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September 11, 2023

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attn: CMS-1700-P P.O. Box 8016 Baltimore, M.D. 21244-8016

Re: File Code-CMS-1784-P; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

The Academy of Nutrition and Dietetics (the "Academy") is pleased to provide comments on File Code-CMS-1784 P RIN 0938-AV07-P published in the Federal Register on August 7, 2023. Representing more than 112,000 registered dietitian nutritionists (RDNs),¹ nutrition and dietetic technicians, registered (NDTRs), and advanceddegree 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.

The Academy supports many of the changes proposed in the payment policies under the Physician Fee Schedule and applauds continued efforts by CMS to work within their regulatory power to fine-tune polices that will support access to and delivery of safe, equitable and effective health care.

With that in mind, the Academy offers specific comments on the following proposed rule items: Section II.D Payment for Medicare Telehealth Services Under Section 1834(m) of the Act Section II.E Valuation of Specific Codes

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 21, 2023.

Section II.I Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT Telehealth Services
Section III.B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
Section III.I Medicare Diabetes Prevention Program (MDPP)
Section III.L. Expand Diabetes Screening and Diabetes Definitions
Section III.S A Social Determinants of Health Risk Assessment in the Annual Wellness Visit
Section IV Updates to the Quality Payment Program
Section VII Regulatory Impact Analysis

Section II.D Payment for Medicare Telehealth Services Under Section 1834(m) of the Act Section II.D.1. B. Requests to Add Services to the Medicare Telehealth Services List for CY 2024

(6) Health and Well-being Coaching

Background: The Academy appreciates the opportunity to provide feedback on CMS' proposal to provide feedback on increasing access to health and well-being coaching services via telehealth. Through the Academy's work with the AMA, we provided input to establish Category III CPT codes for Health and Well-being coaching effective January 1, 2020. Through this work, the AMA defined Health³-wellness coaching and outlined provider qualifications to perform the service:

"The health and well-being coach is qualified to perform health and well-being coaching by education, training, national examination and, when applicable, licensure/ regulation, and has completed a training program in health and well-being coaching whose content meets standards established by an applicable national credentialing organization. The training includes behavioral change theory, motivational strategies, communication techniques, health education and promotion theories, which are used to assist patients to develop intrinsic motivation and obtain skills to create sustainable change for improved health and well-being."

According to the National Board of Health and Wellness Coaching,⁴ "Health & wellness coaches support clients in activating internal strengths and external resources to make sustainable and healthy lifestyle behavior changes . . . use a client-centered approach wherein clients decide their goals, engage in self-discovery or active learning processes, and self-monitor behaviors to increase accountability."

The Academy² defines Medical Nutrition Therapy as "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". As such, MNT and Health and Well-being coaching services have separate CPT codes. Additionally, MNT is a Medicare covered service for both in-person care and telehealth (Category I). To our knowledge, the Health and Well-being CPT Codes (0591T, 0592T, and 0593T) are not currently a Medicare covered service for care provided by either telehealth or in-person.

In 2021, the Academy revised its policy stance "Medical Nutrition Therapy Provider Qualifications" ⁵ to include the following:

"Medical nutrition therapy should only be provided by a registered dietitian nutritionist or by another evidence-based health care provider with knowledge and competencies commensurate to that obtained through the specialized education and training of registered dietitian nutritionists."

³ AMA CPT Manual, 2023

⁴ Health Coach Scope of Practice. <u>https://nbhwc.org/what-is-a-health-coach/</u> Accessed August 30, 2023.

⁵ Academy of Nutrition and Dietetics (2021). Medical Nutrition Therapy Provider Qualifications. Unpublished internal company document.

"With notable exceptions, these high level practitioners [physicians or other health care professionals whose scope of practice may include MNT], in addition to lay providers such as health or wellness coaches and other health care practitioners without the requisite education, experience and competencies, should refer patients and clients to an RDN for nutrition care services that might impact, treat or manage a disease or medical condition."

In 2017, the Academy established its "Health and Wellness Coaches Stance"⁶ to include the following:

"The education and training for health coaches varies widely; some health coaches have limited education and no clinical experience and others are licensed or credentialed health care providers who also hold certification as health coaches, including RDNs and NDTRs. Without standards for education and training, there is no guarantee that the health coaches sought out by the public or by employers have the education, training and credentials to protect the public or provide safe, effective outcomes. The Academy should evaluate various credentials held by health coaches for their credibility and ability to protect consumers and effective positive health outcomes."

The Academy recognizes the integral role health and wellness coaching plays in supporting beneficiaries with meeting their health care goals and taking ownership of their health. It is the Academy's belief that Health coaches who work alongside health care teams are in a unique position to support beneficiaries in discovering and utilizing health and wellness resources, including accessing appropriate referrals. As such, we believe that health coaches play a role in supporting greater access and utilization of MNT and promoting health equity efforts. However, the Academy remains concerned regarding the potential confusion and/or lack of understanding by providers and beneficiaries of the differences between MNT, wellness coaching, and behavioral counseling.

Certification Requirements

The 2017 Scope of Practice for Registered Dietitian Nutritionists⁷ recognizes coaching, a service that does not constitute MNT, may be within the scope of practice of an RDN who has obtained appropriate training in health and wellness coaching and has met demonstrated competencies.

The Academy acknowledges that while there is no national accreditation organization recognized by the U.S. Department of Education for certification of a Health Coach, the NB-HWC provides the most rigorous certification process currently in existence, including minimum education requirements, supervised contact hours, a standardized training and education program, examination, a code of ethics and continuing education requirements. The Academy would like CMS to confirm that the providers who submit claims for Health and Well-being coaching services must hold certification from the National Board of Certified Health and Wellness Coaches (NB-HWC).

Health and Well-being Coaches Provider Eligibility

The Academy requests that CMS confirm that Medicare providers who submit claims for Health and Wellbeing coaching services must also be qualified health care providers. We request that CMS confirm that RDNs are qualified health care providers.

⁶ Academy of Nutrition and Dietetics. (2017) Health and Wellness Coaches Stance. Unpublished internal company document.

Academy Recommendations

- Support addition of Health and Well-being coaches as a temporary service, provided CMS clearly requires:
 - Health and Well-being coaches to also be trained and licensed as a qualified health care provider; and
 - Provides for clearly defined Health and Well-being coaching certification requirements.
- Request that CMS include RDNs in the list of examples of practitioners that meet the definition of a "health care provider."
- Request CMS make clear to beneficiaries and providers who are seeking to refer services:
 - The differences between Medical Nutrition Therapy and Health and Well-being coaching services;
 - Provider types that are qualified to provide Medical Nutrition Therapy and provider types who are qualified to provide health and well-being coaching services.

(7) CMS Proposal to Add new codes to the list – HCPCS code GXXX5 (Administration of a standardized, evidenced based Social Determinants of Health Risk Assessment tool, 5-15 minutes)

The Academy supports CMS' proposal to add HCPCS code GXXX5 to the permanent list of Medicare approved telehealth services.

Academy Recommendations

- The Academy supports CMS' proposal to add HCPCS code GXXX5 as a permanent Medicare approved telehealth service, should CMS finalize the code and establish payment and no beneficiary cost sharing.
- We urge CMS to expand access to SDOH Risk assessment to all Medicare providers, including RDNs who delivered MNT services.

Addition of HCPCS Code G0271 to the Medicare approved telehealth services:

The Academy requests CMS add G0271 to the list of Medicare telehealth services as this service meets the Category 1 criteria. We believe the addition of HCPCS G0271 falls under Category 1 in accordance with section 1834(m)(4)(F)(ii) of the Social Security Act which outlines Category 1 services are "similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services... we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter...We also look for similarities in the telecommunications system used to deliver the service."

The current list of Medicare telehealth services⁸ includes:

- CPT code 97802 Medical nutrition therapy, initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
- CPT code 97803 Medical nutrition therapy, re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes
- CPT code 97804 Medical nutrition therapy, group (two or more individuals), each 30 minutes
- HCPCS code G0270 Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen, individual, face-to-face with the patient, each 15 minutes

⁸ List of Telehealth Services. <u>https://www.cms.gov/Medicare/Medicare-general-information/telehealth/telehealth-codes Accessed</u> <u>August 21</u>, 2023

The MNT HCPCS codes are available when there is need for additional MNT beyond the Part B benefit, and when there is a change in medical condition and a second referral is received from the provider. HCPCS code G0271 is analogous to CPT Code 97804 for group medical nutrition therapy reassessment and subsequent intervention(s) for a change in diagnosis, medical condition, or treatment regimen. The Academy believes that absence of G0271 on the Medicare telehealth approved list does have a negative impact on the ability of beneficiaries to access to MNT services, particularly those in rural population, indigenous groups and those residing in underserved areas.

Recent feedback from Academy members highlighted this issue. To summarize, the inability to deliver group MNT via telehealth has resulted in the need to deliver the same care via individual MNT visits, which results in inefficient use of resources and takes longer to deliver care. This further illustrates the ramifications of the omission of G0271, with one member sharing that his practice conducts approximately 84 individual visits using G0270 and 138 visits with G0271 annually. If G0271 remains excluded from the Medicare telehealth list, they would need to accommodate 222 MNT visits using G0270, nearly doubling the cost to Medicare and substantially reducing MNT availability within his community. Additionally, his group sessions allow for 8 to 10 patients within a 60 to 90-minute timeframe, while individual telehealth appointments will take 30 to 45 minutes per patient.

Academy Recommendation:

• Add HCPCS code G0271, which is analogous to CPT Code 97804 to the list of approved Medicare telehealth services.

Section II.D.1. E. Implementation of Provisions of the CCA, 2023

(3) Originating site requirements and (5) Audio-only Services

The proposed rule seeks to amend 1834(m)(4)(C)(iii) of the Act to temporarily expand the telehealth originating sites for any service on the Medicare Telehealth Services List to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, beginning on the first day after the end of the PHE for COVID–19 through December 31, 2024.

The proposed rule also seeks to amend section 1834(m)(9) of the Act to require that the Secretary shall continue to provide for coverage and payment of telehealth services via an audio-only communications system during the period beginning on the first day after the end of such emergency period and ending on December 31, 2024. The Academy continues to support the continuation of coverage for synchronous audio-only telehealth 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.

Academy Recommendation:

• We support CMS' proposals to extend originating site and audio-only telehealth flexibilities through 2024.

Section II.D. 2. Other Non-face to Face Services Involving Communications Technology under PFS

a. Direct Supervision via Use of Two-way Audio/Video Communications Technology

The Academy is appreciative of CMS extending the flexibility of supervision to be available through audio/video communications technology. The Academy believes this not only provides better access to care for beneficiaries

but also supports the delivery of timely, cost-effective care. The Academy is in support of CMS making these flexibilities permanent.

The National Coverage Determination 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. We believe this flexibility has temporarily removed the burdensome requirements of real-time audio/video supervision by physicians (who recognize RDNs should independently be providing these services) and has subsequently supported practical means for beneficiaries to access the full 22 sessions of the cost-effective and clinically effective IBT services they receive from RDNs.

Academy Recommendation:

• The Academy supports CMS continuation of its policy to allow direct supervision to be delivered through real-time audio/video communication technology. We also support making this flexibility permanent.

e. Telephone Evaluation and Management Services

The Academy is appreciative of CMS' efforts to expand beneficiary access to care and recognition of the value of reducing barriers to providers, including RDNs when concerns arise regarding the nutrition plan of care. We agree with the proposal to continue to assign active payment status to CPT codes 98966-98968 when delivered by a qualified non-physician health care professional for CY 2024 to align with telehealth-related flexibilities.

Academy Recommendation:

• The Academy supports CMS finalize its proposal to continue active payment status for CPT Codes 98966-98968.

<u>Section II.D.4. Payment for Outpatient Therapy Services, Diabetes Self-Management Training and Medical</u> <u>Nutrition Therapy when Furnished by Institutional Staff to Beneficiaries in Their Homes Through</u> <u>Communication Technology</u>

b. Proposal to Extend Billing Flexibilities for Certain Remotely Furnished Services Through the End of CY 2024 and Comment Solicitation

The Academy supports CMS' proposal to extend telehealth coverage through 2024 when institutional staff provide MNT or DSMT to beneficiaries in their home and that both MNT and DSMT should be regulated under Section 1834 (m) of the Act. However, the Academy remains concerned that language specifically instructing hospitals how to bill for MNT and DSMT services when provided by institutional employees still lacks clarity.

To address CMS' request for more information regarding current practices for MNT when billed and to what degree MNT is delivered via telehealth, we offer the following commentary:

Background Billing for MNT in the Hospital Outpatient Department:

Section 105 of the Benefit and Improvement Act (BIPA) of 2008 ⁹authorized Medicare Part B coverage of Medical Nutrition Therapy"¹⁰ and the Social Security Act established RDNs or nutrition professionals as the only

⁹ Pub L. No. 106-554. The Benefits Improvement and Protection Act of 2000

¹⁰ 42 CFR § 410.132

eligible practitioners permitted to furnish and independently bill for MNT.¹¹ In the CY 2000 PFS final rule, CMS established that payment for MNT services furnished in the institutional setting, including hospital outpatient departments (HOPDs), would be made under the PFS, not under the hospital Outpatient Prospective Payment System (OPPS) (66 FR 55279). MNT has been on the list of Medicare approved telehealth services and RDNs have been on the list of distant site providers since 2006.¹² The Medicare Part B MNT benefit specifically cannot be provided as an "incident to" service. RDNs are independent providers of MNT and guidance from CMS should accurately reflect that fact.

The Academy is acutely aware of situations where institutional billing departments, prior to the PHE, did not submit claims to Medicare for MNT services (either for in person or telehealth) when those services were provided in the hospital outpatient department. The rationale for this varied; however, a common thread is the uncertainty on how to bill claims for MNT when provided in hospital outpatient departments. The Academy has requested clarification from CMS regarding the claim submission for MNT services when provided in the HOPD, however we have yet to receive such guidance.

The fact remains that 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 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.

In the July 2020 IFC (CMS-5531-IFC), CMS erroneously stated that Medicare statute does not have a benefit category that "would allow registered dietitians [sic] the ability to directly bill Medicare for their services". ¹³ Outpatient therapy services are a distinct benefit category under Medicare Part B. Prior to the PHE, these services were not on the list of Medicare approved telehealth services, and physical therapists, occupational therapists and speech language pathologists were not recognized as distant site providers for telehealth services. While CMS loosely addressed this issue in CY 21 Fee Schedule¹⁴, we believe that initially placing MNT and DSMT with outpatient therapy services¹⁵ during the public health emergency further contributed to confusion as to whether both MNT and DSMT were paid under the Medicare Physician Fee Schedule or Outpatient Payment Prospective System. To date, the Hospital and CAHs FAQ dated June 26, 2023¹⁶ still lists Medical Nutrition Therapy (CPT Codes 97802, 87903, 97804) and DSMT (G0108 and G0109) as examples of hospital outpatient therapy.

To further add to the confusion, in CY 22 PFS proposed rule¹⁷ CMS reiterated their understanding that payment to hospitals includes payment MNT services. The Academy believes this limitation is predicated upon a misapprehension that MNT services are consistently being provided or paid for in hospital outpatient departments.

¹¹ CMS Manuel: List of Medicare Telehealth Services: <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R790CP.pdf</u>. Accessed: August 21, 2023

¹² 42 CFR, §410.134

¹³ CMS-5531-IFC

¹⁴ CMS-1734-F

¹⁵ Example of Hospital Outpatient Therapy, Counseling and Education Services that May be furnished to a Beneficiary in the Hospital by Remote Hospital Clinical Staff Using Telecommunication Technology During the COVID-19 Public Health Emergency. <u>https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-</u> waivers. Accessed August 21, 2023.

¹⁶ <u>https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf</u>. Accessed August 21, 2023

¹⁷ CMS-1754-P

The Conditions of Participation and Conditions of Coverage¹⁸ for hospitals neither requires provision of MNT services or even references 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. Accordingly, the Academy strongly encourages CMS to leverage this opportunity to work collaboratively with stakeholders to further streamline billing requirements for both in-person and virtual MNT and DSMT services when provided from a HOPD setting.

The Provision of MNT via Telehealth

In 2021, an article¹⁹ published in the *Journal of the Academy of Nutrition and Dietetics* examined practice changes experienced by RDNs in the United States who had delivered MNT face to face prior to and during the COVID-19 public health emergency. More than 2,000 RDNs were surveyed, with 78% reported providing care via telehealth during the PHE, this was an increase from 37% who reported utilizing telehealth prior to the PHE. Survey participants noted that the most frequently reported benefits to having increased access to telehealth include scheduling flexibility. Further literature has supported the efficacy of MNT when provided via telehealth. Patalan et al²⁰, examined the impact of MNT for chronic disease management when delivered via telehealth. The results of their study showed that participants who received MNT via telehealth achieved significantly improved in A1c levels, as well as increased amount of weight loss.

Academy member feedback has anecdotally showed that telehealth provided by RDNs, regardless of being provided from RDNs employed by an institution such as a hospital outpatient department or office setting, has been widely acknowledged as an effective and efficient delivery of MNT. Member reports have indicated that their facilities have been able to effectively increase access to care by greatly reducing barriers related to transportation, inflexible work schedules, and allowing access to nutrition care for beneficiaries whose were once unable access an in-person RDN visit because of immunocompromised status.

MNT and DSMT Utilization

The utilization of MNT by people with diabetes is very low. The <u>CY 2022 Medicare Physician Fee Schedule</u> (pps. 39259 through 39261) reported that between 2018-2020, participation of MNT utilization among Medicare beneficiaries was less than two percent. While this benefit has undergone policy changes aimed at increasing beneficiary utilization of MNT, barriers still exist. In addition to billing challenges as outlined above, the Academy also believes that CMS' waiting period of one day reduces access to care.

The preclusion of payment for DSMT and MNT when delivered on the same day stems from the MNT benefit's law. Despite CMS' own 2002 memo²¹ explicitly finding no need to have a waiting period between DSMT and MNT, CMS determined at the time that the legislative language required some form of waiting period and picked the shortest period possible (one day). The result is that beneficiaries referred to both DSMT and MNT need to schedule their visits on separate days, even if a single clinic or provider can provide them with both services. This waiting period is explicitly not evidence-based per CMS's own findings and therefore, the Academy encourages CMS to consider that implementing a zero-day waiting period, thus allowing DSMT and MNT

¹⁹ https://doi.org/10.1016/j.jand.2021.01.009

¹⁸ § 482.28 Condition of participation: Food and dietetic services. <u>https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482</u>. Accessed, August 21, 2023

²⁰ Patalano, K. Kiver et al. Telehealth's Impact on Chronic Disease Management Through Delivery of Medical Nutrition Therapy Journal of the Academy of Nutrition and Dietetics, Volume 122, Issue 10, A109

²¹ Evidence for Coverage of MNT for Beneficiaries Who Have Received DSMT During the Same Time Period. <u>https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-</u> <u>memo.aspx?proposed=N&NCAId=53&fromdb=true#:~:text=Pursuant%20to%20the%20exception%20at%2042%20CFR%20410.32,orders</u> %20additional%20hours%20during%20that%20episode%20of%20care.

to be delivered on the same day, would meet the definition of a "time period determined by the Secretary" from the law, as nothing in the law requires the time period be a non-zero number of days, and align with subsequent guidance from the agency.

Diabetes Self-Management Training

Diabetes self-management training (DSMT) was also erroneously placed in the category as outpatient therapy services at the start of the public health emergency. The Balanced Budget Act of 1997 established Medicare coverage for DSMT services provided by a certified provider.^{22,23} DSMT is also an allowable service for telehealth. Similar to MNT, DSMT is its own distinct service benefit category.

The Academy aligns our concerns with those of the Diabetes Advocacy Alliance (DAA) and the Association of Diabetes Care & Education Specialists (ADCES) that the language proposed at 410.78(b)(2)(x) which ties the change solely to "any distance site practitioner" will mean that both MNT and DSMT billed under the hospital/clinic National Provider Identifier (NPI) rather than a professional's NPI will still be subject to the original set of telehealth rules that only allow telehealth service to be provided/billed for by a subset of the provider types eligible to deliver such services. This will be crucial if CMS moves forward with regulating both MNT and DSMT delivered in the HOPD setting under 1834 (m).

Academy Recommendations

- The Academy supports CMS' alignment of regulations for telehealth delivery and payment for MNT and DSMT from a hospital outpatient setting under section 1834 (m).
- We ask CMS to clarify in the Medicare Claims Processing and Benefit Policy Manuals on the following:
 - Coverage and billing procedures for MNT and DSMT services, both in person and via telehealth 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.
- As both MNT and DSMT remain severely underutilized services, we request CMS finalize additional changes to further strengthen and expand access to DSMT and MNT services, including allowing:
 - Allow MNT and DSMT to be delivered on the same day

Section II.E Valuation of Specific Codes

(26) Payment for Caregiver Training Services

Definition of Caregiver

The Academy agrees with CMS' definition of caregiver to be broadly defined as a layperson; however, we request that CMS also consider identifying home health aides as part of the definition. For many beneficiaries who do not have family or friend support, home health aides often have the closest relationship with the patient. While they do have some training, they do not receive universal nutrition training, and RDNs can spend a significant amount of time educating home health aides on specialized diets and individualized nutrition needs.

Caregiver Behavior Management/Modification Training Services

Echoing the Academy's comments to the CY 23 PFS, we continue to appreciate CMS' interest and recognition of the important role that caregivers play in supporting the health and well-being of Medicare beneficiaries. Furthermore, the Academy fully supported CMS implementation of payment under PFS for CY 2023 for Caregiver behavior management /training services (now identified as CPT codes 96202 and 96203).

²² Diabetic Self-Management Training (DSMT) Accreditation Program <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/DSMT-Accreditation-Program</u>. Accessed on August 21, 2023

^{23 42} CFR § 410.141

The Academy continues to believe that this code family is of benefit to patients and that there are scenarios where training, instruction or intervention is delivered to a beneficiary by way of a caregiver who can adequately interpret and act upon the information in accordance with the clinical treatment plan. In the absence of such an individual, there is a risk that compliance to the treatment plan will be low, which will ultimately result in poor clinical outcomes.

Academy member feedback illustrated numerous times where nutrition care was delivered to a beneficiary by way of a caregiver; below are two such vignettes:

"An evidence-based pediatric weight management program operating in a community-based setting includes a mixture of child/parent joint education and parent-only sessions. The parent-only sessions focus on topics that would be inappropriate or even harmful for the children to be present for, such challenges that the parents face with affording healthy foods or safety concerns they have about the playgrounds in their neighborhood."

"A dietitian and a speech language pathologist working in a neurology practice offer group education classes for caregivers of people who have suffered a stroke that resulted in chewing/swallowing difficulties. The classes focus on creating meals that comply with the International Dysphagia Diet Standardisation Initiative Framework for modified texture diets/liquids while also meeting the patient's nutritional needs to promote stroke recovery and prevent future strokes."

Caregiver Training Services

The Academy was pleased to see CMS' proposal to further acknowledge and support vital services that are provided to caregivers of Medicare beneficiaries. As stated earlier, we believe that there are instances where training, instruction or intervention may be successfully delivered to a caregiver who is able to carry out the plan of care; when that beneficiary is not present and there is a risk of poor compliance and outcome. While the proposed rule specifically identifies provider types of Physical Therapist, Occupational Therapist, and Speech Language Pathologist as provider types for CPT codes 9X015, 9X016, and 9X017 (caregiver training services under a therapy plan), the Academy asks CMS to consider RDNs as eligible provider types.

The Code language describes 9X015 as follows:

Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes)

Caregiver access to RDN providers is pivotal to ensuring comprehensive access to nutritional care, particularly for patients who need partial or full-time assistance. This is especially true for individuals with mental or cognitive impairments, children, and the elderly. These valuable services could potentially be utilized and tailored most notably by dietitians specializing in geriatric, pediatric, or behavioral and mental health care. RDNs can make effective use of this service to educate caregivers and encompass a wide range of aspects, including suitable diets, curated shopping lists, recipe recommendations, cooking techniques, and comprehensive food/meal tracking methods. Such an approach not only enhances the quality of care but also empowers caregivers to provide informed nutritional support to those for whom they are responsible. The scope and standards of practice for RDNs who provide care to individuals residing in post-acute/long-term care facilities²⁴, individuals with

²⁴ Academy of Nutrition and Dietetics: Revised 2018 Standards of Practice and Standards of Professional performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Post-Acute and Long-Term Care. Sept 2018. J Acad Nutr & Diet 118 (9): p1747-1760 doi: <u>https://doi.org/10.1016/j.jand.2018.06.007</u>

intellectual and developmental disabilities²⁵ and those individuals with requiring enteral and parenteral nutrition support,²⁶ all contain standards of care that direct the RDN to work with caregivers to implement the nutrition care plan when the patient has a physical/functional or mental impairment.

To illustrate further, we offer the following vignettes from Academy members:

"A dietitian who is also a Certified Diabetes Care and Education Specialist (CDCES) works in a clinic and currently trains the caregivers of patients with Type 1 diabetes who are either under the age of 18, developmentally delayed or otherwise incompetent at the skills required to manage their disease. This includes insulin administration, adjusting doses of rapid acting mealtime insulin based on carbohydrate consumption and premeal blood glucose levels, how to recognize and treat hypoglycemia, including administering emergency glucagon to unconscious patient, recognizing, and avoiding diabetic ketoacidosis among other subjects."

"A dietitian is working with a patient with neurodegenerative disorder who has lost his ability to swallow and recently had a PEG placed. This beneficiary has also experienced decreased motor function and the ability to administer enteral feedings. It is very difficult for the beneficiary to attend appointments, as he lacks resources for a wheelchair accessible van. The spouse of the beneficiary is able to attend the dietitian appointment and receive training to properly administer enteral feedings and trouble shoot feeding difficulties when they arise."

Academy Recommendations

- We support CMS' proposal to establish payment for CPT codes 96202 and 96203
- We ask CMS to confirm that RDNs are considered qualified health care providers to deliver Caregiver behavior management services (CPT Codes 96202 and 96206)
- We request that CMS identify home health aides as caregivers
- We request CMS add RDNs as a qualified health care provider for Caregiver Training Services (9X015, 9X016, and 9X017)

(27) Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Inness Navigation services)

- a. Community Health Integration (CHI) Services
- d. Social Determinant of Health (SDOH) proposal to establish a standalone G code

The Academy supports CMS' proposal to create two new G codes to support Community Health Integration Services, and when the services are provided by train auxiliary personnel. In the Academy's response to last year's RFI, we recognized the important role that that community health workers (CHW) play in supporting the health and well-being for communities of people, particularly for people who are medically underserved and part of racial and ethnic minority populations.²⁷ Individuals living with nutrition-related chronic conditions do so in their own respective communities, not in a clinical or hospital-based setting. **CHWs serve a vital role throughout the continuum of care and see their value in supporting health equity, specifically as it relates**

²⁵ Academy of Nutrition and Dietetics: Revised 2020 Standards of Practice and Standards of Professional performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Intellectual and Developmental Disabilities. Dec 2023, *J Acad Nutr & Diet* 120 (12): p 2061-2075 doi: <u>https://doi.org/10.1016/j.jand.2020.08.094</u>

²⁶ Academy of Nutrition and Dietetics: Revised 2018 Standards of Practice and Standards of Professional performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Nutrition Support. Oct 2021. *J Acad Nutr & Diet*, 121 (10): p 2071-2086 doi https://doi.org/10.1016/j.jand.2021.05.026

²⁷ Anthony, S et al. Report of the Massachusetts Department of Public Health Community Health Worker Advisory Council.. December 2009.

to nutrition care. The Academy requests that CMS add Nutrition Dietetics Technician, Registered (NDTR) as auxiliary personnel who may deliver CHI services under the general supervision of the billing practitioner.

Nutrition and Dietetics Technician, Registered²⁸

NDTRs are skilled nutrition professionals whose scope of practice covers a wide variety of food and nutrition related topics. NDTR is a national credential and is granted to individuals who have met educational requirements established by Accreditation Council for Education in Nutrition and Dietetics (ACEND) and the Commission of Dietetic Registration (CDR), both of which serve as the accrediting and certification bodies for RDNs.

NDTRs' educational requirements include general understanding of evidenced based nutrition and the practice of dietetics and nutrition care application. NDTRs may work under the supervision of an RDN when involved directly in patient nutrition care or may work independently when providing general nutrition education to health populations. In the clinic settings, NDTRs work under the supervision of RDNs, and are involved in nutrition screenings and collecting information, including assessment and evaluation, reporting observations, and communicating with the patient, family or caregiver. Many NDTRs also play an active role in the community setting, particularly in nonclinical settings where an RDN may not be directly involved; examples include community nutrition programs, fitness and wellness centers, senior meals and home delivered meal programs, and grocery stores. Additionally, many NDTRs also hold certifications ranging from Certified Health and Well-being coaches, personal training, culinary educators, case management, health education, and food safety. Given their competence and training in nutrition care, NDTRS can play a crucial role in supporting beneficiary understanding of the nutrition plan of care and increase access to food and nutrition care services.

Other Professional Services Eligible for Community Health Integration

The Academy agrees with CMS' suggestion that the Annual Wellness Visit would be an appropriate initiating service that would benefit from CHI services. Under section 1861 of the Social Security Act the AWV can be furnished by a physician or practitioner, or by other types of health professionals, including RDNs whose scope of practice does not include the diagnosis and treatment involved in E/M services, for example a health educator.

Academy Recommendations

- Support CMS finalizing two new G Codes to support Community Health Integration Services
- Request CMS add Nutrition Dietetics Technician, Registered as eligible auxiliary personnel
- Support CMS adding the Annual Wellness Visits as an initiating service for Community Health Integration Services

d. Social Determinant of Health (SDOH) proposal to establish a standalone G code

CMS has proposed to use its authority to add a new, and optional Social Determinants of Health (SDOH) Risk Assessment to the Annual Wellness Visit (AWV). This SDOH Risk Assessment would be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. The Academy is supportive of CMS' proposal to support the increased utilization and payment for screening for health risk assessments among Medicare beneficiaries.

Seniors continue to experience hunger and food security,²⁹particularly older adults who are members of racial and ethnic minority groups. Food insecurity can contribute to and/or exacerbate malnutrition or the development of

²⁸ Academy of Nutrition and Dietetics: Revised 2017 Standards of Practice in Nutrition Care and Standards of Professional Performance for Nutrition and Dietetics Technicians, Registered. J Acad Nutr & Diet. Feb 2018. 118 (2): p317-326. doi: <u>https://doi.org/10.1016/j.jand.2017.10.004</u>

²⁹ The State of Senior Hunger in 2021. Feeding America. <u>https://www.feedingamerica.org/research/state-senior-hunger</u>. Accessed August 30, 2023.

chronic diseases³⁰, which are often compounded by one's limited access to and availability of health care, further negatively impacting health outcomes. Food insecurity screening is important for understanding a patient's overall nutrition status and potential etiology of malnutrition or other chronic diseases. Effective screening for food insecurity can reveal a variety of issues, such as the length of time an individual is experiencing food insecurity, anxiety or worry about the adequacy of their food supply, social accessibility of food sources, quality of food intake, and assessing availably of acceptable or preferred foods.

The Academy supports the use of validated screening tools, through mechanisms such as the Health Risk Assessment, to assess both the continued barriers to food security beneficiaries face, as well as foster referrals to appropriate health care team members, such as RDNs, to address identified issues related to food and nutrition. However, we urge CMS to consider expanding access to the SDOH beyond that of the evaluation and management visits and the Annual Wellness Visit. As a component of whole-person centered care, the Academy believes that it is the responsibility of all Medicare providers to acknowledge and document pertinent SDOH when appropriate.

Academy Recommendations

- We support the addition of G code, GXXX5 (Administration of a standardized, evidenced-based social determinant of health risk assessment) with associated payment and no beneficiary cost-sharing.
- We urge CMS to expand access to SDOH Risk Assessment tool to all Medicare providers, including RDNs who delivered MNT services.

<u>Section II.I Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-</u> <u>Management Training (DSMT) Services by Registered Dietitians and Nutrition Professionals, and DSMT</u> <u>Telehealth Services</u>

3. Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians(RDs) and Nutrition Professionals

The Academy is appreciative of the steps CMS has taken to add language in the federal code that clearly acknowledges that RDNs can bill on behalf of DSMT programs for the care provided by other professionals. Academy agrees that language noted at "§ 410.72(d) has caused confusion" about whether RDNs can bill for DSMT services provided by other providers. CMS's proposed language will distinguish between when RDNs are providing/billing for Medical Nutrition Therapy (MNT) and when they are acting on behalf of an accredited DSMT entity and billing for the services of the program provided by multiple professionals.

The Academy supports CMS' regulatory change updating the regulatory text at § 410.72 to state: Registered dietitians' and nutrition professionals' services: "(d) Professional services. Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them."

Academy Recommendations

- Finalize language that clarifies billing when Registered Dietitian Nutritionists act on behalf of a DSMT entity.
- We reiterate our earlier recommendation as both MNT and DSMT remain severely underutilized services, we request CMS finalize additional changes to further strengthen and expand access to DSMT and MNT services, including allowing MNT and DSMT to be delivered on the same day, eliminating patient cost-sharing, and reimbursing for MNT services for individuals with prediabetes.

³⁰ Ahmed T, Haboubi, N. Assessment and management of nutrition in older people and its importance to health. Clin Interv Aging. 2010; 5: 207–216.

4. DSMT Telehealth Issues

a. Distant Site Practitioners and Telehealth Injection Training for Insulin-Dependent Beneficiaries

The Academy aligns our comments with those of the Association of Diabetes Care and Education Specialists and the Diabetes Advocacy Alliance, and support the elimination of the requirement for in-person injection training. However as previously stated, we are concerned that "distant site practitioner" language may not apply to DSMT programs billing under a facility NPI, rather than a personal provider NPI.

Academy Recommendations

- Extend telehealth flexibilities, including: permanently allowing one-hour trainings required for insulindependent beneficiaries to be provided via telehealth; permanently allowing distant site DSMT practitioners to report DSMT services that are furnished via telehealth (including when performed by others within the DSMT entity); and allow institutional providers to continue to bill for DSMT and MNT services when furnished remotely through the end of CY 2024.
- When finalizing these policies, the Academy recommends including language modifications to account for programs billing under facility NPIs and pharmacy-based programs.

Section III.I Medicare Diabetes Prevention Program (MDPP)

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, as a member of the Diabetes Advocacy Alliance developed comments regarding the MDPP and aligns our recommendations with the DAA, specifically:

- Extending COVID-19 PHE Flexibilities
 - **Academy Recommendation:** Finalize proposals to extend several COVID-19 Public Health Emergency (PHE) flexibilities an additional four years, including allowing alternatives for inperson weight measurements and eliminating the cap on the number of services that may be provided synchronously via distance learning.
- Conforming to CDC Recognition Levels
 - Academy Recommendation: Finalize the proposal to amend § 424.205(a) and (c) to remove "MDPP interim preliminary recognition" and replace it with "CDC preliminary recognition".
 - Strengthening Payment Structure

Academy Recommendations:

- Finalize proposals to strengthen and streamline the program, including allowing payment for up to 22 sessions during the 12-month core services period and converting to a hybrid fee-for-service and weight loss payment structure.
- For those individuals who are unable to meet the 5% weight loss benchmark, the Academy requests that CMS consider adding a provision to refer those individuals back to the Primary care providers for Intensive Behavioral Therapy for Obesity.

Additional Recommendations to Strengthen and Streamline the Program

• Remove Once-in-a-Lifetime Benefit Cap

- Academy Recommendation: CMS should allow repeat participation in the MDPP, just as it is allowed for intensive behavioral therapy for weight loss and smoking cessation programs, which also require intensive behavior change.
- Supplier Registration Requirements
 - Academy Recommendation: Classify suppliers as medium fraud risk to ease supplier registration requirements.
- 100% Online and Virtual MDPP
 - Academy Recommendations
 - Remove the requirement to maintain in-person recognition to allow distance learning-only suppliers to align with CDC's DPRP standards.
 - Allow CDC-defined online providers of DPRP-recognized programs to apply to become suppliers in the MDPP.
- Approving MDPP as a Permanent Medicare Benefit
 - Academy Recommendation: Approve MDPP as a permanent covered Medicare benefit.

Section III.L. Expand Diabetes Screening and Diabetes Definitions

Diabetes Screening

The Academy supports CMS' overarching proposals that are aimed to align the clinical practice of diabetes care with nationally recognized standards of care for the purpose of diagnosis.³¹ We commend CMS' proposal allowing the use of the hemoglobin A1c (HbA1c) test to the types of diabetes screening tests. HbA1c testing has been accepted among the clinical community as a diagnostic test for abnormal glycemic status for well over 10 years. Both the United States Preventive Services Task Force³²and the American Diabetes Association Standards of Care³³ recommend use of any of three testing methods to screen for abnormal blood glucose: fasting plasma glucose, HbA1c, and two-hour plasma glucose.

Additionally, the Academy supports CMS' proposal to simplify frequency limitation for diabetes screening by "aligning to the statutory limitation of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual".³⁴ We believe these changes represent another step aimed at increasing beneficiary access to care by allowing providers tools that facilitate earlier identification of pre-diabetes and diabetes and thus ensuring that more beneficiaries can access evidence-based treatments, such as Medicare Diabetes Prevention Programs, Medical Nutrition Therapy, and Diabetes Self-Management Treatment.

Diabetes Definition

The Academy also applauds CMS' proposal to simplify the regulatory definition of diabetes for the purposes of the DSMT and MNT benefits to remove the codified clinical test requirements. The codifying of clinical tests requirements presents challenges as it relates to the referral process and claim denial, this is most notable when there is a misalignment between the benefit and standard of care. When misalignment occurs, there is a risk that the referral process is delayed and a higher chance of returned referrals and denial of claims – which decreases beneficiary access to care. Recently, this was the case with chronic kidney disease and accessing Medicare Part B MNT benefit. In the CY 2022 Physician Fee Schedule final rule, CMS did algin GFR criteria to 15-59

³¹ U.S. Preventive Services Task Force. Final Recommendation Statement; Prediabetes and Type 2 Diabetes: Screening: Aug 24, 2021. <u>https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes</u>. Accessed August 29, 2023.

³² Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening. U.S Preventive Services Task Force. October 26, 2015. <u>https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-abnormal-blood-glucose-and-type-2-diabetes</u>. Accessed August 22, 2023.

³³ 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.

³⁴ CMS-1784-P

mL/min/1.73m2 to align with national standards. While the Academy remains supportive of this alignment, we urge CMS to consider applying the same rationale to the definition of chronic kidney disease.

Chronic Kidney Disease Screening & Definition

It is well established that patients with diabetes are at high risk for kidney disease and that signs of chronic kidney damage can show up years before their kidney function deteriorates to a level that would qualify them as having chronic kidney disease. The progression of chronic kidney disease (CKD) is often slow and the majority of individuals with symptoms of the CKD do not appear until the disease has progressed to later stages. Both the Kidney Disease Outcomes Quality Initiative (KDOQI)³⁵ and the Kidney Disease: Improving Global Outcomes (KDIGO)³⁶ emphasize the importance of screening and early intervention for CKD in at-risk populations, including those individuals with diabetes, cardiovascular disease and hypertension.

In collaboration with the National Kidney Foundation (NFK), the Academy is working to elevate the importance of screening individuals at greater risk for developing CKD, and for those who are diagnosed initiating treatment. In comments (pending publication) to the USPSTF, the NKF highlights findings from a recent study³⁷ that identified the significance of early, proactive measures in the management of CKD, specifically:

- Systematic CKD screening can drastically diminish kidney failures requiring Kidney Replacement Therapy (KRT), benefiting up to 658,000 individuals across their lifespan.
- During ages 35 to 75 years, screening once prevented dialysis or transplant in 398 000 people and screening every 10 years until age 75 years cost less than \$100 000 per Quality-adjusted life years gained.

According to the CDC, approximately one in three³⁸ adults with diabetes has CKD. Additionally, one in five adults with high blood pressure have kidney disease; hypertension is second leading cause of kidney failure after diabetes.³⁹ Updated guidelines from the American College of Cardiology and the American Heart Association identify nonpharmacologic interventions such as lifestyle modifications (e.g. weight loss for individuals who are overweight or obese, heart healthy diet, sodium restriction, potassium supplementation) as strategy to manage high blood pressure in adults. ⁴⁰ Additionally, literature has shown that MNT is a component of care for the reduction of blood pressure in individuals diagnosed with hypertension (HTN) or pre-hypertension⁴¹. Yet, beneficiaries who are diagnosed with overweight, obesity or hypertension and do not have a diagnosis diabetes, are prevented from accessing critical nutrition care.

§ 410.130 Definitions of the federal code identifies chronic renal insufficiency as a reduction in renal function not severe enough to require dialysis or transplantation; the definition also defines chronic renal insufficient as a GFR 15-59 mL/min/1.73 m2. The Academy firmly supports early nutrition intervention for individuals with chronic kidney disease, MNT in the earlier stages of CKD is a low-cost intervention that has been proven to slow or

³⁵ DOI: <u>https://doi.org/10.1053/j.ajkd.2021.09.010</u>

³⁶ KDIGO 2012 Clinical Practice Guidelines for the Evaluation and Management of Chronic Kidney Disease. <u>https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf</u> Accessed Aug 23, 2023

³⁷ Marika M.Cusick, MS "Population-Wide Screening for Chronic Kidney Disease" ACP Journals, *Annals of Internal Medicine*, June 2023. https://www.acpjournals.org/doi/full/10.7326/M22-3228. Accessed Aug 25, 2023.

 ³⁸ Diabetes and Chronic kidney disease. <u>https://www.cdc.gov/diabetes/managing/diabetes-kidney-disease.html Accessed Aug 23</u>, 2023.
 ³⁹ High Blood Pressure and Chronic Kidney Disease. <u>https://www.kidney.org/news/newsroom/factsheets/High-Blood-Pressure-and-CKD</u>. Accessed Aug 28, 2023.

⁴⁰ 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2018;71:e127-e248.

⁴¹ Academy of Nutrition and Dietetics Evidence Analysis Library. Hypertension (HTN) Guideline Accessed Aug 29 2023: https://www.andeal.org/topic.cfm?menu=5285&cat=5582

prevent CKD progression.^{42,43} Additionally, Medicare expenditures increase dramatically from stages 1-2 to stages 4-5. ⁴⁴ 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 beneficiaries identified with CKD, regardless of stage, would benefit from MNT services under the Part B benefit. **The Academy reminds CMS that there are there are beneficiaries who have a GFR below 15 ml/min/1.73m2 and are not yet on dialysis**. Based on the current definition of chronic renal insufficiency, those individuals are excluded from receiving nutrition care as they are also not eligible to receive nutrition services under the ESRD benefit.

Additionally, the Academy has received feedback from members that the current language in the federal code contradicts the ICD-10 code file associated with MNT NCD (108.1), which includes the ICD-10 codes for all stages of CKD.¹⁶ **This disconnect is a source of confusion for providers and patients alike, and results in patients not receiving the nutrition care to which they are entitled.** The Medicare Part B MNT benefit remains a vastly under-utilized benefit despite that fact that it has been 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. ⁴⁵ MNT provided by an 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.

In 2020, Kidney Medicine, an official journal of the National Kidney Foundation, published a cross-sectional research article that looked at MNT access in CKD. The authors found that despite interest in MNT for patients at all stages for CKD, barriers to accessing the MNT benefit existed. These barriers included low awareness of Medicare coverage for MNT across the board for both patients and providers. Of the practices surveyed, only half billed for MNT services and those that did cited issues such as a complicated billing process, perceived cost for MNT services, limited awareness or unsure about Medicare coverage for MNT, challenges receiving payment, and low reimbursement rates. ⁴⁶ The Academy believes that simplifying the definition of CKD keeps medical decision making squarely in the prevue of the physician, while also greatly reducing confusion regarding eligibility criteria for MNT services when providers seek to refer Medicare beneficiaries to MNT for CKD management. The Academy asks that CMS explore its ability to simplify the regulatory definition in § 410.130 Definitions of chronic kidney insufficiency for the purposes of the MNT benefits to remove the codified clinical test requirements.

Academy Recommendations

- Finalize proposal to simplify the regulatory definition of diabetes.
- The Academy requests the CMS expand coverage of CKD to include Stage 5 (GFR < 15 mL/min/1.73 m2) when the Medicare beneficiary is not receiving dialysis.
- The Academy urges CMS to explore CMS' ability to simplify the regulatory definition for chronic kidney insufficiency by removing codified diagnostic tests.

⁴² 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.

⁴³ 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.

⁴⁴ United States Renal Data System. Chapter 6: Healthcare Expenditures for Persons with CKD. <u>https://adr.usrds.org/2020/chronic-kidney-</u> <u>disease/6-healthcare-expenditures-for-persons-with-ckd</u>. Accessed August 21, 2023

⁴⁵ 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."

⁴⁶ Jimenes, E. Et al. Medical Nutrition Therapy Access in CKD: A Cross-sectional Survey of Patients and Providers. Kidney Medicine Jan 2021, 3 (1) p 31-41 doi:<u>https://doi.org/10.1016/j.xkme.2020.09.005</u>

Section III.S.k A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

In section III.S. of the proposed rule, CMS has proposed to use its authority to add a new, and optional Social Determinants of Health (SDOH) Risk Assessment to the Annual Wellness Visit (AWV). This SDOH assessment would be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV. The Academy is supportive of CMS' proposal to support the increased utilization and payment for screening for health risk assessments among Medicare beneficiaries.

Seniors continue to deal with hunger and food security issues,⁷ particularly older adults who are minorities and those located in rural communities. There are harsh consequences of food insecurity, such as malnutrition or the development of or exacerbation of chronic diseases,⁴⁷ which are often compounded by one's limited access to and availability of health care, and negatively impact health outcomes. One of the main tools used to identify food insecurity is screening, which is important for understanding a patient's overall nutrition status and potential etiology of malnutrition or other chronic diseases. Proper screening for food security can reveal a variety of issues, such as the length of time an individual is experiencing food insecurity, anxiety or worry about the adequacy of the food supply, social accessibility of food sources, quality of food intake, and assessing availably of acceptable or preferred foods.

The Academy supports the use of validated screening tools, through mechanisms such as the Health Risk Assessment, to assess both the continued barriers to food security beneficiaries face, as well as foster referrals to appropriate health care team members, such as RDNs, to address identified issues related to food and nutrition. However, we urge CMS to consider expanding access to the SDOH beyond that of the evaluation and management visits and be included within the AWV. As a component of whole-person centered care, the Academy believes that it is the responsibility of all Medicare providers to acknowledge and document pertinent SDOH when appropriate.

Academy Recommendations

- We support the addition of a social determinant of health risk assessment with associated payment and no beneficiary cost-sharing.
- We urge CMS to expand access to SDOH Risk assessment to all Medicare providers, including RDNs who delivered MNT services.

Section IV Updates to the Quality Payment Program

The Academy is appreciative of CMS's continued efforts to make participation in the Quality Payment Program more meaningful for clinicians while also continuing to reduce barriers for successful participation. We also remain supportive and appreciative of CMS' ongoing focus to address issues surrounding health equity and social determinants of health.

Many RDNs continue to face significant barriers to participating in the QPP, mainly that many practices continue to rely on manual reporting and data collection which can make it difficult to near impossible to participate in quality reporting. Academy member feedback continues to show 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. RDNs that do meet the requirements and are not part of a large practice will likely incur a significant financial burden to ensure compliance with the proposed rules. However, lengthening the performance period for Promoting Interoperability performance and inclusion of a self-attestation of the SAFER guide is likely to improve RDN performance in this area despite the complexities, while simultaneously highlighting potential opportunity areas.

⁴⁷ Ahmed T, Haboubi, N. Assessment and management of nutrition in older people and its importance to health. Clin Interv Aging. 2010; 5: 207–216.

Academy Recommendations

- We support the proposal for a 180-day performance period.
- We support implementation of the SAFER Guide Self-Assessment.

MIPS Value Pathway (MVPs)

The Academy continues to support the rationale and merit behind development of MVPs and believes they will support CMS's goal of strengthening the QPP as a value-based program. The Academy also recognizes that as health care continues to shift towards value-based payments there is an even greater opportunity and need for team-based care.

Medical Nutrition Therapy provided by RDNs is recognized as a key component to management of chronic diseases, including conditions beyond diabetes and renal disease. The Academy remains concerned that, like the overall design of the QPP, MVPS are being done through the lens of physician-providers only and non-physician eligible clinicians, such as RDNs, who are active participants on health care teams and routinely contribute to improving beneficiary health outcomes, are at a disadvantage when it comes to understanding how their discipline will meaningfully participate in MVPs.

The Academy remains concerned that MVPs continue to rely heavily on measures that are not applicable or available to many of the MIPs eligible clinicians who provide care to beneficiaries. Similar to our comments to the CY 2022 Fee Schedule, the Academy acknowledges that with the newness of the MVPs, the focus rests primarily on the major types of participating eligible clinicians. **Given the desire for increasing participation of all MIPs eligible clinicians, the Academy asks CMS to further define how MIPS eligible clinicians, who are also non-physician providers, such as RDNs are to participate in MVPs.**

Section VII Regulatory Impact Analysis

While the Academy recognizes the statutory requirements that CMS must abide by as it relates to payment rates in the Physician Fee Schedule, we continue to urge CMS to explore all avenues, to include working with Congress to prevent the yearly payments cuts that are affecting Medicare providers, including RDNs.

Medical nutrition therapy provided by RDNs has been proven to help 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. As payment rates continue to decline, the Academy is concerned that it will be more difficult for many RDNs who are Medicare providers to continue to accept Medicare assignment. This will result in primary care providers having fewer choices when referring patients to specialists if health care professionals must close or limit their practices because of these cuts.

Many Academy members are small business owners who have been hit hard financially by the PHE and are still recovering from the financial impact. The proposed cuts, sequestration reductions, and the fact that Medicare feefor-service payments have failed to keep up with inflation will force many to reconsider their Medicare provider enrollment status, thus severely diminishing Medicare beneficiary access to critical nutrition services. 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.

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 104 "CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty." CMS's omission of RDNs in Table 104 makes it difficult for the Academy and RDN Medicare providers to recognize the impact of fee schedule changes on their practices. **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 2024 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 <u>jblankenship@eatright.org</u> or Carly Léon at 312-899-1773 or <u>cleon@eatright.org</u> 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,

Glanne Blankenship, MSRDN

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