional screenings into patients’ Welcome to Medicare preventive visits and annual visits, and ensure malnourished patients are connected to community services, access to food, and to registered dietitian nutritionists who can help educate them on their nutrition needs.
HNC strongly recommends that CMS include nutrition quality measures to address health equity in the ASCQR Program, and the inclusion of a diagnosis of malnutrition as part of this reporting. Including a diagnosis of malnutrition in quality reporting for the ASC setting will ensure appropriate identification and nutritional management of malnourished patients, make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive, and address gaps in health equity.

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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
Executive Director

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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.
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.
27 NQF: 2022 Key Rural Measures: An Updated List of Measures to Advance Rural Health Priorities (qualityforum.org), August 2022.
30 Id.