HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

June 24, 2019

Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1716-P; 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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; 84 Fed. Reg. 19158 (May 3, 2019).

Dear Administrator Verma:

On behalf of the Healthcare Nutrition Council (HNC), we are writing in response to the Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) proposed rules for fiscal year 2020. 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. Our organization 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 provide comments on several areas of this year's proposed rule relating to access to nutritional therapies. As is detailed further below, our letter expresses concern about the proposed reclassification of malnutrition complication and comorbidities. HNC also encourages CMS to consider including malnutrition quality measures in the Inpatient Quality Reporting (IQR) Program, as well as LTCH Quality Reporting Program (QRP). Finally, our comments offer support for CMS' proposal to include diet and feeding measures in the Standardized Patient Assessment Data Elements (SPADEs) within the LTCH PPS, and to consider additional measures in the LTCH Quality Reporting Program (LTCH QRP).

I. Background on 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

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

mass index, ranging from under to overweight individuals. Malnutrition often is associated with acute and chronic diseases and injury, such as cancer, stroke, chronic obstructive pulmonary disease, heart failure, 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.[i,ii,iii,iv]

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,[v] pressure ulcers,[vi] nosocomial infections,[vii] and death.[viii] In addition, malnutrition is a risk factor for other severe clinical events, such as falls[ix] and worse outcomes after surgery or trauma.[x] Malnutrition also has negative impacts on patients with specific chronic diseases and conditions, such as stroke,[xi] heart failure,[xii] cancer,[xiii] and COPD.[xiv] 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.[xv]

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.[xvi] 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.[xvii] 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 for malnutrition.[xviii]

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.[xix] However, this figure likely underestimates the total burden of disease-related malnutrition given the diagnosis gap in hospitalized patients.[xx] In addition, malnourished patients and patients with nutrition related or metabolic issues are frequently readmitted to the hospital.[xxi] 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).[xxii] 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.[xxiii]

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.[xxiv] With as many as half of hospitalized patients and

35-85% of older long-term care residents undernourished, the extremely low number of diagnosis for malnutrition represents a screening and diagnosis gap that needs to be addressed.

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 IQR program and its various post-acute care quality reporting programs.

II. HNC Opposes the Reclassification of E43 (Unspecified severe protein-calorie malnutrition)

CMS proposes to reclassify ICD-10 code E43 (Unspecified severe protein-calorie malnutrition) from a major complication or comorbidity (MCC) to a complication or comorbidity (CC) when E43 used as a secondary diagnosis. In addition, CMS proposes to reclassify E44.0 (Moderate protein-calorie malnutrition) from a CC to a MCC. HNC believes the change in E43's status is not supported by data and contrary to sound clinical judgement.

CMS proposes to upgrade E44.0 (described as *moderate*) to an MCC but downgrade E43 (described as *severe*) to a CC. CMS' own data refutes this move, as the FY 2020 NPRM Measure of Impact Use Supplementary File (lines 827-828) shows higher values in all fields for E43 (severe) when compared to E44.0 (moderate). E43 Unspecified Severe Protein-Calorie Malnutrition is the only available ICD-10 code for severe malnutrition. Therefore, E43 should remain as an MCC, consistent with its resource use being higher than E44.0. In addition, reclassifying E43 to CC status would misalign the entire malnutrition code family. E44.1 (*mild* malnutrition) is classified as CC. If CMS were to finalize this proposal, mild and severe malnutrition diagnosis would both be CC, while moderate would be a MCC.

All instances of malnutrition are serious conditions with outsized effect on patient outcomes and resource use. Even if CMS has some data to support the change - besides the fact that data should be presented to stakeholders for comment – CMS wisely does not usually implement changes that are contrary to sound clinical judgement. In this case it is evident, both facially and based on the previously presented evidence regarding the clinical impact of malnutrition, that a moderate malnutrition diagnosis should not be considered more resource intensive than a severe malnutrition diagnosis. **For the aforementioned reasons, CMS should not finalize its proposal to reclassify E43 and retain its status as an MCC.**

Finally, HNC supports CMS reclassifying E44.0 as an MCC. Due to the evidence discussed before regarding the seriousness of malnutrition, CMS should always err towards weighing malnutrition more heavily. Upgrading E44.0, but not downgrading E43, would properly align the malnutrition family of codes, with moderate and severe being a MCC, and mild being a CC.

III. HNC Urges CMS to Include Nutrition Related Electronic Clinical Quality Measures (eCQMs) in the Inpatient Quality Reporting (IQR) Program

CMS states that the goal of the Inpatient Quality Reporting (IQR) Program is to drive quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care. Due to the momentous role nutrition plays in patient care and outcomes, CMS should incorporate malnutrition items into the IQR program to ensure patients have a complete picture about the vital elements of care provided by hospitals. **HNC recommends the following malnutrition electronic clinical quality measures (eCQMs) which have been adopted by the National Quality Forum (NQF) be included in the hospital IQR Program:**

- NQF #3087/MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission
- NQF #3088/MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening
- NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
- NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis

IV. HNC Supports Inclusion of Nutrition Related Long-Term Care Hospital (LTCH) Standardized Patient Assessment Data Element (SPADE) Items and Requests Consideration of Additional Nutrition Quality Measures in LTCH Quality Reporting Program (QRP)

CMS proposes to include four nutritional related items in the Standardized Patient Assessment Data Elements (SPADEs) for Long-Term Care Hospital (LTCHs). The SPADEs are 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. Therefore, HNC supports inclusion of the Parenteral/IV Feeding, Feeding Tube, Mechanically Altered Diet, and Therapeutic diet data elements in the SPADEs for LTCHs and encourages CMS to finalize its proposal. In addition, we request that a diagnosis of malnutrition be considered a standard data element, to ensure appropriate identification and nutritional management of malnourished patients.

In addition to supporting inclusion of nutritional measures in the LTCH SPADEs, HNC encourages CMS include additional nutritional in the LTCH QRP. We were encouraged to see nutritional quality measures and measure concepts on the list of areas under consideration for future inclusion in the LTCH QRP in this proposed rule. As HNC recommended for the IQR Program, HNC recommends CMS consider the following NQF items for inclusion in the LTCH QRP:

- NQF #3087/MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission
- NQF #3088/MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening

- NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment
- NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis

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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 you have any questions or would like additional information, please contact Jonathan Gold via email or at 202-860-1004.

Sincerely,

Robert Rankin
Executive Director
Healthcare Nutrition Council

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