

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1751-P
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Baltimore, MD 21244-8016

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Re: File Code-CMS-1751-P; Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; (July 23, 2021)

Dear Administrator Brooks-LaSure:

The Academy of Nutrition and Dietetics (the “Academy”) is pleased to provide comments on File Code-CMS-1751-P published in the Federal Register on July 23, 2021. Representing over 107,000 registered dietitian nutritionists (RDNs),¹ 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 independently provide professional services such as medical nutrition therapy (MNT)² under Medicare Part B and are recognized as Eligible Clinicians (ECs) and Qualified APM Participants (QPs) in Medicare’s Quality Payment Program. RDNs provide high quality, evidence-based care to patients and deliver substantial cost-savings to the health care system.

Beneficiaries and health care providers alike continue to navigate the evolving health care landscape, and the Academy applauds the continued efforts by CMS to work within their regulatory power to fine-tune policies that will support access to and delivery of safe, equitable, and effective health care during a public health emergency (PHE).

With that in mind, the Academy offers specific comments on the following proposed rule items:

1. Telehealth and Other Services Involving Communications Technology (**Section II.D.**)
2. Valuation of Specific Codes (**Section II.E.**)
3. Payment for Medical Nutrition Therapy Services and Related Services (**Section II.K.**) and Medical Nutrition Therapy (**Section III.I.**)
4. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (**Sections III.A.**)

¹ 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.

² 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 August 18, 2021.

5. Removal of Select National Coverage Determinations (**Section III.G.**)
6. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (**Section III.H.**)
7. Medicare Diabetes Prevention Program (MDPP) (**Section III.L.**)
8. Updates to the Quality Payment Program (**Section IV.**)
9. Regulatory Impact Analysis (**Section VII**)

1. Telehealth and Other Services Involving Communications Technology (Section II.D)

The Academy supports CMS's continued efforts to expand beneficiary access to care and recognizes the value of reducing barriers to adequate mental health services. In similar vein, the Academy encourages CMS to continue beneficiary access to Medical Nutrition Therapy (MNT) services via audio-only communication. We believe that CMS's rationale for continuing audio-only access to mental health services squarely aligns with the rationale for audio-only MNT services. MNT services, like mental health services, "primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to provision of the service."³

The U.S. has been and continues to pay a high price for overlooking the importance of nutrition in both preventing and treating costly and chronic conditions such as diabetes, cardiovascular disease, chronic kidney disease, obesity, and hypertension. The CDC estimates that six out of 10 Americans has at least one chronic disease⁴ and according to the CMS Chronic Conditions Dashboard, nearly 70% of Medicare Beneficiaries currently have one or more chronic conditions, accounting for nearly 90% of Medicare spending.⁵ MNT provided by the RDN is a widely recognized component of medical guidelines for the prevention and treatment of many chronic diseases and conditions. It is critical that beneficiaries have access to timely, safe, and effective nutrition services that can improve their health and better manage their chronic diseases.

The Academy urges CMS to extend audio-only coverage to RDNs providing MNT services when audio-only telehealth services are appropriate, based on individual patient needs. We support CMS's belief that two-way, audio/video communications technology is the appropriate, general standard for telehealth services. There are, however, situations where the availability of telehealth services for nutrition care via audio-only communications would increase access to care. Beneficiaries located in areas with poor broadband infrastructure and those who either do not wish to use, do not have access to, and/or are unable to utilize devices that permit a two-way, audio/video interaction, are unable to fully access their MNT benefit or will often go without the service to which they are entitled. And much like services for mental health, the need for coverage of audio-only telehealth visits by RDNs is unlikely to disappear once the PHE has ended. Lastly, we acknowledge and agree with CMS that there are guardrails and parameters that should be put in place to guide audio-only encounters.

³ <https://www.federalregister.gov/documents/2021/07/23/2021-14973/medicare-program-cy-2022-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part> Accessed August 19, 2021.

⁴ CDC: National Center for Chronic Disease and Health Promotion Center, Chronic Disease Interactive Data Applications. <https://www.cdc.gov/chronicdisease/pdf/infographics/chronic-disease-H.pdf>. Accessed August 16, 2021.

⁵ Medicare Chronic Conditions Dashboard https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreportslink?evt=2048001&src=mstrWeb.2048001&documentID=FE7B7B934CB8184F214E39982EB1F435&visMode=0¤tViewMedia=1&Server=E48V126P&Project=OIPDABI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer Accessed August 16, 2021

The public health emergency (PHE) has highlighted barriers that beneficiaries encounter when attempting to access quality health care, including access to quality and safe nutrition care. While MNT delivered via telehealth has been available to Medicare beneficiaries since 2006, limitations such as originating site requirements, poor internet infrastructure, and limited technology literacy and/or access have hampered utilization. The provision of audio-only telenutrition during the PHE has offered beneficiaries the opportunity to increase their access to quality care. Member feedback has highlighted access to and coverage for audio-only telenutrition has allowed RDN providers a mechanism to better track and manage beneficiary health status (monitor compliance, outcomes, and adjustment of nutrition care plans) and has improved show rates as beneficiaries have been able to keep appointments through audio-only visits under the parameters of the current flexibilities.

The Academy believes the continuation of coverage for synchronous audio-only telenutrition visits based on patient limitations, technical challenges, and patient needs post-PHE will create a more connected model of nutrition service delivery that will improve access for those individuals who may not otherwise be able to receive care.

*Other Non-Face-to-Face Services Involving Communications Technology under the PFS:
Expiration of PHE Flexibilities for Direct Supervision Requirements*

The Academy is appreciative of the flexibilities CMS provided relating to direct supervision requirements during the PHE which allowed the supervising physician (or other supervising practitioner) the ability to be available through audio/video communications technology and confirming “that individual practitioners were in the best position to make decisions about how to meet the requirement to provide appropriate direct supervision based on their clinical judgment in particular circumstances.”⁶ The Academy believes this not only provided better access to care for beneficiaries but also supported the delivery of timely, cost-effective care. **The Academy is in support of CMS making these flexibilities permanent.**

The NCD for intensive behavioral therapy (IBT) for obesity services is one important example of where this decision can achieve CMS’s goal of continued access to high quality, cost-effective care while keeping patients and providers safe. Many RDNs provide IBT for obesity under direct supervision of primary care providers in primary care settings. The CDC has identified several subgroups who are at higher risk for severe illness from COVID-19.⁷ To date, this group continues to include individuals with overweight, obesity, or severe obesity. We believe this provision would remove the burdensome requirements of real-time audio/video supervision by physicians (who recognize RDNs should independently be providing these services) and ensures it will still be practicable for beneficiaries to access the full 22 sessions of the cost-effective and clinically effective IBT services they receive from RDNs.

2. Valuation of Specific Codes (Section II.E.)

The Academy supports CMS’ proposal to adopt CPT codes 99X22-5 for principal care management services and the RUC recommended RVUs for CCM/CCCM/PCM services. Patients with a single high-

⁶ Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2021. <https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf>

⁷ CDC: Coronavirus 2019: Groups at Higher Risk for Severe Illness. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. Accessed August 30, 2021.

risk disease or complex chronic condition may require significant resources to manage their care, including MNT services provided by RDNs. Data show that MNT provided by an RDN is linked to improved clinical outcomes and reduced costs related to physician time, medication use and hospital admissions for people with obesity, diabetes, and disorders of lipid metabolism, as well as other chronic diseases.⁸ RDNs are an essential part of the health care team and are well-qualified and frequently do provide care management services to patients with a single high-risk disease or complex chronic condition (including but not limited to diabetes or renal disease). As CMS looks at ways to support important care management services, **the Academy urges CMS to recognize the wide range of qualified non-physician practitioners located outside of the physician office setting who effectively provide such services as part of the patient-centered health care team. These non-physician team members are critical to achieving successful patient and population health outcomes and controlling the progression of chronic disease. Thus, there needs to be a payment mechanism for these essential services that is not exclusively tied to physician providers and/or limits the definition of “clinical staff” to those physically located in and/or employed by the physician office practice.**

The Academy recommends CMS make permanent its policy during the COVID-19 PHE to allow stakeholders to obtain beneficiary consent for such services under general supervision. Experience during the PHE has shown this to be a safe and effective practice that reduces administrative burden and maintains quality of care while continuing to respect the importance of beneficiary consent prior to receiving these services.

3. Payment for Medical Nutrition Therapy Services and Related Services (Section II.K.) and Medical Nutrition Therapy (Section III.I.)

Overall, the Academy commends CMS for proposing actions aimed to increase utilization of a vastly under-utilized Medicare benefit clearly proven to reduce chronic disease risk, delay disease progression, enhance the efficacy of medical/surgical treatment, reduce medication use, and improve patient outcomes including quality of life.⁹ MNT provided by the RDN is a widely recognized component of medical guidelines for the prevention and treatment of heart disease, diabetes, renal disease, obesity, cancers, and many other chronic diseases and conditions as well as in the reduction of risk factors for these conditions. The Academy supports all the proposed changes related to the Part B MNT benefit for the reasons noted by the agency but notes CMS has not gone far enough in taking action to meet this goal. To that end, the Academy recommends:

- a. **Update the definition of diabetes in § 410.130 Definitions to include HbA1c \geq 6.5% as recommended in national standards of medical care for diabetes.** As is the case with classification and diagnostic guidelines for kidney disease, the definition of diabetes for the purposes of the MNT benefit has not been updated since the original NCD. HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for at least 10 years. Both the United States Preventive Services Task Force¹⁰ and the American

⁸ Academy of Nutrition and Dietetics Evidence Analysis Library. *Medical Nutrition Therapy Evidence Analysis Project 2008*. <http://www.andevidencelibrary.com/mnt>.

⁹ Grade 1 data. Academy Evidence Analysis Library, <http://andevidencelibrary.com/mnt>. [Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation Grade I, “Good evidence is defined as: “The evidence consists of results from studies of strong design for answering the questions addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power.”]

¹⁰ Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. U.S Preventive Services Task Force. October 26, 2015. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes>. Accessed August 17, 2021.

Diabetes Association Standards of Care¹¹ recommend use of any of three testing methods to screen for abnormal blood glucose: fasting plasma glucose, HbA1c, and two-hour plasma glucose.

- b. **Further expand the definition of renal disease in § 410.130 Definitions to include G Stage 1 Kidney Damage with normal kidney function (GFR 90 ml/min/1.73m² or higher) and G Stage 2 Mild CKD (GFR 60-89 ml/min/1.73m²) to include the full breadth of non-dialysis dependent chronic kidney disease.**¹² Section 1861(s)(2)(V)(ii) of the Social Security Act allows for MNT for a “beneficiary with ... renal disease who...is not receiving maintenance dialysis.” Medicare expenditures increase dramatically from stages 1-2 to stages 4-5.¹³ Covering MNT for these earlier stages of CKD is a low-cost intervention proven to slow or prevent CKD progression.¹⁴ ¹⁵ Also, some G Stage 5 patients with a GFR below 15 ml/min/1.73m² may not yet be on dialysis and so not receiving nutrition services under the ESRD benefit. Such patients would benefit from MNT services under the Part B benefit. Of note, the ICD-10 code file associated with the MNT NCD (180.1) and issued by CMS to the Medicare Administrative Contractors for claims processing purposes includes the ICD-10 codes for all stages of CKD.¹⁶ To address potential concerns about risk of fraudulent billing, the Academy suggests **CMS create a modifier code to be appended to claims for Part B MNT services to indicate when a Medicare beneficiary with Stage 5 CKD is not receiving dialysis.**
- c. As CMS moves all regulatory provisions for MNT, DSMT, and registered dietitians as Medicare providers under one area of regulations, **we recommend CMS also provide additional clarity in Medicare Claims Processing and Benefit Policy Manuals on the following two items:**
 - I. **Coverage and billing procedures for these services under the Physician Fee Schedule in all associated settings, including hospital clinics (billing on CMS 1500, billing on UB04), Federally Qualified Health Centers, Rural Health Clinics, and Critical Access Hospitals.** Currently, providers and billers need to navigate a complex path of cross-referencing numerous documents to understand Medicare policies, requirements, and guidelines. The myriad of practical questions faced when trying to set up care delivery and billing systems and the challenges in trying to find answers to those questions came to the forefront at the onset of the COVID-19 PHE when the need for telehealth flexibilities became apparent. While MNT and Diabetes Self-Management Training (DSMT) services have always been on the list of Medicare approved telehealth services, instructing a hospital to bill for Part B MNT services the same as in-person services became problematic as facilities did not know how to bill for it as an in-person service.
 - II. **Whether a physician (MD or DO) can co-sign a referral for MNT services when supervising a nonphysician provider (e.g., NP or PA) practicing under a collaborative practice agreement as required by state law.** In both urban and rural areas, NPPs manage and coordinate care for many persons with diabetes and earlier stages of CKD.

¹¹ Classification and Diagnosis of Diabetes: *Standards of Medical Care in Diabetes—2021*. American Diabetes Association. Diabetes Care Jan 2021, 44 (Supplement 1) S15-S33; DOI: 10.2337/dc21-S002.

¹² National Kidney Foundation. Estimated Glomerular Filtration Rate (eGFR). <https://www.kidney.org/atoz/content/gfr>. Accessed August 17, 2021.

¹³ United States Renal Data System. Chapter 6: Healthcare Expenditures for Persons with CKD. <https://adr.usrds.org/2020/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd>. Accessed August 17, 2021.

¹⁴ de Waal D, Heaslip E, Callas P. Medical Nutrition Therapy for Chronic Kidney Disease Improves Biomarkers and Slows Time to Dialysis. *J Ren Nutr*. 2016; 26(1): 1-9.

¹⁵ Kramer H, Yakes Jimenez E, Brommage D, et al. Medical Nutrition Therapy for Patients with Non-Dialysis-Dependent Chronic Kidney Disease: Barriers and Solutions. *J Acad Nutr Diet*. 2018; 118(10): 1958-1965.

¹⁶ <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR12027.zip> Accessed August 17, 2021.

While we recognize the current statutory language notes the referral needs to come from a MD or DO, a review of CMS regulations and manuals provides no guidance on whether this scenario would comply with the statute. If it is permissible, providing clear guidance would help to increase appropriate utilization of an important service already noted to be a medically necessary and recognized component of clinical care for these conditions.

To that end, the Academy welcomes opportunities to collaborate with CMS on developing and reviewing resources that will support providers.

- d. **We encourage CMS to clarify its basis for asserting that MNT services are both being provided and paid for in hospitals and SNFs and the regulatory provisions mandating such provision and payment.** The proposed rule would add a new § 410.72 that includes limitations on “[c]overed registered dietitian and nutrition professional services” to exclude services provided to inpatients of either a Medicare-participating hospital or Skilled Nursing Facility (SNF). CMS explains that this determination was made “[i]n the CY 2001 PFS final rule [on the basis that] our payment to hospitals and SNFs includes payment for MNT services.” The Academy believes this limitation is predicated upon a misapprehension that MNT services are consistently being provided or paid for in these facilities consistent with national protocols. The Conditions of Participation and Conditions of Coverage for these facilities neither require provision of MNT services or even reference them specifically, reflecting the fact that payment made to these facilities is for the RDN’s role in dietary services, including overseeing provision of regular and therapeutic diets and conducting nutritional assessments. Nutritional assessment is only the first step in the nutrition care process and does not capture the full scope of services that contribute the most significant value to patients/residents, namely nutrition diagnosis, nutrition intervention (beyond oversight of provision of diets) and nutrition monitoring and evaluation. We welcome the opportunity to work with CMS to ensure Medicare beneficiary inpatients in these facilities receive these critical services going forward under Medicare Part B.

4. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (Sections III.A.)

Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs

CMS has indicated that nearly 70% of Medicare beneficiaries are dealing with at least 2 or more chronic conditions and the value of MNT provided by the RDN has been previously outlined in earlier sections of this comment letter. **The Academy supports CMS’s proposal to allow Rural Health Clinics and Federally Qualified Health Centers the ability to bill for transitional care management services and chronic care management services that are furnished for the same beneficiary during the same service period should all requirements for billing each code are met.** MNT provided by RDNs can be offered to beneficiaries who elect to participate in CCM services in both the RHC and FQHC settings, with RDNs performing this service under the general supervision of the billing practitioner. We believe this policy will not only help to improve patient health outcomes but also will align with CMS’s efforts to improve access to care in a way that is both timely and efficient to the beneficiary.

5. Removal of Select National Coverage Determinations (Section III.G.)

The Academy agrees with CMS’s assessment that portions of NCD 180.2 Enteral and Parenteral Nutritional Therapy are outdated. We stand aligned with comments submitted by the American Society

of Parenteral and Enteral Nutrition and the Healthcare Nutrition Council and offer the following comments of our own.

Overall, the Academy prefers NCDs over LCDs to avoid variations in coverage policies that could produce varying access to and quality of care. We appreciate the efforts by the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) to work collaboratively to develop these two LCDs to set in place policies that support safe and medically necessary access to critical forms of nutrition support in accordance with current clinical standards and evidence-based guidelines within the current confines of the prosthetic device benefit. It also reduces unnecessary patient and provider burden. **We are concerned, however, about the potential for unintended consequences for access to medically necessary and appropriate care if the current NCD is retired and all relevant CMS guidance is not updated to reflect the new LCDs.** For example, the revised HEN LCD (38955) references language in the current NCD:

Future LCD 38955: Home Enteral Nutrition (HEN), Summary of Evidence, paragraph 5 Coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2. Additionally, benefit category and billing guidance for enteral nutrition are outlined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120 and the Medicare Claims Processing Manual (CMS Pub. 100-4), Chapter 20, Section 30.7. The guidance outlined in these manuals are reflected in the remainder of the LCD.

Without the NCD language or a thorough effort to bring all CMS documents into alignment, we are concerned that certain coverage criteria may not be clear, thereby risking misinterpretation and misapplication of the LCDs that goes against current clinical standards and prevents appropriate beneficiary access to care. In addition, lack of clarity could result in increased and unnecessary administrative burden and costs for providers, CMS, and CMS auditors.

To truly align policies for enteral and parenteral nutrition with current evidence on appropriate use of these treatment modalities, the Academy believes CMS should initiate a new National Coverage Determination to move coverage of this nutritional therapy from under the prosthetic device benefit to its own benefit. The prosthetic device benefit includes onerous requirements for a permanently inoperative internal body organ or function thereof that denies access to short-term use of enteral and parenteral nutrition in situations supported by current clinical evidence used by the MACs in their LCD. Such evidence strongly supports short-term coverage for Medicare beneficiaries with conditions including stroke recovery, short-term inability to swallow requiring home enteral nutrition (HEN), post-surgical gastrointestinal (GI) complications with temporary impairment to GI tract requiring HEN, head & neck cancer, short-term swallowing bypass requiring HEN, trauma requiring finite HEN use, and HEN use in burn patients.^{17 18}

¹⁷ American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients, 2009. JPEN J Parenter Enteral Nutr. 2009 May-Jun;33(3):255-9. doi: 10.1177/0148607109333115. PMID: 19398611.

¹⁸ Worthington P, Balint J, Bechtold M, Bingham A, Chan LN, Durfee S, Jevonn AK, Malone A, Mascarenhas M, Robinson DT, Holcombe B. When Is Parenteral Nutrition Appropriate? JPEN J Parenter Enteral Nutr. 2017 Mar;41(3):324-377. doi: 10.1177/0148607117695251. Epub 2017 Feb 1. PMID: 28333597.

A new NCD should also address a critical component of clinical standards of care that both the NCD and LCDs fail to address, namely the important role of the RDN as part of the health care team in supporting both the ordering physician and the Medicare beneficiary in developing, implementing, and monitoring the enteral or parental nutrition plan of care. RDNs are best qualified^{19 20} to determine the individualized nutrients needed “to maintain weight and strength commensurate with the beneficiary’s overall health status.”²¹ Current CMS regulations and guidelines fail to ensure access to the professional services of RDNs that help to ensure safe and appropriate use of enteral and parenteral nutrition support. **The Academy urges CMS to provide coverage for medically necessary MNT provided by RDNs in conjunction with enteral and parenteral nutritional therapy.**

6. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (Section III.H.)

The Academy supports CMS’s proposal to add Pulmonary Rehabilitation (PR) services for Medicare Beneficiaries who have been hospitalized with COVID-19 diagnosis and continue to experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge.

Evidence supports the importance of the RDN providing MNT to adults with progressive lung disease, specifically lung disease that is characterized by airflow limitation and obstruction such as Chronic Obstructive Pulmonary Diseases (COPD). RDNs are integral to the interdisciplinary health care team caring for patients with progressive lung disease, particularly those patients who are vulnerable to nutrition deficits due to the effects of smoking, poor diet, and inactivity. In many cases, COPD is accompanied by weight loss, nutritional abnormalities, and loss of skeletal muscle and/or function. The primary goals of MNT for people with progressive lung disease are to achieve and maintain appropriate body weight and composition, maximize pulmonary status, reduce mortality, and improve quality of life (QOL).²²

Individuals who have contracted severe COVID-19 infections and require intensive care unit (ICU) admissions are at higher risk for both morbidity and mortality.²³ Additionally, malnutrition (either overnutrition/obesity or undernutrition) is a strong indicator of disease risk and severity for beneficiaries who’ve contracted severe COVID-19 infections. A study conducted by Zellner et al, compared the respiratory muscle strength of well-nourished individuals versus those who were malnourished and found that there were differences between the two groups,²⁴ when sniff nasal inspiratory pressure is measured. While the study authors state that additional research in this area is needed, the finding aligns with previous studies that demonstrated a strong correlation between respiratory muscle strength and nutrition.

¹⁹ Corrigan ML, Bobo E, Mogensen KM, Rollins C. Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: revised 2021 standards of practice and standards of professional performance for registered dietitian nutritionists (competent, proficient, and expert) in nutrition support. *J Acad Nutr Diet* 2021; in press.

²⁰ DeLegge MH, Kelley AT. State of nutrition support teams. *Nutr Clin Pract* 2013;28(6):691-697.

²¹ <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38954&ContrId=389>. Accessed August 17, 2021.

²² Academy of Nutrition and Dietetics Evidence Analysis Library. Chronic obstructive pulmonary disease project. 2019. <https://www.andeal.org/topic.cfm?menu=5301>. Accessed August 19, 2021.

²³ Nutritional management of individuals with obesity and COVID-19: ESPEN expert statements and practical guidance. *Clinical Nutrition*, April 20, 2021. [https://www.clinicalnutritionjournal.com/article/S0261-5614\(21\)00248-X/pdf](https://www.clinicalnutritionjournal.com/article/S0261-5614(21)00248-X/pdf) Accessed August 17, 2021.

²⁴ Differences in Respiratory Muscle Strength Measures in Well-Nourished and Malnourished Hospitalized Patients. <https://doi.org/10.1016/j.jand.2019.01.004> Accessed August 17, 2021.

Based on the experience of our members working in facilities that offer pulmonary rehabilitation, nutrition services provided by an RDN are underutilized due to lack of coverage. However, member feedback has also further supported that the needs for nutrition care in this clinical setting are increasing and have been exacerbated by COVID-19. Our members have reported that individuals recovering from severe COVID -19 infections, specifically those that are post ICU stays, that once discharged, are continuing to deal with nutrition -related issues such as malnutrition, acute kidney injury and dialysis, hypertension, and medication-related events such as elevated blood glucose levels.

7. Medicare Diabetes Prevention Program (MDPP) (Section III.L.)

Academy members provide services in the continuum of diabetes care that includes diabetes prevention programs, MNT, DSMT and other interventions in the context of team-based care. **The Academy largely supports the proposed changes to the MDPP, with some suggested modifications, and urges CMS to take additional actions to increase the number of suppliers, beneficiary participation, and Medicare's return on investment.**

The Academy, more specifically, supports the following:

Removal of the provision of ongoing maintenance sessions unless the beneficiary has started his/her first core session on or before Dec. 31, 2021. Academy members report that the two-year commitment to the program is overwhelming for many beneficiaries, and money-losing for suppliers in the context of low participation. The proposed modification in the MDPP to remove the ongoing maintenance services aligns with the duration of the lifestyle change program as delivered by suppliers that also serve other populations as part of the Centers for Disease Control & Prevention's National Diabetes Prevention Program. This change may better enable suppliers to provide the same services to multi-payer populations.

Redistribution of a portion of the ongoing maintenance performance payments for core maintenance services. The Academy supports the proposed change to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session payments. This augmentation of the payments for the core sessions is an important step to addressing historical payments that did not fully support both the delivery of the lifestyle intervention program and the administrative costs of offering MDPP.

Redistribution of the payments should incentivize completion of the program (i.e., MDPP core services and MDPP core maintenance). The Academy recommends that CMS not increase the payment for 5% weight loss to \$179.00; rather, CMS should maintain the current (2021) payment for the achievement of 5% weight loss (\$169.00) and increase the payments for attendance of the Core Maintenance Sessions from \$52.00 to \$62.00. The payment methodology for 2022 should provide a stronger financial incentive for attendance, demonstrated to be an important predictor of weight loss, and acknowledged in this proposal. For this reason, suppliers should be equally incentivized to encourage participant attendance when 5% weight loss has not been achieved during the first nine core sessions. The proposed increase of the payment to \$179.00 for 5% weight loss could have the unintended consequence of encouraging programs to pursue ongoing participation by those who have already achieved 5% weight loss over those that have not yet achieved the 5% weight loss during the nine core maintenance sessions, which may include individuals who may need additional or ongoing support to prevent the onset of diabetes. There should be an adequate financial incentive for suppliers to promote

attendance amongst individuals who do not achieve 5% weight loss in the first six months of the program.

Waiving of the Medicare application fee for organizations enrolling in Medicare as MDPP suppliers.

Waiving of the fee beyond the COVID-19 PHE will address one significant barrier related to supplier enrollment. The waiving of the fee, alone, may not provide adequate incentive for programs, especially for community-based organizations, to apply and enroll as Medicare Suppliers. The proposed rule points out that “approximately 39 percent of these entities are non-traditional suppliers that serve their local communities to increase diversity, equity, and inclusion of their services, including but not limited to YMCAs, county health departments, community health centers, and non-profit organizations that focus on health education that otherwise would neither enroll nor be able to enroll as a Medicare supplier” and that “they frequently furnish non-health care services to the community”. Additional changes to both the supplier enrollment, qualifying criteria, performance outcomes and the payment structure will be necessary to adequately incentivize more eligible diabetes prevention programs to enroll.

More Changes to MDPP Expanded Model Still Needed to Realize Large Scale Return on Investment

In addition to the four proposed changes to the MDPP that the Academy most-strongly supports, the Academy recommends CMS make additional changes to the MDPP to better meet the needs of all stakeholders and positively impact the prediabetes and diabetes epidemic facing the country. Specifically, the Academy recommends:

- a. **Allow participation in the MDPP more than once-in-a lifetime** Beneficiaries should have additional opportunities to participate in the MDPP, and in a similar manner as other preventive services that are centered on behavioral change, including Intensive Behavioral Therapy for Obesity²⁵ and Smoking and Tobacco-Use Cessation Counseling.²⁶ These are two examples of behavioral interventions where Medicare allows beneficiaries to receive services more than once, as long as national coverage determination criteria are met.

As noted in the proposed rule, MDPPs are vastly under-utilized with only 3,600 beneficiaries participating in the MDPP. The current once-in-a lifetime benefit limit may be a deterrent to enrollment, as some individuals might delay enrollment knowing that they have only one opportunity, or because they are ambivalent about participation. Preventing or delaying diabetes requires ongoing adherence to lifestyle change, and the limitation ignores the complexities of the lives of many beneficiaries. The MDPP should aim to engage beneficiaries early in the continuum of prediabetes and those who may be ambivalent.

CMS should remove the once-in-a lifetime benefit limit and study the outcomes of repeat participation, specifically, whether repeat participation continues to delay the onset of disease. It should be noted that the original Diabetes Prevention Program from which the NDPP was created was a 3-year intervention.²⁷ If repeat participation does not realize extended prevention, CMS could then limit utilization because it is evidence-based. As the benefit currently stands, CMS is limiting

²⁵ Intensive Behavioral Therapy for Obesity National Determination of Coverage. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=353> Accessed September 2, 2021.

²⁶ Smoking and Tobacco-Use Cessation Counseling. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=308&ncdver=1&bc=AAAAQAAAAAAAAA%3D%3D> Accessed September 2, 2021.

²⁷ Nathan, DM et al. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications: the DPP outcomes study, *Lancet Diabetes Endocrinology*. 2015 Nov; 3(11): 866-875.

repeat participation in the program without evidence to support the once-in a lifetime benefit limitation.

- b. CMS should cover Hemoglobin A1c testing for both the screening and diagnosis of diabetes.** CMS and the MDPP are out of step with the standards of practice in terms of screening and diagnosing both prediabetes and diabetes. MDPP criteria recognizes A1c as one of the qualifying criteria, however, the test is not covered for beneficiaries. Currently, the A1c test is covered only after Medicare beneficiaries have a diagnosis of diabetes.
- c. Additionally, Medicare should recognize $\geq 0.2\%$ reduction in the A1c as an acceptable alternative performance benchmark to 5% weight loss, qualifying programs for performance-based payments in instances where individuals have not achieved 5% weight loss.** The CDC Diabetes Prevention Recognition Program 2021 Standards²⁸ recognize at least a 0.2% reduction in baseline HbA1c (recorded within one year of enrollment) as an acceptable outcome for risk reduction at 12 months. Risk reduction and the prevention of diabetes via participation in the MDPP does not always require 5% weight reduction. There are individuals who achieve reductions in glucose through dietary modification and improvement in insulin action from increased physical activity and other lifestyle changes in the absence of 5% weight loss. A1c is an important factor in the risk stratification and management strategies for prediabetes²⁹ and has been adopted by the American Diabetes Association.³⁰
- d. Modify and simplify the payment methodology for MDPP Services.**

The performance-based payments methodology should be modified to provide an adequate and predictable payment stream to cover the cost of providing services to beneficiaries, as long as beneficiaries attend sessions. CMS could consider prospective bundled payments for a certain number of initial core sessions, maintain performance-based payments for weight loss, and increase payments for attendance for MDPP core maintenance services. The payments have been incommensurate with the complex claims submission process and the additional administrative costs of providing services to Medicare beneficiaries. The administrative burden is particularly challenging, especially for the 39% of organizations that are non-traditional suppliers. Medicare pays provider claims for the IBT for obesity benefit, regardless of weight loss achievement, until a reassessment at 6-months. CMS should provide programs with an adequate revenue stream for program delivery as long as participants attend sessions, including during the core maintenance period even if beneficiaries do not achieve 5% weight loss during the first nine sessions. The complex payment methodology runs counter to CMS's goal of Burden Reduction, Patients Over Paperwork,³¹ and increases the operating costs of both Medicare suppliers and the MACs alike. The payment methodology needs to be modified to include some portion of prospective payments, coupled with performance-based payments which would enable programs to address the challenges of recruitment and retention.

²⁸ CDC Diabetes Prevention Recognition Program Standards and Operating Procedures. May 1, 2021, <https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf> Accessed September 2, 2021.

²⁹ Tuso, P. Prediabetes and Lifestyle Modification: Time to Prevent a Preventable Disease, Perm J. 2014 Summer; 18(3): 88–93. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4116271/> Accessed: September 3, 2021.

³⁰ Prediabetes: Strategies for effective screening, intervention, and follow-up. American Diabetes Association. <https://professional.diabetes.org/sites/professional.diabetes.org/files/media/prediabetes.pdf> Accessed: September 3, 2021.

³¹ CMS: Burden Reduction-Patients over Paperwork. <https://www.cms.gov/About-CMS/Story-Page/patients-over-paperwork> Accessed: September 3, 2021.

- e. **The Academy recommends that CMS extend temporary capabilities to provide synchronous fully virtual delivery of the MDPP outside of the public health emergency to enable more data collection and robust evaluation of fully virtual delivery in Medicare populations.** To date, most participants receiving fully virtual diabetes prevention program services receive them through employer-sponsored programs. It is imperative to understand the acceptance and effectiveness of synchronous virtual delivery of the MDPP in the Medicare population in the context of the expanded model before making synchronous virtual delivery a permanent option.

The Academy acknowledges the potential to reach thousands of Medicare beneficiaries in states and localities where no in-person MDPP suppliers exist through fully virtual MDPP. Fully virtual suppliers may be able to address some health inequities by reaching beneficiaries in rural areas and making their programs available in urban and suburban areas to beneficiaries who have mobility, transportation, caregiving, and other issues that preclude them from being able to attend in-person instruction. At the same time, careful consideration should be given to the adoption of all virtual programs to provide patients with safe, and appropriate instruction. The biggest concern is for Medicare beneficiaries with prediabetes with multiple co-morbidities requiring expertise beyond what non-RDN providers in the MDPP may be able to safely provide. It may be more difficult to identify participants who are not appropriate for the DPP in a fully virtual program.

The current CDC program recognition standards do not include any specific requirements to ensure higher risk beneficiaries are identified and appropriately referred to necessary health care services and providers. Experience of Academy members delivering Diabetes Prevention Programs or providing MNT services to participants of such programs reveals the unfortunate frequent occurrence of participants being provided with incorrect nutrition information and advice that is detrimental to their health. Data to date on CDC recognized programs indicates some of the most successful programs use both lay coaches and health professional coaches, such as RDNs. **The Academy continues to urge CMS to require MDPP services, whether virtual or in-person, to be delivered by or under the supervision of qualified health care providers, such as an RDN, NDTR, or CDCES.**

The Academy would like to see regulatory changes to address this concern but realizes that a statutory solution may be required. To achieve this goal the Academy is supporting the PREVENT DIABETES Act (HR 2807³²/S.2173³³), which would permit CDC-recognized virtual diabetes prevention program suppliers to be included in the MDPP Expanded Model conducted by CMMI under section 1115A of the Social Security Act (42 U.S.C. 1315a). Congressional sponsors have re-introduced this bill in the House (April 22, 2021) and Senate (June 22, 2021).

Finally, the Academy aligns with other concerns and recommendations noted in comments submitted by the Diabetes Advocacy Alliance, of which the Academy is a member. The Academy recommends that CMS lower the categorical risk for MDPP suppliers. The requirements for the classification of high categorical risk are onerous, especially for community-based organizations. Lowering the categorical risk for the MDPP would be a significant step to increasing the number of MDPP suppliers.

³² H.R.2807 Prevent Diabetes Act. <https://www.congress.gov/bill/117th-congress/house-bill/2807/text?q=%7B%22search%22%3A%5B%22H.R.+2807%22%5D%7D&r=1&s=1> Accessed September 3, 2021.

³³ S.2173 Promoting Responsible and Effective Virtual Experiences through Novel Technology to Deliver Improved Access and Better Engagement with Tested and Evidence-based Strategies Act. <https://www.congress.gov/bill/117th-congress/senate-bill/2173/text> Accessed September 3, 2021.

8. Updates to the Quality Payment Program (Section IV.)

CMS, in light of the continued COVID-19 PHE, is proposing modest changes to the Quality Payment Program for which the Academy is both appreciative and supportive. Furthermore, the Academy welcomes CMS's continued efforts to make participation more meaningful for clinicians and reduce barriers to successful participation for small practices. We also support CMS's continued focus to address issues surrounding health equity and social determinants of health.

MIPS Value Pathway (MVPs)

The Academy also agrees with CMS's decision to delay the implementation of MIPS Value Pathways (MVPs) until performance year 2023 as many small practices and health systems are continuing to face challenges related to the COVID-19 PHE. The Academy agrees with the rationale behind and development of MVPs and believes they will support CMS's goal of strengthening the QPP as a value-based program.

While we recognize the merit and continue to support the development of MVPs, **the Academy remains concerned that, like the overall design of the QPP, it is being done through the lens of physician-providers only.** For example, the current population health measures available for selection by MVP participants, while important, are not applicable to all MIPS eligible clinicians. So, in the case of an RDN, unless such a provider participates in an MVP under the multispecialty group or APM entities option, they would not meet MVP Foundational Layer reporting requirements. While CMS proposes these measures would be excluded from scoring if the measure doesn't meet case minimum, such action negatively impacts the potential for such MIPS eligible clinicians to achieve positive payment adjustments. A similar concern applies to the Promoting Interoperability (PI) Performance Category under the Foundational Layer as not all MIPS eligible clinicians are able to report under this category. **The Academy supports the proposal to align reweighting policies for the redistribution of category weights for final MVP scoring with traditional MIPS and asks CMS to consider the implications of such policies as they pertain to the MVP Foundational Layer and the full spectrum of MIPS eligible clinicians.** As health care continues to shift towards value-based payments, the Academy is concerned that eligible clinicians who are active participants on health care teams and contributing to better health outcomes for beneficiaries are without a mechanism to achieve positive payment adjustments. Without a payment mechanism in place, valuable non-physician providers will eventually be lost from team-based care. **Therefore, when MVPs are developed, we encourage CMS to look beyond the physician community for inclusion in the development of future MVPs.**

Team based care often provides some of the best health outcomes for beneficiaries, and, as we have stated throughout this comment, MNT provided by RDNs is recognized as a key component to management of chronic diseases, including conditions beyond diabetes and renal disease. In five of the seven proposed MVPs, nutrition therapy is a component in either the management or treatment of the disease or condition. Those MVPs include:

- Advancing Rheumatology Patient Care MVP
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP
- Advancing Care for Heart Disease MVP
- Optimizing Chronic Disease Management MVP
- Improving Care for Lower Extremity Joint Repair MVP

The Academy acknowledges that CMS is early in the development of MVPs and that the focus will be on major types of eligible clinicians; however, the Academy encourages CMS to expand Improvement Activity measures within each of these MVPs that will better capture both the need and utilization of all care team members.

Specifically, we recommend the following core set of Improvement Activities for each of the 5 MVPs noted above:

- IA_PM_13 Chronic care and preventative care management
- IA_EPA_2 Use of telehealth services that expand practice access
- IA_BE_16 Evidenced-based techniques to promote self-management into usual care
- IA_BE_20 Implementation of condition-specific chronic disease self-management support programs
- IA_BMH_2 Tobacco use
- IA_BMH_4 Depression screening

We believe the inclusion of additional Improvement Activities would support more non-physician eligible clinicians with greater flexibility and participation within the proposed MVPs. Furthermore, we believe that this is an opportunity for CMS to better support team-based care that can lead to better outcomes. We encourage CMS to keep this important point in mind as additional MVPs are developed.

Many RDNs continue to face significant barriers to participating in the QPP. RDN practices were not included in the EHR Incentive Program, which was designed to make access to health information technology and interoperability among all providers a reality. Many RDN practices continue to rely on manual reporting and data collection which can make it difficult to near impossible to participate in quality reporting. Member feedback reveals that while there is interest in participating in the QPP, the complexities of the program prove to be too burdensome. In addition to technology barriers, many RDNs have expressed concerns when selecting which measures to report, and meeting participation thresholds. **The Academy continues to encourage CMS to provide financial support (e.g., grants) and continued technical assistance to all provider types not previously included in the EHR Incentive Program so that they can actively and meaningfully participate.**

Merit-based Incentive Payment System (Traditional MIPS)

The Academy appreciates the agency's recognition of the continued impact of COVID-19 on the ability of MIPS eligible clinicians to complete data submission as they focus on caring for patients. We also appreciate CMS's continued efforts to facilitate greater participation by small practices.

Specifically, the Academy supports the following proposals for the reasons cited by CMS:

- Maintain the data completeness criteria threshold of at least 70 percent for the 2021 and 2022 MIPS performance periods (2023 and 2024 MIPS payment years)
- Postpone the sunset of the CMS Web Interface by extending the availability of the CMS Web Interface as a collection and submission type for the 2022 MIPS performance period
- Use performance period benchmarks for the CY 2022 performance period and to expand the baseline period to 3 performance periods prior for measures that are suppressed two performance periods prior
- Continue doubling the complex patient bonus for the 2021 performance year with proposed limitations
- Implementation of special scoring policies for small practices

Quality Performance Category

Nutrition/Dietician Measure Set:

The Academy requests that CMS add the MNT CPT codes (97802, 97803, 97804, G0270, G0271) to the denominator criteria of the measure specification for Depression Screening (NQF#0418/Quality#134) and subsequently add to the Nutrition/Dietician Measure Set.

Depression continues to be a major public health concern and all Medicare providers should be doing their part to address the issue. Depression, particularly in older adults, has been linked to malnutrition and food insecurity,³⁴ both of which are issues RDNs actively address to not only provide guidance and intervention but also assist in the coordination of care with other appropriate subspecialties.

Screening for depression is often a routine part of the comprehensive nutrition assessment performed by RDNs as nutrition status is closely linked to mental health and optimizing the nutrition status of an individual with mental illness has been shown to improve both cognitive and emotional functioning.³⁵ RDNs use various tools and resources, including practice guidelines from federal associations such as the National Institutes of Health and other professional organizations, to guide nutrition care.³⁶ The Nutrition Care Process³⁷ and the Academy's Standards of Professional Practice for RDNs in Mental Health and Addiction³³ guide RDNs to assess and consider other factors affecting intake, nutrition, and health status (e.g., cultural, ethnic, religious, lifestyle influencers, psychosocial and social determinants of health). RDNs work with beneficiaries to create a nutrition care plan which includes developing and prioritizing goals based on individual needs and evidenced based best practice, provide nutrition counseling, and make referrals to appropriate resources and programs when needed. Beyond MNT services, RDNs may perform depression screens as recognized providers of the Annual Wellness Visit (AWV). Given the RDN Scope of Practice, it would be appropriate to add this measure to the Nutrition/Dietician Measure set.

The Academy has been in conversations with the measure steward for the following Quality Measures: Diabetes: Hemoglobin A1c Poor Control (>9%) (NQF#/Quality#001) and Tobacco Screening (NQF#0028/Quality#226). We have asked the measure steward to add the MNT CPT codes (97802, 97803, 97804, G0270, G0271) to the denominator criteria for the measure specifications of both measures, noting both areas fall under the scope of practice of RDNs³⁸ and evidence-based clinical care guidelines.³⁹

³⁴ Doner B, et al. *Position of the Academy of Nutrition and Dietetics: Individualized Nutrition Approaches for Older Adults: Long-Term Care, Post-Acute Care, and Other Settings*. JAND, April 2018, 118 (4) Number 4, p 724-35.

³⁵ Academy of Nutrition and Dietetics: *Revised 2018 Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Mental Health and Addictions*. Journal of the Academy of Nutrition and Dietetics, October 2018, Volume 118, Number 10.

³⁶ Academy of Nutrition and Dietetics: *Revised 2017 Scope of Practice for the Registered Dietitian Nutritionist*. Journal of the Academy of Nutrition and Dietetics, January 2018 Volume 118 Number 1.

³⁷ The Nutrition Care Process (NCP) is defined as systematic method to providing high-quality nutrition care based on evidenced-based nutrition research, critical thinking and decision-making. *Nutrition Care Process and Model: An Academic and Practice Odyssey*. Journal of the Academy of Nutrition and Dietetics, December 2014 Volume 114 Number 12.

³⁸ Academy of Nutrition and Dietetics: *Revised 2017 Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Diabetes Care*. Journal of Nutrition and Dietetics, May 2018 Volume 118 Number 5.

³⁹ Diabetes Care 2021 Jan; 44 (Supplement 1): S226-S232. <https://doi.org/10.2337/dc21-in01>

Registered dietitians provide care to persons with diabetes through the Medicare Part B MNT benefit and have been shown to help improve HbA1c control.^{40 41} Under PQRS and the early years of MIPS, RDNs reported this quality measure, and nothing has changed with standards of practice or clinical practice guidelines that would support a change in their accountability for managing HbA1c.

Screening for tobacco is often a routine part of the comprehensive nutrition assessment performed by RDNs and addresses a major public health concern which all Medicare providers should be addressing within their professional competency. RDNs use various tools and resources, including practice guidelines from federal associations such as the National Institutes of Health and other professional organizations, to guide nutrition care.⁴² The Nutrition Care Process (NCP) guides each RDN to assess and consider factors affecting intake, nutrition, and health status (e.g., cultural, ethnic, religious, lifestyle influencers (such as smoking), psychosocial and social determinants of health). Smoking and poor diet quality are well known risk factors for the development of chronic disease and an RDN will evaluate the impact of substance use disorder (e.g., alcohol, tobacco, drugs) on ability to care for self.⁴³ A study completed in 2017 by Shepard, et. al. at Bellevue Hospital Center and NYU Langone Medical Center demonstrated a negative correlation between smoking and diet quality among adults with a median age of 60 years old, who were undergoing coronary angiography. Adult smokers have been reported to have poorer diet quality in comparison to non-smokers.⁴⁴ Beyond MNT services, RDNs may perform tobacco use screening as recognized providers of the Annual Wellness Visit (AWV).

Based on conversations with the measure steward, the Academy requests that CMS retain Diabetes: Hemoglobin A1c Poor Control (>9%) (NQF#/Quality#001) in the Nutrition/Dietician Measure set and add Tobacco Screening (NQF#0028/Quality#226).

Improvement Activities Performance Category

To address the impact of social determinants of health, CMS has proposed a new improvement activity measure “Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols” to be added for the 2022 Performance Year. **We commend CMS for recognizing the importance of food security in preventing malnutrition and we remind CMS that malnutrition in food secure individuals can present as either undernutrition or overnutrition. We hope that this IA is one of many steps CMS will take to address malnutrition in the Medicare population.**

Proposed Activity ID: IA_AHE_XX Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols

As indicated in the Improvement Activity, opportunity to use the Malnutrition Quality Improvement Initiative (MQii) framework is one way for implementation of food insecurity and nutrition risk identification and treatment protocols resulting in two pathways for appropriate support of nutritional outcomes. Poor nutrition status, which can stem from food insecurity, often results in clinical

⁴⁰ Academy of Nutrition and Dietetics Evidence Analysis Library. Diabetes Type 1 and 2 Systematic Review project. 2015. <https://www.andean.org/topic.cfm?menu=5305&pcat=5491&cat=5161> Accessed September 2, 2021.

⁴¹ Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report, Diabetes Care 2019;42:731–754.

⁴² Academy of Nutrition and Dietetics: *Revised 2017 Scope of Practice for the Registered Dietitian Nutritionist*. Journal of the Academy of Nutrition and Dietetics, January 2018 Volume 118 Number 1.

⁴³ Academy of Nutrition and Dietetics: *Revised 2018 Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Mental Health and Addictions*. Journal of the Academy of Nutrition and Dietetics, October 2018, Volume 118, Number 10.

⁴⁴ Shepard, T. et al. *Association Between Smoking Status and Diet Quality Among Patients Referred for Coronary Angiography in New York City*. Journal of the Academy of Nutrition and Dietetics, Sep 2017, Suppl 1., 117 (9) p A-81.

malnutrition or undernutrition. The outpatient setting pathways must provide appropriate food insecurity screening tools and adapt the validated malnutrition risk screening tools to outpatient needs. The MQii framework uses Quality Improvement Projects to transition to outpatient settings for RDN-led protocols with interventions aimed at improving nutrition health equity and food access outcomes (i.e., education, counseling, at-home services, and coordination with community organizations for resources).

Cost Performance Category

MNT plays a critical role in diabetes management; it also is an integral component of care for many post-gastrointestinal surgery patients. The Academy supports the inclusion of both the Diabetes and Colon and Rectal Resection episode-based cost measures. We were pleased to have RDNs participate on the clinical care subcommittees that were charged with developing these new episode-based measures. **The Academy looks forward to continued opportunities to participate in the future and urges CMS to continue to include the full range of provider types in the development of such measures to fully capture the total cost of care involved in these episodes of care.**

Promoting Interoperability

CMS is proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for certain types of non-physician practitioner MIP eligible clinicians for the performance period in 2021, including registered dietitians or nutrition professionals. **The Academy supports the continued reweighting policy as there currently are not sufficient measures applicable and available to RDNs under this performance category.**

The Academy has ongoing efforts underway to support the development and testing of nutrition content as part of the HL7 FHIR specification which currently includes the NutritionOrder, NutritionIntake, and NutritionProduct resources, as well as involvement in other HL7 and FHIR artifacts that include nutrition and support the care plan through inclusion of the whole care team. As the FHIR standard, implementation guides, and interoperability evolves, this pathway may provide RDNs and other specialty providers more efficient ways to support electronic referral loops among MIPS eligible and non-MIPS providers. **We encourage CMS to consider creating future interoperability measures that support the inclusion of all types of clinicians to demonstrate performance in this category.**

Regulatory Impact Analysis (Section VII)

The proposed CY 2022 PFS conversion factor is \$33.58, a 3.75 percent decrease compared to CY 2021. As the nation's health care system continues to be stressed by the COVID-19 pandemic, now is not the time to subject Medicare providers to severe cuts in payment. **The Academy strongly urges CMS/HHS to continue to utilize its authority under the continued PHE declaration to preserve patient access to care and mitigate financial distress due to the ongoing pandemic by waiving budget neutrality requirements.** The proposed cuts, as estimated in Table 123, are devastating to health care professionals, their practices, and most importantly, to their patients. Payment reductions of this magnitude would be a major problem at any time, but to impose cuts of this magnitude during or immediately after the COVID-19 pandemic is unconscionable.

Seniors that require nutrition/diet interventions, including diabetes and chronic kidney disease, are suffering from the worst COVID-19 outcomes, including higher rates of death. MNT provided by RDNs has been proven to help these patients control their blood sugar, blood pressure and weight, slow the progression of diabetes and kidney disease, lower medication use, and avoid unnecessary emergency room visits and hospitalizations.

Physicians will have fewer choices when referring patients to specialists if health care professionals must close or limit their practices because of these cuts. Many of our members are small business owners hit hard financially by the PHE. The proposed cuts, on top of Medicare fee-for-service payments that have failed to keep up with inflation along with the 2% sequestration reductions, will force many to reconsider their Medicare provider enrollment status or even close their doors, thus severely diminishing Medicare and non-Medicare patient access to critical nutrition services. Such cuts also may negate CMS's efforts under this proposed rule to increase utilization of MNT. While some have pointed to the Quality Payment Program as an opportunity to offset these cuts, access to the Merit-based Incentive Payment System and Advanced Alternative Payment Models cannot be considered a meaningful or accessible offset.

The Academy urges CMS to explore all avenues, including working with Congress, to prevent drastic cuts from occurring while RDNs and other Medicare providers are still trying to recover and gain their financial footing from the effects of the pandemic.

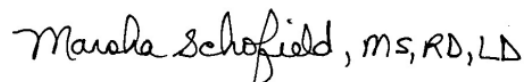
Finally, CMS routinely and inexplicably omits analysis of the impact of the proposed physician fee schedule changes for the RDN specialty; RDNs are not listed in Table 123 "CY 2022 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty." CMS's omission of RDNs in Table 123 makes it difficult for the Academy and RDN Medicare providers to recognize the impact of fee schedule changes on their practices. **Once again, the Academy urges CMS to annually include the RDN specialty in this table to facilitate an analysis of fee schedule changes on this vital healthcare specialty.**

Thank you for your careful consideration of the Academy's comments on the proposals for the CY 2022 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies. Please do not hesitate to contact Jeanne Blankenship by phone at 312-899-1730 or by email at jblankenship@eatright.org or Marsha Schofield at 312-899-1762 or by email at mschofield@eatright.org with any questions or requests for additional information. The Academy looks forward to continued opportunities to work with CMS to design a health care delivery and payment system that improves the health of the nation and meets the needs of all stakeholders.

Sincerely,



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