HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

August 12th, 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: Request for Information; Reducing Administrative Burden To Put Patients Over Paperwork (CMS-6082-NC), 84 Fed. Reg. 27070 (June 11, 2019).

Dear Administrator Verma:

On behalf of the Healthcare Nutrition Council (HNC), we are writing in response to the Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI) regarding reducing administrative burden for Medicare providers and suppliers. HNC is an association representing manufacturers of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), parenteral nutrition (PN) formulas, supplies and equipment.[1] HNC's 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 this mission, we are providing comments on unnecessary administrative burden for providers of nutrition support therapies and supplies to Medicare beneficiaries. As is detailed further below, our letter expresses concern about documentation rules and claims adjudication for enteral and parental nutrition and related supplies. HNC urges CMS to amend and streamline requirements to allow providers to devote more resources to necessary patient care, and less on administrative responsibilities. However, to begin, this letter discusses the importance of timely and robust access to nutrition support therapies.

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 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

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

that as many as half of hospitalized patients and 35% to 85% of older long-term care residents are undernourished.[2,3,4,5]

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,[6] pressure ulcers,[7] nosocomial infections,[8] and death.[9] In addition, malnutrition is a risk factor for other severe clinical events, such as falls[10] and worse outcomes after surgery or trauma.[11] Malnutrition also has negative impacts on patients with specific chronic diseases and conditions, such as stroke,[12] heart failure,[13] cancer,[14] and COPD.[15] 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.[16]

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.[17] A study published in 2016 found that malnutrition in U.S. hospitalized patients is associated with a more than 50 percent higher rate

[2] Robinson MK, Trujillo EB, Mogensen KM, et al: Improving nutritional screening of hospitalized patients: The role of prealbumin. *JPEN J Parenter Enteral Nutr*. 2003 27:389-395.
[3] Chima CS, Barco K, Dewitt MLA, et al: Relationship of nutritional status to length of stay, hospital costs, discharge status of patients hospitalized in the medicine service. *J Am Diet Assoc* 1997 97:975-978.
[4] Braunschweig C, Gomez S, Sheean PM: Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. *J Am Diet Assoc* 2000 100:1316-1322.
[5] Crogan NL, Pasvogel A: The influence of protein-calorie malnutrition on quality of life in nursing homes. *J Geronotol A Biol Sci Med Sci* 2003 58A(2):159-164.
[6] Callahan CM, Wolinsky FD. Hospitalization for pneumonia among older adults. *J Gerontol*. 1996; 51A:M276-M282.
[7] Mechanick JI. Practical aspects of nutritional support for wound-healing patients. *Am J Surg*. 2004;188:52S-56S.
[8] Schneider SM, Veyres P, Pivot X, et al. Malnutrition is an independent factor associated with nosocomial infections. *Br J Nutr.* 2004; 92:105-111.
[9] Correia MI, Waitzberg DL. The impact of malnutrition on morbidity, mortality, length of hospital stay and costs evaluated through a multivariate model analysis. *Clin Nutr*. 2003;22:235-239.
[10] Meijers JMM, Halfens RJG, Neyens JCL, et al. Predicting falls in elderly receiving home care: the role of malnutrition and impaired mobility. *J Nutr Health Aging*; 2012; 16: 654-658.
[11] Marik PE and Flemmer M. Immunonutrition in the surgical patient. *Minerva Anestesiologica*. 2012; 78: 336-342.
[12] Davalos A, Ricart W, Gonzlez-Huix F, et al. Effect of malnutrition after acute stroke on clinical outcome. Stroke. 1996;27:1028-1032.
[13] Zapatero A, Barba R, Gonzalez N, et al. Influence of obesity and malnutrition on acute heart failure. *Rev Esp Cardiol*. 2012; 65(5): 421-426.
[14] Lis CG, Gupta D, Lammersfeld CA, et al. Role of nutritional status in predicting quality of life outcomes in cancer – a systematic review of the epidemiological literature. *Nutr J*. 2012; 11:27: 2-18.
[15] A.S.P.E.N. Board of Directors and the Clinical Guidelines Task Force. Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients. *JPEN J Parenter Enteral Nutr*. 2002;26(1suppl):1SA-138SA.
[16] Chima CS, Barco K, Dewitt ML, et al. Relationship of nutritional status to length of stay, hospital costs, and discharge status of patients hospitalized in the medicine service. *J Am Diet Assoc*. 1997; 97: 975-978.
[17] Alvarez-Hernandez J, Planas Vila M, Leon-Sanz M, et al. Prevalence and costs of malnutrition in hospitalized patients; the PREDyCES® Study. *Nutr Hosp*. 2012; 27(4): 1049-1059.

of readmission within 30 days, compared to patient stays not associated with malnutrition.[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 for malnutrition.[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 of malnutrition and largely depend 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) for patients with malnutrition 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 with a 16% reduction in length of stay and a 15.8% cost savings – an average of $3,079 -- per episode.[24]

Patients with malabsorption conditions are a greater risk for malnutrition and the inability to access appropriate nutrients to promote health. These beneficiaries require specialized enteral nutrition such as peptide-based diets.[25] Due to the administrative documentation burdens that can be associated with these elemental and semi-elemental specialty formulas (such as HCPCS B4153), providers and prescribers may not be providing the most appropriate enteral nutrition formulas which can lead to compromised nutrient delivery, increased ER visits and additional healthcare costs and resources.[26]

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

[18] Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. *HCUP Statistical Brief #218.* 2018. 1-18.
[19] Zapatero A, Barba R, Gonzalez N, et al. Influence of obesity and malnutrition on acute heart failure. *Rev Esp Cardiol.* 2012; 65(5): 421-426.
[20] Snider J, et al: Economic burden of community-based disease-associated malnutrition in the United States. JPEN J Parenteral Enteral Nutr. 2014;38:55-165.
[21] Snider JT, Linthicum MT, Wu Y, et al. Economic burden of community-based disease-associated malnutrition in the United States. *JPEN J Parenter Enteral Nutr*. 2014; 38 (Suppl 2): 77S-85S.
[22] Braunschweig C, Gomez S, Sheean PM. Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. *J Am Diet Assoc*. 2000;100:1316-1322.
[xxii] Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. *HCUP Statistical Brief #218.* 2018. 1-18.
[24] Thomas DR, Zdrowski CD, Wilson MM, et al. Malnutrition in subacute care. *Am J Clin Nutr*. 2002;75:308-313.
[25] Liu, MY et al., Peptide-based enteral formula improves tolerance and clinical outcomes in abdominal surgery patients relative to a whole protein enteral formula. World J Gastrointest Surg, 2016. 8(10):p. 700-705.
[26] Mundi MS, Pattinson A, Mc Mahon MT, Davidson J, Hurt RT. Prevalence of Home Parenteral and Enteral Nutrition in the United States.

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.[27] 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.

II. The Administrative Requirements for Coverage of Nutritional Therapies Places Unnecessary Burdens on Providers and Patients

Medicare covers enteral nutrition (EN) [28]and paternal (PN)[29] nutritional products outside of facility settings under the Medicare Part B prosthetic device benefit. However, CMS covers EN and PN products under only very narrow circumstances. CMS does not cover such therapy for temporary impairments. Instead, CMS states that for coverage the patient must "have a *permanently* inoperative internal body organ or function thereof [emphasis added]."[30] In addition, CMS states that for coverage requirements to be met, the medical record must demonstrate "the impairment will be of *long and indefinite* duration [emphasis added]."[31] In addition to the narrow coverage rules, CMS has extensive and redundant documentation requirements for providers and suppliers wishing to provide EN, PN, and necessary infusion pumps to Medicare beneficiaries.

The documentation requirements for EN, PN, and related supplies impose unnecessary and burdensome requirements that do little but delay care and place administrative burden on providers as well as Medicare and its contractors. In order for EN or PN to be covered, there must be a written physician order for the EN or PN, and there must also be robust documentation in the medical record that would allow the independent conclusion that the EN or PN is medically necessary.[32] In addition to the EN and PN itself, an infusion pump is often necessary to deliver the nutrients. On top of the medical necessity requirements for the EN and

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[28]EN includes nutrition delivered through the gastrointestinal (GI) track, such as oral nutrition and tube feeding. Enteral Therapy may be given by a nasogastric, jejunostomy, or gastrostomy tubes. For example, tube feeding is a form of EN when a a highly specialized liquid food formula is administered to patients through different types of tubes into the Gl track.

[29] PN is the intravenous administration of vital nutrition for patients whose GI tract is not functional. It is administered via an IV catheter and requires the use of an infusion pump. PN is essential for patients with a variety of diseases or medical conditions that impair food intake or nutrient digestion or absorption.

[30] Medicare National Coverage Determinations (NCD) Manual, §180.2, Enteral and Parenteral Nutritional Therapy.

[31] *Id.*

[32] *Id.*

PN, CMS also requires health care providers to provide robust documentation that the pump is medically necessary, separate and apart from the medical justification for the EN and PN. Moreover, each of these claims for both the EN or PN and pump "must be approved on an individual, case-by-case basis."[33] This requirement subjects all EN and PN claims to manual medical review – a process usually reserved for providers who have failed previous audits. This is both unnecessary and overly burdensome, particularly for providers that have demonstrated an acceptable compliance rate with prior claims.

Another inefficiency in the current coverage rules is that CMS requires providers to file repeated claims for the same treatment for the same patient. Despite the fact that CMS will only cover EN and PN for beneficiaries considered to have *permanent* impairment, CMS requires providers to recertify claims within small timeframes. More specifically, CMS requires that the claim for EN or PN must be resubmitted in intervals of no more than three months.[34] Even more confusingly, CMS rules state that Medicare will only pay for one month's supply of EN or PN nutrients at any time.[35] This forces providers to file the same claim over again each month for patients whose medical record demonstrates that they have a *permanent* impairment. Given the required condition of the patients, recertification of claims is a wholly unnecessary exercise. Furthermore, any gaps in coverage could lead to the patient trying to pay for the product out-of-pocket and/or put them at risk of missed feedings which could result in preventable malnutrition and undue financial burden on the patient.

In addition to usual documentation requirements, CMS imposes additional burden on providers and suppliers for specialized formulas. Despite EN products reviewed and assigned HCPCS codes by CMS, a physician written order, and medical necessity documentation, CMS still requires providers and suppliers to undergo a documented trial and failure process on standard products (B4150 or B4152) before covering specialty formulas for post-acute care patients that were already receiving the specialty formula during their hospital stay. In addition to delaying proper recovery for patients, this adds extra unnecessary administrative burden to providers and suppliers.

CMS also continues to require that providers submit a durable medical equipment information form (DIF) for all claims for EN and PN, and a separate DIF for infusion pumps.[36] These forms must be included with each claim, which, as explained above, is far too often. These forms were once used to attest to medical necessity, but as previously described, EN and PN claims are now subject to manual medical review of the beneficiaries' record. Therefore, it serves little purpose for the provider to fill out a form asking questions about whether there is sufficient evidence in the medical record, when the medical record will be thoroughly reviewed in every instance.

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[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Medicare Program Integrity Manual, § 5.3.1, Completing a Certificate of Medical Necessity (CMN) or Durable Medical Equipment Information Form (DIF).

CMS can take a number of steps to significantly reduce administrative burden on providers and suppliers of EN and PN and enhance access to this life-changing care. HNC recommends that CMS streamline the claim process for EN, PN, and infusion pump claims, so that providers only need to submit one claim for the duration of time that the patient will need the nutrition support therapies. For example, if a physician orders EN or PN for a patient, and based on their medical judgement (and supported by the medical record) the patient will need the nutrition support therapy for a minimum of 6 months, CMS should approve claims for supplies to last that duration. This will eliminate providers needing to regularly resubmit the same paperwork over and over. Further, CMS can prevent overutilization by requiring that providers notify CMS if a patient's condition changes prior to the end of the approval period, and the claim can be adjusted based upon the new needs of the patient.

In addition to eliminating the requirement that providers resubmit identical claims, CMS should also eliminate the requirement that providers submit a DIF. As previously mentioned, the DIF no longer serves its original purpose of attestation of medical necessity, and is now completely redundant of the medical record reviews conducted to approve claims. Therefore, as part of its commitment to reducing paperwork, CMS should eliminate this required form.

Finally, CMS should also eliminate the requirement that every EN and PN claim be subject to manual medical reviews. This process slows down claims payments, jeopardizing access to services, and is also a tremendous burden on the Medicare program and staff resources. The CMS recently implemented initiative called "Targeted, Probe and Educate (TPE)" reduces burden on providers by only manually reviewing a minimum number of claims, taking corrective actions for errors, and only subjecting providers that continually fail audits to pre-payment reviews for all claims.[37] CMS should similarly take a targeted approach to EN and PN claims, conducting selective audits and identifying providers that may be billing in error for further action.

Recommendations:

1. CMS should permit EN, PN, and infusion pump claims to be approved for the duration of the anticipated need of the patient. This will eliminate the need for the provider to submit redundant claims for the same, continued services.
2. CMS should eliminate the requirement that EN, PN, and infusion pump claims include a DIF, as this form is redundant of the medical record and no longer serves any purpose.
3. CMS should no longer subject all EN and PN claims to manual medical review. Instead, in order to process claims in a more timely manner and save Medicare precious resources, it should take a more targeted approach to reviews of these claims.

[37] *See* CMS, Center for Program Integrity, Targeted Probe and Educate (https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Targeted-Probe-and-EducateTPE.html).

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Identifying and properly addressing malnutrition through proven clinical interventions should be a top priority for CMS. Not only does timely access to proper nutrition improve patient health and lives, it also can save Medicare significant resources. **HNC urges CMS to implement these recommendations, which will lessen the burden on both providers and Medicare, and allow more resources to be devoted to needed patient care.** HNC stands ready to work with CMS to help implement these reforms. 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