Submitted via Email

June 28, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program; CMS-1752-P

Dear Administrator Brooks-LaSure:

The Healthcare Nutrition Council (HNC) is providing comments on the Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System proposed rule for Federal Fiscal Year 2022. 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:

- Urges the inclusion of the Global Malnutrition Composite Score (NQF #3592) in the Hospital Inpatient Quality Reporting (IQR) Program;
- Strongly supports inclusion of frailty and malnutrition as future LTCH Quality Reporting Program (QRP) quality measures; and
- Strongly recommends that CMS adopt a diagnosis of malnutrition as a Standardized Patient Assessment Data Element (SPADE) in the LTCH care setting.

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

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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-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

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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 urges the inclusion of the Global Malnutrition Composite Score (NQF #3592) in the IQR Program.

We were disappointed that a malnutrition-related measure was not included in the 2022 Proposed IQR Program. CMS has long recognized the burden of hospital malnutrition and has previously indicated interest in a composite malnutrition quality measure for inpatient reporting. The Global Malnutrition Composite Score (NQF #3592) was under consideration and received considerable support from a diverse group of stakeholders including CMS' measures application committees and the National Quality Forum endorsement committee. We believe it is essential that CMS make nutritional status a key component in both its reimbursement policies and its efforts to improve the quality and value of care delivery. As such, we urge CMS to move forward with inclusion of the Global Malnutrition Composite Score in the IQR Program in the FY 2022 IPPS final rule.

II. HNC strongly supports inclusion of frailty and malnutrition as future LTCH QRP quality measures.

CMS is seeking input on the importance, relevance, appropriateness, and applicability of measures and concepts under consideration for future years in the LTCH QRP. The LTCH QRP currently has 17 measures for the FY 2022 program year, including Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay). 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.

We strongly support the inclusion of frailty on the list of measures and concepts under consideration since a diagnosis of frailty is linked to a risk of falls and adverse clinical events following a fall. Malnutrition contributes to frailty, and these two conditions share overlapping risk factors.[27]

Malnutrition also contributes to sarcopenia and the loss of the lean body mass, which can contribute to frailty and risk of falling. The prevalence of sarcopenia in intensive care unit (ICU) patients is documented at 56-71%.[28] Regardless of hospitalization, it is estimated that 5-13% of

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adults over age 60 years and approximately 50% of adults over 80 years have sarcopenia.[29] 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.[30,31]

Malnutrition is a critical issue and travels with the patient through all healthcare settings. In one study, 42.5% of patients whose stay in an acute care hospital was equal to or greater than two weeks were diagnosed with malnutrition.[32] Patients should be screened for malnutrition when admitted to an LTCH, and rescreened throughout their stay and prior to transitioning to another setting to ensure continuity in care.

For these reasons, HNC urges CMS to include malnutrition as a quality measure in the LTCH QRP for future years.

III. HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a SPADE in the LTCH care setting.

CMS is seeking guidance on any additional SPADEs that could be used to assess health equity in the care of LTCH patients, for use in the LTCH QRP.

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."[33] 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.

CMS notes that significant and persistent inequities in health outcomes exist in the United States, and the COVID-19 pandemic has emphasized many longstanding health inequities, with higher rates of COVID-19 infection and mortality among black, Latino, and Indigenous and Native American persons relative to white persons. HNC commends CMS for addressing these important and ongoing issues, and is seeking comment on the possibility of revising measure development, and the collection of other SPADEs that address gaps in health equity, to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for providers and patients. Therefore, HNC implores CMS to include assessing and identifying malnutrition in these important changes.

SPADEs are an important tool to gather information about care being provided across care settings. SPADEs should incorporate all relevant aspects of patient care and outcomes, and nutritional related elements are a crucial aspect of that care.

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HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a standardized data element, to 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 to 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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