Submitted via Email

June 7, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1748-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program Proposed Rule; CMS-1748-P

Dear Administrator Brooks-LaSure:

The Healthcare Nutrition Council (HNC) is providing comments on the Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal Fiscal Year 2022 and Updates to the IRF Quality Reporting Program (QRP) 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.

HNC is pleased to provide comments on IRF quality reporting requirements in response to the Centers for Medicare and Medicaid Services' (CMS) request for information relating to measures and concepts under consideration for future years in the IRF QRP, and additional items for use in the IRF QRP, including Standardized Patient Assessment Data Elements (SPADEs), that could be used to assess health equity in the care of IRF patients. As detailed further below, HNC:

- Supports the inclusion of frailty as a future IRF QRP quality measure, and requests consideration of additional nutrition quality measures for inclusion; and

- Strongly recommends that CMS adopt a diagnosis of malnutrition as a SPADE to ensure the 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.

I. Background on the importance of addressing malnutrition

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

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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. 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 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] 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 vulnerable to becoming malnourished.[18]

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 of malnutrition, and largely depend on Medicare, are estimated at $51.3 billion annually.[19] However, this figure likely underestimates the total burden of disease-related malnutrition given the diagnosis gap in hospitalized patients.[20] In addition, malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital.[21] Further, the average costs per readmission for patients with malnutrition were found to be 26-34 percent higher ($16,900 to $17,900) for patients with malnutrition compared to those without malnutrition ($13,400).[22] 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.[23]

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 the Agency for Healthcare Research and Quality using the Healthcare Cost and Utilization Project database, only about 7 percent of hospitalized patients are diagnosed with malnutrition. The extremely low number of diagnosis for

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malnutrition represents a screening and diagnosis gap that needs to be addressed. The COVID-19 pandemic has highlighted 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. Additionally, outside of a healthcare setting, the economic and social consequences resulting from the pandemic contribute to the risk of food insecurity and malnourishment.[24]

Based on the aforementioned evidence, 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. This should include being mindful of the outsized clinical value of nutritional status, despite the fact malnutrition is often only indicated as a secondary or comorbid condition for many patients. Further, CMS should continue to implement more nutritional-related items into its quality and value programs, including in the IRF Quality Reporting Program (QRP).

II. HNC supports frailty as a future IRF QRP quality measure, and in addition, strongly recommends the inclusion of nutrition quality measures.

CMS is seeking input on the importance, relevance, appropriateness, and applicability of measures and concepts under consideration for future years in the IRF QRP. The IRF 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 are encouraged to see frailty included 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.[25]

Malnutrition also contributes to sarcopenia and the loss of the lean body mass. In the rehabilitation setting, approximately 50% of older patients are diagnosed with sarcopenia.[26] The prevalence of sarcopenia in intensive care unit (ICU) patients is documented at 56-71%.[27] 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.[28] 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.[29,30]

For these reasons, HNC strongly recommends that CMS also consider the inclusion of nutrition quality measures in the IRF QRP for future years.

III. HNC strongly recommends that CMS adopt a diagnosis of malnutrition as a SPADE to ensure the 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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CMS is seeking guidance on any additional items, including SPADEs, that could be used to assess health equity in the care of IRF patients, for use in the IRF QRP.

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."[31] 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 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.

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 infection and mortality among black, Latino, and Indigenous and Native American persons relative to white persons. HNC is pleased that CMS is 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.

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. HNC supported the standardization of the Parenteral/IV Feeding, Feeding Tube, Mechanically Altered Diet, and Therapeutic Diet data elements in the IRF Quality Reporting Measures Program in response CMS's FY 2018 IRF Prospective Payment System Proposed Rule (CMS-1671-P).

HNC strongly recommends that CMS now 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, encourages proper nutrition and the development of cost-effective nutrition therapy products, and 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

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you have any questions or would like additional information, please contact Berit Dockter, Healthcare Nutrition Council, at bdockter@healthcarenutrition.org or 202-207-1112.

Sincerely,

Robert Rankin

Robert Rankin
Executive Director

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