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www.eatright.org

120 South Riverside Plaza
Suite 2190
Chicago, Illinois 60606-6995
800.877.1600

1150 Connecticut Avenue NW
Suite 615
Washington, D.C. 20036
800.877.0877

March 6, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-2023-0010
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2023-0010 Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Ms. Brooks-LaSure:

The Academy of Nutrition and Dietetics (the "Academy") is pleased to provide comments on File Code-CMS-2023-0010 published in the Federal Register on February 1, 2023. Representing more than 112,000 registered dietitian nutritionists (RDNs),[i] nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of nutrition and dietetics practitioners committed to accelerating improvements in global health and well-being through food and nutrition.

RDNs' extensive formal education and training provides expertise in all aspects of food and nutrition, enabling us to play a key role in improving people's nutritional status to prevent and treat chronic disease. RDNs are recognized for their unique ability to conduct and translate science and evidence through education, medical nutrition therapy (MNT) and intensive behavior therapy.[ii] The National Academies of Sciences, Engineering, and Medicine maintains that "the registered dietitian is currently the single identifiable group of health-care practitioners with standardized education, clinical training, continuing education and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy."

RDNs actively deliver nutrition care services for Medicare Advantage beneficiaries in both the outpatient and inpatient setting by providing high quality, evidence-based care generating cost-savings

to the health care system[iii]. Additionally, RDNs improve transitions of care, support care coordination (e.g., home health, outpatient care), address social determinants of health (e.g., food insecurity), and lead and participate in quality improvement initiatives.

The Academy appreciates the opportunity to submit comments regarding the CMS' Advanced Notice and offer the following comments relating to Section G. CMS-HCC Risk Adjustment Model for CY 2024. **The Academy strongly opposes CMS' proposal to remove malnutrition related codes in the CMS-HCC model.**

Malnutrition, Health Equity, & Cost of Care

The 2016 Healthcare Costs and Utilization Project, *Non-maternal and Non-neonatal inpatient stays in the United States Involving Malnutrition*[iv]*,* clearly showed that malnutrition in hospitalized patients is associated with longer lengths of stay, higher mortality, higher readmissions, and higher cost. Data from this report suggests that malnutrition, along with its associated ICD-10 diagnostic codes, was associated with $49 billion dollars in hospital costs in 2016. Of those hospitalized patients, 64% had Medicare (FFS and Managed care) as the payer.[v] A review of nationally representative data on cost and utilization indicated that only around 9% of patients actually had a coded diagnosis of malnutrition[vi]. Additionally, data demonstrated that those who were clinically diagnosed with malnutrition were "older, had longer lengths of stay, and incurred higher costs, as compared with those without a [coded malnutrition diagnosis]… [and had] higher readmission rates and higher inpatient mortality. [vii] Even so, these statistics do not illustrate the full depth and expense associated with malnutrition, since studies show that 20-50% of hospitalized patients actually have malnutrition yet those diagnoses are not translated to medical claims documentation to be included in the coded diagnoses of malnutrition evaluated through HCUP. [viii]

Literature has established that, among older adults, malnutrition is a leading cause of morbidity and mortality.[ixx] In 2012, Dr. Su Lin Lim published *Malnutrition and its impact on cost of hospitalization length of stay, readmission and 3-year mortality*; this highly regarded study showed that of the 818 patients admitted to the medical center, as many as one third were diagnosed with malnutrition (within a DRG code), the cost of care was higher on average than well-nourished individuals ($p = 0.014$), had higher mortality at one year (34% vs 4%; $p<0.001$), had longer hospitalizations (6.9 ± 7.3 days vs. 4.6 ± 5.6 days, $p< 0.001$), and were more likely to be readmitted within 15 days (adjusted relative risk = 1.9, 95%CI 1.1–3.2, $p= 0.025$).[xi] Similarly, when Agarwal et al[xii] evaluated the Australasian Nutrition Care Day Survey (ANCDS) data (3122 patients, 90-day outcomes to include length of stay, readmissions and in-hospital mortality), they found patients who had malnutrition had greater length of stay (15 days vs 10 days, $p<0.0001$) and readmission rates (36% vs 30%, $p=0.001$), as compared to well-nourished patients. The authors concluded that the odds of 90 day in-hospital mortality were two times greater for patients with malnutrition (CI:1.09-3.34, $p=0.023$)[xiii]. Both the Lim and Agarwal studies utilized a validated diagnostic tool, subjective global assessment (SGA) to determine whether the patient had malnutrition.

The economic impact of malnutrition goes far beyond the "four walls" of inpatient care. Underrepresented communities disproportionately bear the burden of health disparities within the United States, in particular older adults who are minorities and those located in rural communities.[xiv] Protein-calorie malnutrition, particularly in older adults, can be a contributing factor to health inequities. There

are harsh consequences for Medicare Advantage beneficiaries dealing with health inequity, which are compounded by one's limited access to and availability of health care, that negatively impact health outcomes. Often these consequences include the development or exacerbation of chronic disease,[xv] including malnutrition. Additionally, malnutrition is often not the sole diagnosis affecting a beneficiary. Generally speaking, the three causes of malnutrition among older adults can be characterized as either starvation related, chronic disease related, or acute disease or injury related.[xvi]

In 2021, MA plans provided coverage for 27 million Americans[xvii], and, given the continued prevalence, burden, and associated costs of malnutrition, it is not only crucial that there are adequate systems in place to identify malnutrition but also that there is sufficient staff and financial resources in place to support the care and treatment, with a long-term goal of establishing individual and population level interventions to prevent malnutrition. Removing malnutrition from the HCC diagnostic list will further dis-incentivize healthcare facilities from ensuring that malnutrition diagnoses are included in claims forms, which will perpetuate the problem of having higher rates of malnutrition than what is reflected in the HCUP data for coded diagnoses of malnutrition.

Academy and ASPEN Indicators to diagnose Malnutrition (AAIM) Validation

While both the Lim et al and Agarwal et al studies were conducted outside of the United States, the hospital systems and care were comparable to systems within the USA. A recent study conducted in the U.S. also found that patients who were diagnosed with severe malnutrition were more likely to have poor 90-day outcomes. Within this recent and currently unpublished data (Clinicaltrials.gov: NCT03928548), adult patients were first screened using the validated malnutrition screening tool and assessed with a dietitian rated nutrition complexity score of low, moderate, or high. Then, the Academy and ASPEN Indicators to diagnose Malnutrition (AAIM) tool was used to determine malnutrition (indicating both presence and severity). Thirty-two hospitals located in 17 states were included in the study between August 2019 and September 2022. The data was collected by RDNs, which included a complete nutrition focused physical examination and use of AAIM to diagnose malnutrition.

Unlike previous studies, this was a prospective evaluation and RDNs were required to evaluate for all six AAIM parameters: inadequate energy intake, weight loss, subcutaneous fat loss, muscle wasting, presence of edema, and decreased functional status as determined by a hand grip strength test. A total of 264 patients were included within the statistical models which evaluated predictive validity of the diagnostic AAIM tool. In a multilevel position model including random effect of site and acuity level with the Charleston comorbidity index, severe malnutrition was significantly predictive of a 90-day composite outcome including emergency room visits and hospital readmissions. Within the AAIM validation study, results showed that individuals who were female, Asian and Black were more likely to have poor 90-day outcomes. The results of the AAIM validation study are in alignment with the findings from both Lim and Agarwal and all indicate the importance of malnutrition in terms of outcomes and cost, and the need to address health inequities in minority populations that lead to chronic diseases like malnutrition. Of note, the SGA diagnostic tool is comprised of the same categories of parameters as the AAIM tool which are weight and dietary intake changes, functional capacity, and physical exam findings. SGA additionally evaluates gastrointestinal symptoms.

In a 2017 survey conducted by Mordarski and Hand[xviii], 71% of the 766 RDNs surveyed used the AAIM tool for diagnosis of malnutrition (previously called the Malnutrition Clinical Characteristics tool). Of

those, 88% and 90% used moderate and severe language when designating a diagnosis; these numbers were statistically higher than the same survey administered in 2014. Now six years later, it is hypothesized that the numbers are even higher. **The AAIM tool is validated and has shown to accurately identify malnutrition and its severity.**

Gold Standard Nutrition Care: Malnutrition

Registered dietitian nutritionists follow the Nutrition Care Process (NCP) Framework to deliver highly customizable care to an individual. The NCP is a systematic method that is comprised of four steps: nutrition assessment and reassessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation.

Nutrition assessment and reassessment involve the assessment of dietary intake, anthropometry, physical assessment, and signs or symptoms of nutritional deficiency or excess. RDNs utilize validated tools and/or markers for comprehensive nutrition assessment as they are essential for accurate evaluation of nutrition status. Use of the Nutrition Care Process does not mean that all patients follow the same prescriptive care plan, but rather nutrition care is individualized. Use of the NCP leads to more efficient and effective care. It is also a holistic approach and considers the individual's needs and values while using the best evidence available to make decisions. The consistent use of the diagnostic terminology that is part of the NCP contributes to the interoperability of medical record documentation in electronic health records.

The Academy would like to draw attention to a few recent well-designed trials that look at the impact of nutrition intervention on hospitalized patients with malnutrition. These intervention studies occur in patients with different medical diagnoses, but all are at increased risk for malnutrition, as malnutrition is often a contributing diagnosis for patients with complex chronic diseases.

- Britton et al[xix], *performed a stepped-wedge, randomized clinical trial where the intervention was provided by dietitians to patients with head and neck cancer. Patients who received the dietitian-led care had significantly better SGA scores at the critical end-of treatment time point (p=.0.3).*

- Hersberger et al[xx] *conducted a trial in hospitalized patients with chronic heart failure. This study used the Nutrition Risk Screening (NRS 2022) tool to determine whether the patient was at risk for malnutrition and the intervention was focused on nutritional support with energy, protein, micronutrients and included disease specific adaptations. The primary outcome of this study was all-cause mortality up to day 30 after inclusion within the trial. Patients with high nutrition risk compared to moderate were statistically more likely to have all-cause mortality day 180 (OR 1.65 (1.21 to 2.244); p=0.01). When the intervention vs control group was assessed, patients who received the nutrition intervention were significantly more likely to survive (p=0.00115).*

The Academy believed it to be prudent, based on emerging information in the literature, to signify that patients with malnutrition who receive nutrition intervention have better outcomes than the individuals with malnutrition who do not. The gold standard of nutrition care is to follow the Nutrition Care Process

(NCP) framework, which directs RDNs to assess and treat the patient systematically and holistically. The NCP guides clinicians to apply evidence-based nutrition interventions best suited for that individual[xxi]. Nutrition care plans can include a wide range of interventions for individuals with the same diagnosis whose nutrient needs must be met with individualized care based on the person's specific circumstances that take into account biological, psychosocial, economical, cultural and other variables. Evidence suggests that improvements in body weight, lean body mass and grip strength are achieved with individualized nutrition interventions.[xxii] Guided by the NCP, important steps to improve care include screening for malnutrition, documenting the presence of malnutrition upon identification using a validated tool and acting immediately on interventions for malnutrition.[xxiii] [xxiv]

Malnutrition Audit

The Academy is concerned that CMS' proposal to remove Protein Calorie Malnutrition from the HCC payment model is in part related to the ongoing clinical malnutrition audits conducted by the Office of the Inspector General (OIG). The Academy is committed to accurately identifying and coding malnutrition. Since 2016, and as part of a larger organizational taskforce, the Academy in good faith has repeatedly attempted to work with CMS and its auditors to address the concerns brought forth in the OIG audits. Our taskforce aims to actively collaborate on efforts to help the U.S. Department of Health and Human Services, the OIG, and CMS understand the best practices for diagnosing, documenting, and coding for malnutrition. **Frustratingly, we have received minimal response from the agency in eight years.**

The Academy has repeatedly requested CMS provide us with written policies and procedures for what they consider to be the correct criteria for diagnosis and coding of severe malnutrition. As this has not come to fruition, we remain concerned about the lack of transparency surrounding both OIG and CMS auditors reviewing malnutrition claims. Anecdotal reports from our members and review of CMS auditor reports raise concerns about not only inappropriate use of criteria, such as serum albumin, but also the wide pendulum of "criteria" used to assess severe malnutrition related claims.

Academy member reports citing rationale provided for severe malnutrition denials are outlined below.

WHO criteria	Inconsistent documentation between provider and dietitian
Missing Albumin and/or Pre-albumin	"ASPEN/AND by itself is NOT adequate, we need another indicator such as albumin, electrolyte balance, etc., to build a clinical picture"
Lack of Physician documentation of malnutrition/Conflicting physician documentation	"we don't have criteria, but there needs to be more evidence, specifically "starvation-like"
BMI > 18.5	Physician did not include malnutrition diagnosis in the discharge summary
Not severe enough weight loss	No TPN or IV Albumin provided
Ideal Body weight was not low enough	Auditor reported that CMS does not use ASPEN criteria. When asked what criteria to

	use to diagnose severe malnutrition, none was provided.
Patient not receiving enteral or parenteral nutrition	
Dates for weights to assess weight loss	

The inconsistent application of criteria among CMS and OIG auditors has real life and lasting implications for our health care system as a whole. Recently, Vidant Health of North Carolina successfully defended an OIG audit claim that sought repayment for claims their auditor found to be incorrectly billed to Medicare for severe malnutrition. Of the denied claims, Vidant was able to successfully defend 77 of the implicated claims. In their situation, **the auditor was incorrect for 89% of the claims implicated**.

Summary of the Vidant Audit and Resolution
Vidant Health in North Carolina was one of the first facilities to receive an OIG audit claiming incorrect billing of Medicare inpatients relating to the diagnosis of severe malnutrition. A random sample of 100 claims from 2013-2015 that had a diagnosis of severe malnutrition were reviewed. Out of those hundred claims, 11 were deemed to be documented correctly with severe malnutrition, while 87 of the remaining 89 were denied - two of the claims with severe malnutrition did not change the DRG or payment and were removed.

Out of the 87 denials, Vidant Health reviewed the cases and indicated they could defend 77 of the severe malnutrition diagnoses. Over the next several years, the team at Vidant were able to site the documentation in the chart of each case that supported the severe malnutrition diagnosis. From 2013 to mid-2014, the nutrition team at Vidant had yet to fully implement the Academy/ASPEN malnutrition criteria.

These cases were reviewed for specific terminology and data that is evidence-based to indicate malnutrition, such as cachexia, wasting, decreased protein and/or calorie intake, decreased appetite, weight loss, etc.

*From mid-2014 through 2015, chart reviews were able to utilize the Academy/ASPEN malnutrition criteria to indicate the diagnosis of severe protein calorie malnutrition. It is important to note that **during this time frame the ICD-9-CM codes were in use**. In the ICD-9-CM coding system, severe malnutrition was included in code 261, which was titled "Nutritional Marasmus". Many of Vidant's denials were based, at least in part, on the allegation that the patient did not have nutritional marasmus. The OIG reviewers failed to acknowledge that, per coding guidelines, diagnosis code 261 should also be used to code severe malnutrition. Thus, Vidant was able to successfully defend the 77 severe malnutrition diagnoses and received a fully favorable ruling from the Administrative Law Judge in September 2022, confirming Vidant had appropriately diagnosed and coded severe malnutrition.*

Inconsistent and poorly applied audit criteria undermines the extraordinary amount of work being done to address malnutrition in the U.S. population as a whole. The true impact of this discrepancy will negatively impact hospital-wide efforts that require increased financial support to address and care for patients with malnutrition, and ultimately the beneficiaries themselves will suffer the greatest harm.

Furthermore, it will undermine efforts to motivate hospitals to self-select the electronic clinical quality measure for the global malnutrition composite score for the hospital Inpatient Quality Reporting program.

Inclusion of malnutrition codes within CMS models is important for three main reasons:
- Patients who have malnutrition cost more during hospitalizations than those who do not
- Patients who have malnutrition when hospitalized or acquire malnutrition during the duration of the stay have worse outcomes than those who do not, and
- Intervening with nutrition in patients who are diagnosed with malnutrition may improve health outcomes and subsequently save resources.

In the Advance Notice, CMS shared part of their rationale for updates to HCCs based on utilization of codes used more frequently in MA plans relative to Fee-For-Service payment model. The Academy is concerned that malnutrition is present, and perhaps even more under diagnosed in the FFS setting (Medicare Part B) as well. The 2014 IPPS Final Rule,[xxv] stated the "RDs are the professionals who are best qualified to assess a patient's nutritional status and to design and implement a nutritional treatment plan in consultation with the patient's interdisciplinary care team". As such, it is the RDN's assessment in collaboration with the rest of the multidisciplinary care that supports the application of uniform criteria for identifying malnutrition, the documentation supporting the diagnosis along with specificity, and finally the intervention which may likely include medical nutrition therapy.

In the CY 2022[xxvi] and 2023[xxvii] Medicare Physician Fee Schedules, CMS stated their concerns regarding the underutilization of Medical Nutrition Therapy Services. Unfortunately, due to the statutory limitations of the Medicare MNT Part B benefit (limited to beneficiaries with a diagnosis of diabetes and chronic kidney disease), access to nutrition assessment and care by RDNs may be restricted in settings where there is not support for the RDN position. Anecdotally, we know that some MA plans go beyond the Part B MNT coverage determination to include coverage for additional diagnoses, which opens the door to increasing better access to RDNs. However, due to the lack of report requirements for MA Plans and uncertainly about nutrition related care, many Medicare MA beneficiaries who are in need of or are seeking MNT services to address their nutrition-related needs are left on their own to sort it out or elect to forgo nutrition care altogether.

The Office of the Inspector General February 2023 Issue Brief (OEI-03-21-00389)[xxviii] highlighted additional concerns as it relates to Medicare Advantage Plans and denial of claims. While this report focused on increasing transparency of MA Claim denials, it behooves the Academy to call attention to the OIG's statement that if a Medicare Advantage Organization "inappropriately deny payments, this may contribute to financial harm to enrollees or providers and may discourage providers from ordering needed health care". It is the Academy's belief that the utilization of malnutrition codes from FFS as a bellwether for malnutrition claims in Medicare Advantage, given the confusion around denials of claims in MAOs, is misleading.

Through the lens of quality of care, CMS has acknowledged the importance of malnutrition as a clinical imperative and has proposed quality measures for identifying, treating, and documenting malnutrition as a diagnosis[xxix]. The Joint Commission has also recognized the importance and impact of malnutrition and has supported quality measures for malnutrition, as well as mandating nutritional screening for all patients admitted to a hospital [xxx]. The removal of malnutrition as an HCC diminishes the importance of

recognizing the condition, treating it, and properly reporting it and is in stark contrast to CMS quality stance and Joint Commission statements. The dropping of malnutrition as an HCC will negatively impact the health, well-being, and clinical outcomes of Medicare beneficiaries.

Furthermore, the foundational purposes for the development of the HCC system and Medicare Advantage programs was to create stable and measurable characteristics to easily predict future costs, to spread high risk and associated costs of care over a larger population, and to incentivize quality and efficiency of care.[xxxi] Clinical evidence overwhelmingly shows higher costs of care, longer length of stay, worse outcomes, higher complications, and higher rates of readmission are associated with the diagnosis of malnutrition. From both risk adjustment and financial impact perspectives the dropping of malnutrition from the HCC list is not consistent with clinical evidence or the purpose of the HCC system.

The Academy strongly opposes CMS' proposal to remove malnutrition related codes in the CMS-HCC model. Inclusion of malnutrition related codes into CMS-HCC models will provide more accurate estimation of true healthcare resource use. The Academy strongly recommends the solution to solving this issue is not the removal of the Protein-Calorie Malnutrition from the CMS-HCC model, **but rather CMS to provide a policy that delineates evidenced based criteria for the identification of severe malnutrition and to invest in better training of their investigators to fully understand and apply the evidenced based criteria for diagnosing malnutrition throughout the full continuum of malnutrition and care.**

The Academy urges CMS to delay removal of protein-calorie malnutrition from the CMS-HCC payment model until other data can be analyzed to support or refute the proposed changes. In lieu of removal, the Academy requests that CMS meet with us to work past the significant issues surrounding investigation of severe malnutrition claims. The Academy and our partners are willing to work with CMS and other third-party investigators to provide education regarding malnutrition identification and evidenced based nutrition management.

Thank you for your careful consideration of the Academy's comments on the Medicare Advantage Advance Notice. Please do not hesitate to contact Jeanne Blankenship by phone at 312-899-1730 or by email at jblankenship@eatright.org or Carly Léon at 312-899-1773 or by email at cleon@eatright.org with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS, RDN
Vice President, Policy Initiatives & Advocacy
Academy of Nutrition and Dietetics

Carly Léon MS RD CD CNSC
Manager, Education & Advocacy
Academy of Nutrition and Dietetics

[i] The Academy has approved the optional use of the credential "registered dietitian nutritionist (RDN)" by "registered dietitians (RDs)" to more accurately convey who they are and what they do as the nation's food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

[ii] Medical Nutrition Therapy (MNT) is an evidence-based application of the Nutrition Care Process. The provision of MNT (to a patient/client) may include one or more of the following: nutrition assessment/reassessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation that typically results in the prevention, delay or management of diseases and/or conditions. **Academy of Nutrition and Dietetics' Definition of Terms list** updated February 2021. Accessed February 28, 2022.

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[v] *ibid*

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[vii] *Id.*

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