Healthcare Nutrition Council

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October 7, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1632-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Quality Measure Development and Maintenance for CMS Programs Serving Medicare-Medicaid Enrollees and Medicaid-Only Enrollees. Measures for dual enrollees and Medicaid beneficiaries using home- and community-based services (HCBS)

Dear Acting Administrator Slavitt:

The Healthcare Nutrition Council (HNC), representing manufacturers of enteral nutrition formulas, parenteral nutritional formulas, supplies and equipment, submits these comments on Quality Measure Development and Maintenance for CMS Programs Serving Medicare-Medicaid Enrollees and Medicaid-Only Enrollees. Measures for dual enrollees and Medicaid beneficiaries using home- and community-based services (HCBS). Our primary recommendation to CMS can be summarized as follows:

> *HNC urges CMS to advance quality measures that promote systematic nutrition screening, assessment, diagnosis, and appropriate nutrition intervention when considering quality measures appropriate for this population of Medicaid enrollees. A set of malnutrition care quality measures has recently been submitted to CMS by the Academy of Nutrition and Dietetics and is described in more detail in the following comments. As one of the stated goals of CMS' project is to "identify and prioritize candidate measures and measure concepts for development," we urge CMS to prioritize nutrition measures given their importance, scientific validity and reliability to assess the enrollee's overall health.*

It is widely recognized that nutritional status plays a significant role in health outcomes and healthcare costs. Malnutrition generally is defined as "an acute, subacute or chronic state of nutrition, in which varying degrees of over nutrition or undernutrition with or without inflammatory activity have led to a change in body composition and diminished function."[i] **Malnutrition has also been defined as a state of nutrition in which a deficiency, excess, or imbalance of energy, protein, and other nutrients cause measurable adverse effects on body function and clinical outcomes.**[ii] There are three common types of malnutrition diagnoses for adults in clinical practice settings: (1) starvation-related malnutrition; (2) chronic disease-related malnutrition; and (3) acute disease or injury-related malnutrition.[iii]

In these comments, we refer to chronic disease-related malnutrition, acute disease or injury-related malnutrition as well as hospital-acquired malnutrition generically as disease-related malnutrition. Disease-related malnutrition can have similar distinct nutrient requirements altered across all spectrums of body mass index, ranging from under to overweight individuals.

For over 30 years, 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.[iv,v,vi,vii,viii,ix,x] Patients living in the community also may be malnourished and at risk of malnutrition, with reports of malnourished residents in long-term care institutions as high as 57% .[xi] According to Kaiser Et.al. "In the community, poor nutritional status is present before disease appears, as is risk of malnutrition…systematic and structured nutritional screening is recommended for early detection of malnutrition to counteract the decline of health status caused by deficiencies in macro- and micronutrients.

Significantly, patients' nutritional status often is not evaluated or diagnosed in a timely manner despite the common occurrence and clinical relevance of malnutrition in older adults. 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.[xii] With as many as half of hospitalized patients and 35 to 85% of older long-term care residents undernourished, the extremely low number of diagnosis for malnutrition represents a diagnosis and gap that needs to be addressed. Towards this end, effective quality measures associated with malnutrition are particularly important when considering quality measures for development in regards to dual enrollees and Medicaid beneficiaries HCBS and will improve diagnosis rates and treatment among this population of enrollees.

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. Many of these conditions may also qualify an enrollee dependent upon income for Medicaid long-term care utilizing HCBS. These diseases and conditions may cause an individual to become malnourished with malassimilation and/or inappropriate provision of nutrients. Overall patient care and outcomes are affected by nutrition care management, which includes timely diagnosis and application of appropriate treatment of malnutrition. Key measureable outcomes that can be positively affected by appropriate nutrition intervention, such as oral nutrition supplements, enteral or parenteral nutrition, include the following:

- **Morbidity, Complications and Mortality:** Malnourished patients are more likely to experience complications, such as pneumonia,[xiii] pressure ulcers,[xiv] nosocomial infections,[xv] and death.[xvi, xvii]In addition, malnutrition is a risk factor for other severe clinical events, such as falls[xviii] and worse outcomes after surgery or trauma.[xix] Malnutrition has a negative impact on patients with specific chronic diseases and conditions, such as stroke patients,[xx, xxi] and patients with heart failure,[xxii] cancer,[xxiii, xxiv] or COPD.[xxv]
- **Length of Stay:** 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.[xxvi xxvii xxviii]
- **Readmission, Institutionalization and Ongoing Services:** Disease-related malnutrition is a common reason for patients to be readmitted to hospitals.[xxix] One recent study found that malnourished patients with heart failure were 36 percent more likely to be readmitted to the hospital within 30 days than nourished patients with heart failure.[xxx] Additionally, hospitalized

patients at risk of malnutrition are 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.[xxxi, xxxii] A recent retrospective health economic study found that providing oral nutritional supplements 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.[xxxiii]

- **Health Care Costs:** Disease-related malnutrition, particularly when not diagnosed and treated, increases the cost of care due to the factors described above: increased morbidity, complications and mortality, longer hospitalizations, and more readmissions, continued institutionalizations and ongoing health care services.
    - **A 2014 study estimates that the annual burden of disease-related malnutrition for older adults aged 65 years and older across eight diseases was $51.3 billion.[xxxiv] The authors hypothesize that their findings likely underestimate the total burden of disease-related malnutrition since its rates are much higher in hospitalized patients.[xxxv]** The cost impact of untreated malnutrition is illustrated below:
    - **Costs Related to Increased Morbidity and Complications:** High-risk malnourished patients are 2.1 times more likely to develop pressure ulcers than well-nourished patients.[xxxvi] One study cited the average cost for hospital treatment of a stage IV pressure ulcer acquired in the hospital (including the treatment of associated medical complications) to be $129,248. The average cost of hospital treatment of a stage IV pressure ulcer acquired in the community (including the treatment of associated medical complications) was $124,327.[xxxvii]
    - **Costs Related to Hospitalizations:** Hospitalized malnourished patients, patients at risk for disease-related malnutrition and patients who experience declines in their nutritional status while hospitalized have higher health care costs than well-nourished patients, patients not at risk for malnutrition, and patients who remain properly nourished during their hospitalizations, respectively.[xxxviii, xxxix, xl] Patients frequently experience declines in their nutritional status while hospitalized.
    - **Costs Related to Readmissions:** Malnourished patients and patients with nutrition related or metabolic issues are frequently readmitted to the hospital.[xli, xlii] Studies have demonstrated that readmissions are 24-55% more costly than initial admissions and account for 25 percent of Medicare expenditures.[xliii] One study found that there were 11,855,702 Medicare fee-for-service patients discharged from hospitals between October 1, 2003 and September 30, 2004 who were at risk for rehospitalization; 19.6 percent of the patients were readmitted within 30 days, resulting in a cost of $17.4 billion.[xliv]

Timely, appropriate clinical nutrition therapies can improve or maintain patients' nutritional status, and result in less morbidity and fewer complications, shorter hospital stays, fewer hospitalizations, reduced hospital readmissions and savings. For example, oral nutritional supplements (ONS) for hospitalized patients are associated with reductions in hospital lengths of stay, admission rates and costs.[xlv] Specialized nutritional products designed to meet the unique nutritional needs of major surgery patients with distinct nutrient ingredients have been proven to significantly reduce post-operative infectious complications which include nosocomial pneumonia, surgical site infections, anastomotic leaks, and urinary tract infections.[xlvi,xlvii] Despite these benefits, utilization has been low among hospitalized patients since providers are not incentivized under the Medicare fee-for-service payment model to furnish ONS to these patients.[xlviii]

Similar to ONS, early usage of parenteral nutrition products in combination with enteral nutrition products or when enterals alone are not feasible also results in many of the beneficial patient outcomes noted above. For example, the early administration of combined parenteral and enteral nutrition has been shown to decrease ICU stays and decreases in nosocomial infections, antibiotic use, and lead to shorter duration of mechanical ventilation.[xlix] [l] Other recent research has shown no significant difference in 30 and 60 day mortality or infection rates associated with the route of delivery, either parenteral or enteral, of early nutritional support in critically ill adults.[li] [lii] Regardless of the route of delivery, the research clearly shows that early diagnosis and effective treatment of malnutrition can improve patient outcomes, reduce morbidity and lower overall costs of care.

We urge CMS to take action on the health and economic impact of disease-related malnutrition to help achieve our shared goals of "Better Care, Smarter Spending and Healthier People." A key step towards addressing the health and economic impact of disease-related malnutrition is to establish quality measures that promote systematic nutrition screening, assessment, diagnosis and appropriate nutrition intervention to both measure progress and better assess the overall health of enrollees. This is particularly important in the context of dual enrollees HCBS given the expectation that enrollees will be treated over relatively long periods of time and the HCBS goals of focusing on the nature and quality of individuals' experiences and increasing care delivery in a manner reflecting personal preferences and ensuring health and welfare. Good nutrition care can help decrease disability which is critical for older adults to remain independent and in their own homes.

In 1974, a seminal paper was published that identified several factors that contribute to malnutrition such as: lack of awareness of increased nutritional needs for injury/illness and the role of nutrition in infection; not prioritizing nutrition for surgical patients; gaps in communication between clinical teams and physicians; and delayed nutrition intervention.[liii]

These issues are still relevant in our current healthcare delivery system, including in long-term and community/home based care settings and may adversely affect timely diagnosis, patient care, outcomes, and healthcare costs. However, screening patients for malnutrition, providing follow-up assessments when indicated, documenting the medical diagnosis in the electronic medical record, and furnishing appropriate nutrition interventions can be cost-effective, improve patient care and outcomes, and ensure that the condition of malnutrition is available for reporting and continuity of patient care.

The Academy of Nutrition and Dietetics and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) has published a consensus statement that provides an overview of the general characteristics used to diagnose malnutrition and strategies to implement these criteria as part of a comprehensive malnutrition program.[liv] Detecting risk factors and accurately diagnosing malnutrition can be done easily by routinely screening patients in all settings for malnutrition and providing patients with timely, follow-up assessments, if needed. Once a diagnosis is determined, and if further nutritional intervention is indicated, then providing patients with appropriate nutrition therapies, including oral nutrition supplements, enteral or parenteral nutrition, and nutrition-related services in a timely manner can improve or maintain patients' nutritional status. As a result of detecting, preventing, diagnosing, and treating disease-related malnutrition, individuals will experience less morbidity and fewer complications, shorter hospital stays, and fewer hospitalizations and hospital readmissions. Quality of life indicators, such as increased or sustained mobility, will also increase.

HNC commends CMS for recognizing the importance of evaluating and maintaining patients' nutritional status, such as the recent Proposal for Provision of Services: Authorizing Dieticians to Write Therapeutic Diet Orders in Critical Access Hospitals. In addition, a final rule that was published in the Federal Register on May 12, 2014, CMS expanded the scope of professionals who may prescribe patient diets in the hospital setting to include registered dietitian nutritionists and other clinically qualified nutrition professionals.[lv] HNC encourages CMS to continue pursuing policies that promote identifying, preventing, diagnosing, and treating disease-related malnutrition in a timely manner.

HNC strongly believes that malnourished patients in all settings of care, including the hospital, long-term care and community/home care settings, should be identified and furnished with timely, clinically indicated nutritional treatments. Thus, HNC recommends CMS promote quality measures that:

1. Identify untreated malnutrition, including disease-related malnutrition as a hospital-acquired condition to encourage hospitals to develop and implement policies and procedures that encourage nutrition screening, assessment, diagnosis, and appropriate nutrition intervention. As demonstrated above, untreated malnutrition satisfies the requirements for being included as a hospital-acquired condition since it is (1) high cost or high volume or both, (2) can result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) can reasonably be prevented through the application of evidence-based guidelines.[lvi] In addition, undiagnosed and untreated malnutrition increases the likelihood that patients will experience other patient safety conditions already included on CMS' list of hospital-acquired conditions, such as stage III and IV pressure ulcers, falls and trauma, as well as surgical site infections.
2. Promote the development of quality measures that encourage nutrition screening, assessment, diagnosis, and appropriate nutrition intervention. HNC suggests that CMS incorporate such measures into a future Inpatient Quality Reporting Program, Hospital Value-Based Purchasing Program, Long-Term Care Hospital Quality Reporting Program and other appropriate initiatives that measure quality of care.

While we are not aware of any existing endorsed National Quality Forum (NQF) quality measures related to adult nutrition, we believe this is a critical gap and this project offers one opportunity to address it. Towards this end, we call your attention to the electronic Clinical Quality Measures (eCQMs) recently submitted by the Academy of Nutrition and Dietetics (AND) to the NQF for endorsement and to CMS for consideration. The four malnutrition electronic measures were provided to CMS for review and acceptance into the Federal Quality Program - Hospital Inpatient Quality Reporting Program. They include the following:

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

HNC believes that these eCQMs represent a major step forward in accurately quantifying quality in the healthcare system as it relates to malnutrition care, a key component of patient health. Measuring and reporting on these four eCQMs will help to ensure that care is delivered safely, effectively, equitably and timely. As such, HNC urges CMS to accept these measures and consider similar measures for other quality programs such as this project. We also note that these proposed eCQMs can be applicable to other Medicare and Medicaid enrollee populations, including those outside of hospital setting, such as those in community or home care programs.

Thank you for the opportunity to comment on this proposed rule. If you have any questions or would like additional information, please contact me at ngardner@kellencompany.com or 202-207-1116.

Sincerely,

Nicholas Gardner
Executive Director
Healthcare Nutrition Council

[i] American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors and Clinical Practice Committee. Definition of terms, style, and conventions used in A.S.P.E.N. Board of Directors–approved documents. American Society for Parenteral and Enteral Nutrition. http://www.nutritioncare.org/Professional_Resources/Guidelines_and_Standards/Guidelines/2012_Definitions_of_Terms,_Style,_and_Conventions_Used_in_A_S_P_E_N__Board_of_Directors-Approved_Documents. Published May 2012. Accessed April 9, 2014.

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