
Healthcare Nutrition Council

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July 12, 2017

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

RE: Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients CMS-9928-NC

Dear Administrator Verma:

The Healthcare Nutrition Council (HNC), representing manufacturers of enteral nutrition formulas, parenteral solutions, supplies and equipment, submits these comments on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI), "Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act (PPACA) & Improving Healthcare Choices to Empower Patients (CMS-9928-NC)". Investing in the health of our nation's most vulnerable patients is critically important and will result in better patient outcomes and lower costs associated with complications in these populations. We applaud the Agency for its attention to ways in which healthcare system can be more patient-centered and adhere to the key healthcare principals of affordability, accessibility, quality, innovation, and empowerment. HNC would like to specifically provide feedback for CMS on enhancing affordability for the current and future healthcare system. The issuance of this RFI and review of stakeholder feedback is an important step to ensure healthier Americans and a better grasp of the regulatory burdens restricting quality care, access and affordability for patients.

Our primary recommendations to CMS can be summarized as follows:

HNC recommends CMS focus on the adoption of malnutrition quality measures and additional cost-cutting measures related to nutrition and malnutrition that lead to the earlier screening, diagnosis and treatment of malnutrition. Proactive nutrition support and nutrition care focused on prevention is fundamental to keeping patients healthy. Those suffering from acute and chronic conditions can be particularly at risk for malnutrition which can impact both the course and treatment of their disease as well as their long-term health outcomes. HNC urges CMS to keep in mind that malnutrition increases the cost of care due to factors such as increased morbidity, complications and mortality, longer hospitalizations and more readmissions, continued institutionalizations and ongoing health care services when looking at regulatory burdens and enhancing affordability in the healthcare system.

Malnutrition Background

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 generically as disease-related malnutrition. 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, chronic obstructive pulmonary disease, heart failure, infection, trauma and surgical procedures. In fact, these diseases

and conditions may cause an individual to become malnourished with malassimilation and/or inappropriate provision of nutrients. 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}

Addressing malnutrition is necessary to reduce hospital-acquired conditions, lower healthcare costs and improve the health and well-being of vulnerable patients. Research has shown that malnourished older adults make more visits to physicians, hospitals and emergency rooms than non-malnourished patients. Malnourished or at-risk patients can also continue to worsen through an inpatient stay, for instance acquiring a hospital-acquired condition, which may lead to increased healthcare costs for the patient and their family. Also, a 2017 statistical brief released by AHRQ presented national data on U.S. hospital discharges involving malnutrition, demonstrating that significant burden that malnourished patients face. For example, patients tend to be older, have up to 100% longer lengths of stay and 100% costlier episodes of inpatient care (up to \$25,000 versus \$12,500).^{xi} Due to the link between malnutrition and healthcare acquired infections and complications, there have been recent calls for healthcare policy change to address this issue.^{xii}

Malnutrition Linked to Poor Health Outcomes

HNC agrees with CMS that “malnutrition is associated with many adverse outcomes.” Unaddressed, it also 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,^{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 also has negative impacts on patients with specific chronic diseases and conditions, such as stroke,^{xx xxxi} and heart failure,^{xxii} cancer,^{xxiii xxiv} and COPD.^{xxv} 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}
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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.^{xxix} 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 identified with malnutrition.^{xxx} Another 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.^{xxxi} 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.^{xxxii, xxxiii} A 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.^{xxxiv}

Adopting malnutrition related quality measures will help to improve monitoring for disease-related malnutrition, ensure timely diagnosis and treatment with appropriate clinical nutrition therapies, and will help improve or maintain patients’ nutritional status contributing to their overall health. Appropriate and timely 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. Oral nutritional supplements (ONS) for hospitalized patients are associated with reductions in hospital lengths of stay, admission rates and costs.^{xxxv} Additionally, the early usage of parenteral nutrition products in combination with enteral products when enterals alone are not feasible result in many beneficial patient outcomes. The early administration of combined parenteral and enteral nutrition has been shown to decrease intensive care unit (ICU) stays and decreases in nosocomial infections, antibiotic use, and lead to shorter duration of mechanical ventilation.^{xxxvi xxxvii} Given the potential complications that result when a patient is malnourished, adopting malnutrition measures and prevention techniques will help to promote shorter hospital stays, reduced hospital readmissions and result in overall and long-term health care savings.

Malnutrition Linked to Increased Health Costs

Disease-related malnutrition, particularly when not diagnosed and treated, increases the cost of care due to the factors described above: increased morbidity, complications, mortality, readmissions, longer hospitalizations, continued institutionalizations and ongoing healthcare services. The economic burden of malnutrition across care settings in the United States was estimated at \$157 billion in 2014. 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.^{xxxviii} However, this figure likely underestimates the total burden of disease-related malnutrition given the diagnosis gap in hospitalized patients.^{xxxix} Malnutrition is a silent epidemic in the U.S. today.

The existing literature provides a wealth of data supporting the association between malnutrition and increased morbidity, complications, hospitalizations, and readmissions. For example, malnourished patients and patients with nutrition related or metabolic issues are frequently readmitted to the hospital.^{xi xli} Studies have demonstrated that readmissions are 24-55% more costly than initial admissions and account for 25 percent of Medicare expenditures.^{xliii} Data from 2013 showed that 30-day hospital readmission rates for all causes (other than maternal or neonatal) to be more than 50 percent higher for patients with malnutrition. Rates of readmission were found to be highest among adults aged 18-64 years, those paid by Medicaid and those residing in metropolitan areas. 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).^{xliiii} Another study shows that patients with a high-risk of malnutrition are 2.1 times more likely to develop pressure ulcers than well-nourished patients.^{xliv} One study even 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.^{xlv}

Including Malnutrition Measure Set to Address Malnutrition

Addressing malnutrition through these cross-cutting quality measures are essential to enhancing affordability by collecting data to improve overall healthcare and may ultimately reduce economic burden incurred when caring for the oldest and sickest Americans. We agree with CMS that “there is an opportunity for hospitals to improve nutrition screening and assessment”, which includes timely diagnosis and application of appropriate treatment of malnutrition.

Malnutrition measures serves a specific role for ensuring that a multidisciplinary care team comprised of nurses, dietitians, physicians and others care for the patient with a focus on risk identification and risk reduction. HNC urges CMS to specifically adopt four malnutrition electronic clinical quality measures (eCQMs) to address the first four key components in the nutrition care process beginning with screening to identify those patients truly at risk, continue with the nutrition assessment performed by a registered dietitian to outline the patient’s nutrition status and provide recommendations to guide the care plan, and conclude with the provider medical diagnosis of malnutrition.

The four malnutrition quality measures HNC supports are listed below:

- **MUC16-294: Completion of a Malnutrition Screening within 24 hours of Admission:** Screening patients upon admission to a healthcare facility is a low-burden way to identify patients at-risk for poorer outcomes due to their nutritional status and initiate appropriate care.
- **MUC16-296: Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 hours of a Malnutrition Screening:** A full nutrition assessment outlines patient nutrition status, provides a detailed review of issues compromising nutritional status, recommendations to guide the care plan, and informs the provider of the patient’s medical diagnosis of malnutrition. The diagnosis of malnutrition is a critical first step in early intervention of those found to be malnourished, as well as in determining a proper treatment plan for these vulnerable patients.
- **MUC16-327: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment:** A nutrition care plan is driven by the nutrition assessment and is required to record vital patient care information, including nutrition status, interventions, diagnosis, and monitoring recommendations.^{xlvi xlvi} A patient’s nutrition assessment-based care plan provided in the hospital setting is what all clinicians who interact with the patient refer to when providing care and services to the patient.

- **MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis:** Along with the diagnosis of malnutrition, appropriate documentation is an important step to confirm results of a nutrition assessment, communicate nutritional status to other providers within the hospital and ensure malnutrition support is carried out throughout the continuum of care. In particular, the appropriate documentation of a malnutrition diagnosis is critical for the coordination of care between acute and post-acute care (PAC) settings.

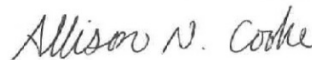
We believe that adopting this patient-centered, malnutrition measure set will also improve care coordination and eventually decrease costs to the system. HNC has previously commented on “Quality Measure Development and Maintenance for CMS Programs Serving Medicare-Medicaid Enrollees and Medicaid-Only Enrollees” urging CMS to promote quality measures that identify untreated malnutrition and implement policies and procedures that encourage malnutrition screening, assessment, diagnosis, and appropriate nutrition intervention including the provision of oral nutrition supplements, enteral or parenteral nutrition.

Conclusion

As CMS continues to consider ways to improve the regulatory burdens of PPACA and draft policy changes to the healthcare system, we urge the prioritization of prevention, diagnosis, and treatment of malnutrition measures that includes access to appropriate clinical nutrition therapies across the continuum of care. A large body of published research supports the positive impact of nutrition care on patient outcomes and the benefits to the healthcare system at-large. Early diagnosis and treatment of malnutrition of patients will result in improved health outcomes, increased quality of life, higher quality of care and, ultimately, lower healthcare costs. HNC urges 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.” If CMS adopts the recommendations outlined above, this will be a key step towards enhancing affordability of healthcare, addressing the health and economic impact of disease-related malnutrition, and promoting systematic nutrition screening, assessment, diagnosis and appropriate nutrition intervention.

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 acooke@kellencompany.com or 202-207-1130.

Sincerely,



Allison Cooke, MPH
Executive Director
Healthcare Nutrition Council

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- 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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