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January 27, 2019

Secretary Alex Azar
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Scope of Practice (Executive Order 13890)

Dear Secretary Azar:

The Academy of Nutrition and Dietetics (the "Academy") appreciates the opportunity to submit comments to the U.S. Department of Health and Human Services (HHS) (''the Department'' or HHS) related to its December 26, 2019 request for feedback on scope of practice as specified in Executive Order 13890 (the "Executive Order").[1] Representing more than 107,000 registered dietitian nutritionists (RDNs),[2] nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of nutrition and dietetic professionals in the United States. Our members provide various medical and professional services in the clinical and community settings, conduct significant research, and are committed to improving the health of all Americans through the transformative power of food and nutrition.

I. SYNOPSIS OF RECOMMENDATIONS

The Academy strongly encourages HHS to endorse regulatory reforms that (1) recognize nutrition as a key component of care for Medicare beneficiaries with chronic conditions; (2) allow early access to RDNs as qualified providers of such services; (3) establish baseline payments that support having RDNs as part of the care team; and (4) reward changes in beneficiary behaviors that will positively impact risk factors for chronic disease (rather than just anthropometrics such as BMI). Nutrition care provided by RDNs should be a required part of any care delivery model in any setting where Medicare beneficiaries receive services. The number of hours or visits per year should not artificially be limited; instead, providers should use evidence-based and expert-informed clinical practice guidelines to determine the frequency and dose of nutrition care, in collaboration with the patient. In furtherance of the principles and goals for improving Medicare in the executive order, the Academy recommends the following specific Medicare reforms to ensure RDNs can provide services at the height of their scope of practice, with rationales for each detailed below:

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[1] Protecting and Improving Medicare for Our Nation's Seniors. 84 Fed. Reg. 53573 (October 8, 2019) ("Executive Order").

[2] The Academy 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.

- Enable RDNs' Therapeutic Diet Ordering Ability in Dialysis Facilities
- Allow RDNs to Independently Provide Intensive Behavioral Therapy (IBT) for Obesity
- Allow RDNs to Independently Provide IBT for Cardiovascular Disease
- Reform Burdensome and Inefficient "Incident-to" Billing
- Allow Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) to Be Provided on the Same Date of Service
- Revamp Antiquated Telehealth Requirements
- Reform Burdensome Limits on Referrals for MNT
- Include RDNs in Any Model Treating Patients with Nutrition-Related Chronic Diseases or Medical Conditions

II. AMERICA'S CHRONIC DISEASE CRISIS

For too long, our nation's health policy has failed to focus on disease prevention, wellness, or healthy lifestyles, although recent reform efforts intended to change that emphasis. Nearly half of Americans suffer from preventable chronic conditions, but relatively few resources have been committed to the broad array of potential solutions that influence whether and how individuals choose to achieve and maintain health. As a result, health care in the United States is the most expensive in the world, accounting for 17.7 percent of the American economy.[3] Despite the fact that the United States spends a significant amount of money on health care, most of our citizens do not receive quality care that is comprehensive, coordinated, or prevention-focused.

A. The High Cost of Chronic Disease

Medicare's costs continue to rise in large part because our nation is paying the price for overlooking the importance of nutrition in preventing and treating costly chronic diseases. The Academy notes that the treatment of chronic disease accounts for 93 percent of Medicare spending. Costs of chronic disease place an enormous financial burden on American families, our economy and our nation's healthcare system.

Obesity alone accounts for 21% of total national health care spending and is growing, totaling as much as $210 billion annually in 2009.[4] Medicare and Medicaid costs related to obesity totals $61.8 billion per year, and eradicating obesity would result in an 8.5% savings in Medicare spending.[5] One out of every four federal health care dollars is spent

[3] Hartman M, Martin AB, Benson J, Catlin A. National Health Care Spending In 2018: Growth Driven By Accelerations In Medicare And Private Insurance Spending. Health Aff (Millwood). 2020;39(1):8-17.

[4] Finkelstein et al. "Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates." Health Affairs, 28, no. 5 (2009). 27 July. Available at http://content.healthaffairs.org/content/28/5/w822.full.pdf+html.

[5] *Ibid.*

treating people with diabetes.[6] The total cost of diabetes to our health care system in 2017 is estimated to be $327 billion, including $237 billion in excess medical expenditures and $90 billion in reduced national productivity.[7] The average yearly health care costs for a person with diabetes is $16,750, with $$9,600 due to diabetes alone.[8] As the American Diabetes Association found, "After adjusting for inflation, economic costs of diabetes increased by 26% from 2012 to 2017 due to the increased prevalence of diabetes and the increased cost per person with diabetes."[9] Notably the study concluded, "The growth in diabetes prevalence and medical costs is primarily among the population aged 65 years and older."[10] Combined, this amounts to an economic burden exceeding $1,000 for each American in 2017

B. RDNs and NDTRs Are Cost- and Clinically-Effective Solutions

The single most transformative policy to improve outcomes with patients living with four of the top six leading causes of death is cost-effective nutrition and diet counseling and interventions provided by RDNs. Thus, any meaningful reform must include services that demonstrably improve the nutritional status of Americans and reduce the rates of obesity, cardiovascular disease, renal disease, hypertension, diabetes, HIV, forms of cancer, celiac disease, stroke, and other medical conditions. As detailed in the MNT Effectiveness Project published in the Academy's Evidence Analysis Library, MNT and other evidence-based nutrition services, from pre-conception through end-of-life, are an essential component of comprehensive health care, whether provided as frontline therapy to prevent disease, delay disease progression, or as an intervention in chronic care management.[11]

RDN-provided MNT is not only clinically effective, including it comprehensively in a health plan is cost effective. As just one example, a 2001 study conducted at Massachusetts General Hospital demonstrated a savings of $4.28 for each dollar spent on MNT. [12] Another study found that for every dollar invested in an RDN led lifestyle modification program there was a return of $14.58.[13] According to a Blue Cross Blue Shield study, "[h]ealth plans

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[6] American Diabetes Association (2017). Economic Costs of Diabetes in the U.S. in 2017. Economic Costs of Diabetes in the U.S. in 2017. Diabetes Care. 2018;41(5):917-928.

[7] *Id.*

[8] *Id.*

[9] *Id*.

[10] *Id.*

[11] Grade 1 data. ADA Evidence Analysis Library, http:www.adaevidencylibrary.com/topic.cfm?cat=3949. [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."

[12] Delahanty LM, Sonnenberg LM, Hayden D, Nathan DM. Clinical and cost outcomes of medical nutrition therapy for hypercholesterolemia: A controlled trail. J Am Diet Assoc, 2001;101:1012-1016.

[13] Wolf AM, Siadaty M, Yaeger B, et al. Effects of lifestyle intervention on health care costs: Improving Control with Activity and Nutrition (ICAN). J Am Diet Assoc. 2007;107(8):1365-73. Program accepted for

that have added these services to their benefits packages (up to unlimited visits) report the additional cost has been 3 cents per member per month." [14] Additionally, according to Wolf, *et al*, for every dollar an employer invests in the lifestyle modification program for employees with diabetes, the employer would see a return of $2.67 in productivity. [15] MNT provided by RDNs generally impacts productivity; the study indicated the RDN-led lifestyle intervention provided to patients with diabetes and obesity reduced the risk of having lost work days by 64.3% and disability days by 87.2%, compared with those receiving usual medical care. [16] **Nutrition interventions reduce and even eliminate the need for costly long-term medications and reduce hospitalizations.** HHS previously found that nutrition services for obesity alone reduce premiums by 0.05 to 0.1 percent. As such, they meet the criteria of good stewardship of resources. [17]

C. Our Health Care System Neglects Preventive Nutrition Care Services

Virtually all prevalent chronic illnesses have a nutrition component, yet there remain huge gaps in the way our health care system addresses the important role of nutrition in preventing and treating such diseases—particularly in the Medicare program. Under current law, Medicare only covers outpatient medical nutrition therapy services provided by RDNs for beneficiaries with diabetes, chronic renal insufficiency/end-stage renal disease (non-dialysis renal disease) or post kidney transplant. The current Medicare program offers too little nutrition care too late and does not incentivize the use of other members of the health care team with specific expertise in areas such as nutrition counseling. To the extent nutrition services are provided at all in Medicare (outside of diabetes and renal disease), they must meet unnecessarily burdensome supervisory, setting, and billing requirements that limit access to care, increase costs, and preclude RDNs from working at the height of their scope of practice.

For example, instead of providing effective and inexpensive MNT services to beneficiaries with prediabetes to prevent or delay onset of the disease, Medicare denies coverage until the disease itself is diagnosed. Medicare's intensive behavioral therapy for obesity benefit is similarly limited to secondary and tertiary prevention. Moreover, and as detailed below, Medicare only covers intensive behavioral therapy for obesity services provided by primary care providers in primary care settings—despite these being the very providers and settings the United States Preventive Services Task Force (USPSTF) concluded were least effective. Pursuant to the Executive Order, we strongly encourage CMS to reform the obesity benefit consistent with the recommendations of the USPSTF to cover services

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presentation at the American Diabetes Association 69th Scientific Sessions (169-OR), June 7, 2009, New Orleans, LA.

[14] Bradley DW, Murphy G, Snetselaar LG, Myers EF, Qualls LG. The incremental value of medical nutrition therapy in weight management. Manag Care. 2013;22(1):40-5.

[15] Wolf AM, Conaway MR, Crowther JQ, et al. Translating lifestyle intervention to practice in obese patients with type 2 diabetes: Improving Control with Activity and Nutrition (ICAN) study. Diabetes Care. 2004; 27:1570–6.

[16] *Ibid*.

[17] Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41736 (July 19, 2010).

provided by RDNs, obesity medicine specialists, endocrinologists, clinical psychologists, and other highly qualified Medicare providers outside of the primary care setting.

Nutrition coverage for beneficiaries at risk for cardiovascular disease (CVD) or those with cancer, eating disorders, or numerous other disease states and conditions is essentially non-existent. To solve long-term problems in the Medicare program, we must aim for both earlier intervention and prevention in cases where it is demonstrated to pay off.

It is unrealistic to think we can ameliorate Medicare beneficiaries' chronic diseases without making significant changes to their medical care before they turn 65 years old. Similarly, it is unrealistic to think the best solution to the pervasiveness of chronic disease among Medicare beneficiaries is denying demonstrably effective medical nutrition therapy services to beneficiaries until they are already diagnosed with costly, preventable diseases. To reduce costs and improve health, any meaningful reform must include implementation of whole-population prevention strategies and specific chronic disease management that includes nutrition counseling and self-care to provide patients of all ages and medical conditions with the knowledge and tools necessary to improve their health.

We share the administration's commitment to ensuring beneficiaries "receive affordable, high-quality care from providers of their choice," and offer below a number of common-sense, cost-efficient, and clinically effective Medicare reforms that will enable registered dietitian nutritionists to practice at the height of their license or professional scope of practice. These recommended regulatory reforms are variously intended to improve care and lower costs within Medicare's traditional fee-for-service payment system, Medicare Advantage, and a variety of existing and proposed payment and delivery models.

III. THERAPEUTIC DIET ORDERING AND RDN SCOPE OF PRACTICE

The Academy and CMS continue to work together to reform burdensome Medicare regulations preventing RDNs working at the height of their scope of practice by ordering therapeutic diets in CMS-regulated facilities. When RDNs are prevented from ordering therapeutic diets, every initiation, modification, or other change to a therapeutic diet required a physician's signature, leading to well-documented delays in patient and resident care. The process was inherently inefficient and required physicians to rubber stamp the recommendations of the facility's nutrition expert, upon whom physicians relied for the specifics of each diet order. When RDNs are able to independently order therapeutic diets, nutrition delays are reduced and fewer burdens are placed on providers. The studies cited by CMS when it proposed the rule allowing RDNs to order therapeutic diets confirm that providing the revised regulatory authority will produce substantial cost savings, allow RDNs to see and treat more patients, and reduce delays in the ordering of therapeutic diets (including nutritional supplements), particularly parenteral nutrition and enteral nutrition diet orders, complex infant formula orders, and in the monitoring of associated lab parameters.[18]

[18] Medicare and Medicaid Programs; Part II-Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, 78 Fed. Reg. 9215 (February 7, 2013).

These efforts align directly with the president's directive in the Executive Order to "reduce the burden on providers and eliminate regulations that create inefficiencies or otherwise undermine patient outcomes" and reduce "delays for patients in receiving needed care."[19] The Academy continues to seek regulatory reforms enabling RDNs to order therapeutic diets across the continuum of care in CMS-regulated facilities that authorize them to do so; we urge HHS to revise regulations for dialysis centers to specifically allow RDNs to order therapeutic diets if authorized to do so by the facility or if delegated the ability to do so by the attending physician.

A. Successful Reforms for Hospitals and Long-Term Care Facilities

In 2014, the Centers for Medicare and Medicaid Services (CMS) announced a final rule[20] providing greater flexibility for hospitals and medical staffs to enlist the services of non-physician practitioners to carry out the patient care duties for which they are trained and licensed, specifically including the ability for "qualified dietitians and other qualified nutrition professionals" to independently order therapeutic diets if consistent with state law and authorized by the hospital's governing body. CMS determined that this regulatory change was necessary to allow non-physician practitioners to meet the needs of their patients most efficiently and effectively, saving an anticipated $500 million annually as a result. According to the final rule, "[t]he addition of ordering privileges enhances the ability that RDNs already have to provide timely, cost-effective, and evidence-based nutrition services as the recognized nutrition experts on a hospital interdisciplinary team."[21]

The Academy strongly advocated for this rule change, and continues to work with our state affiliates to ensure state laws and hospital policies facilitate RDNs working to the full extent of their professional and legal scope of practice. Hospitals' governing bodies can authorize RDNs to undertake these complex tasks at the height of their scope of practice either by including them on the medical staff or by undertaking a thorough credentialing and competency review to grant privileges.[22] Following the successful implementation of independent order writing in hospitals across the country, the Academy worked with CMS in 2016 to modify the Conditions of Participation for long-term care facilities to allow physicians to delegate the ability to write therapeutic diet orders to qualified RDNs.

B. Ongoing Reform Efforts for Renal Dialysis Facilities

RDNs working in dialysis centers have the professional competency to independently order therapeutic diets for renal patients and should be permitted to do so in accordance with their state-legislated scope of practice . A renal dietitian nutritionist "[m]anages enteral/parenteral nutrition and specialized nutrition support therapy, including formula selection and adjustment based on patient/client laboratory results, using physician-

[19] Executive Order, Section 10.

[20] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II. 79 Fed. Reg. 27105 (May 12. 2014), codified at 42 C.F.R. 482.28(b)(2).

[21] *Id.*

[22] *Id.*

approved protocols, clinical privileges for order writing, or similar documents consistent with facility organization policies."[23] Unfortunately, at present, Medicare's Conditions for Coverage for End-Stage Renal Disease Centers do not specifically include language allowing RDNs to provide the same effective, efficient care RDNs are able to provide in hospitals and long term care facilities.

The ESRD Conditions for Coverage address a dietitian's personnel qualifications but do not address the RDN ordering therapeutic diets or other nutritional components. As noted above, CMS has recently used rulemakings to specifically permit RDNs to order therapeutic diets in accordance with state law in hospitals, critical access hospitals, and long term care facilities, and further note that the practical implications for defining and ordering therapeutic diets are consistent across the continuum of care. Thus, the Academy encourages CMS to uniformly adopt its most recent interpretive coding guidelines for understanding therapeutic diets for dialysis facilities and in other regulated facilities across the continuum of care.

Therapeutic diets currently ordered in renal dialysis facilities consistent with state and federal regulations are essential to enhancing patient care during dialysis and remain a critical part of the dialysis patient's record during transitions of care. RDNs' training and education best qualifies them to order patient diets both initially upon acceptance to the dialysis center and after a nutrition assessment that considers the connection between a patient's complex medical problems, nutrition status, and actual nutrition risk. Regrettably, there are delays in patient care because RDNs are not able to provide the services for which they are most qualified.

Thus, the Academy strongly encourages CMS to ease patient and provider burdens and reduce inefficiencies by revising the Conditions for Coverage for ESRD facilities to allow RDNs with authorization of the attending physician to:

- Order all patient diets, including therapeutic diets;
- Order both standard and disease-specific nutrition supplements;
- Order enteral nutrition or parenteral nutrition;
- Order nutrition-related laboratory tests needed to inform nutrition decisions and orders; and
- Order therapeutic diets in states that do not license RDNs if delegated ordering privileges by the attending physician and consistent with state law.

We appreciate the ongoing collaboration with CMS to-date to improve outcomes, reduce delays in care, lower costs, minimize provider burdens, and eliminate inefficiencies by reforming therapeutic diet ordering regulations, and we encourage HHS and CMS to formally propose the above regulatory reforms in the Conditions for Coverage of ESRD facilities consistent with directives and principles of the Executive Order.

[23] Kent PS, Mccarthy MP, Burrowes JD, et al. Academy of Nutrition and Dietetics and National Kidney Foundation: revised 2014 standards of practice and standards of professional performance for registered dietitian nutritionists (competent, proficient, and expert) in nephrology nutrition. J Acad Nutr Diet. 2014;114(9):1448-1457.e45.

IV. REFORM PROVIDER AND SETTING LIMITATIONS ON INTENSIVE BEHAVIORAL THERAPY FOR OBESITY AND INTENSIVE BEHAVIORAL THERAPY FOR CARDIOVASCULAR DISEASE BENEFITS

A. Intensive Behavioral Therapy is within RDNs' Scope of Practice

Medicare Part B covers intensive behavioral therapy (IBT) for obesity and IBT for cardiovascular disease (CVD) consistent with the limitations and requirements in their respective decision memoranda issued November 29, 2011 and November 8, 2011, respectively.[24] The decision Memorandum for IBT for CVD defines the benefit as consisting of three services; the second is commonly part of nutrition assessments by many RDNs and the third is a common nutrition intervention that few practitioners other than physicians, other primary care providers, and RDNs have within their legal scope of practice:

> 1. Encouraging aspirin use for the primary prevention of cardiovascular disease when the benefits outweigh the risks for men age 45-79 years and women 55-79 years;
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> 2. Screening for high blood pressure in adults age 18 years and older; and
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> 3. Intensive behavioral counseling to promote a healthy diet for adults with hyperlipidemia, hypertension, advancing age and other known risk factors for cardiovascular and diet-related chronic disease.[25]

The decision memorandum for IBT for obesity defines the benefit as consisting of three services falling squarely within the scope of practice of licensed or registered dietitian nutritionists as part of nutrition assessments and nutrition interventions:

> 1. Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed in kg/m2);
>
> 2. Dietary (nutritional) assessment; and
>
> 3. Intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.[26]

Moreover, the intensive behavioral counseling benefits for obesity and CVD are nutritional diagnostic, therapy, and counseling services for the purpose of disease management within the definition of the preventive service "Medical Nutrition Therapy" in section 1861(vv)(1) of the SSA that RDNs provide and independently bill for as an existing Medicare provider.[27] Significantly, according to the National Academies of Sciences, Engineering, and Medicine (formerly the Institute of Medicine), "the registered dietitian is currently the single

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[24] See https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=253 and https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=248

[25] https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=248

[26] *See,* 29 November 2011 CMS NCD on Intensive Behavioral Counseling for Obesity.

[27] "The term 'medical nutrition therapy services' means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1))."

identifiable group of health-care professionals with standardized education, clinical training, continuing education and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy."[28]

B. Coverage Limits Preclude Provision of Most Effective Care

Medicare Part B covers intensive behavioral therapy (IBT) for obesity and IBT for cardiovascular disease (CVD) consistent with the limitations and requirements in their respective decision memoranda issued November 29, 2011 and November 8, 2011., respectively.[29] The benefits have two coverage limitations that prevent RDNs and other Medicare providers from practicing at the height of their scope of practice: (1) IBT services must be provided by primary care providers and (2) IBT services must be provided in primary care settings. Neither coverage limitation, which were predicated upon an inaccurate understanding of how the USPSTF's applied an Institute of Medicine's definition of "primary care," were actually recommended by or consistent with the USPSTF recommendations from which the IBT benefits were derived. In fact, the USPSTF has since clarified that its "recommendations address services offered in the primary care setting ***or services referred by*** primary care professionals."[30]

The decision memoranda do not account for this critical fact that the USPSTF explicitly does not make recommendations limited to primary care providers or primary care settings. Instead, USPSTF declares that recommended services must be "primary care-relevant," defined as "[e]ither conducted in a primary care setting or judged to be feasible in primary care . . . or must be primary care–referable, such that it is available for referral in most communities."[31] **Notably, the USPSTF recommendation leading to the IBT for CVD benefit specifically stated that primary care providers should refer patients to dietitians or nutritionists who would work outside the primary care setting**. The 2013 USPSTF recommendation for screening and management of obesity in adults also

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[28] Committee on Nutrition Services for Medicare Beneficiaries. "The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population." Washington, DC: Food and Nutrition Board, Institute of Medicine; January 1, 2000 (published).

[29] *See* Decision Memo for Intensive Behavioral Therapy for Obesity (CAG-00423N). Available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=253. Accessed January 15, 2019. *See also*, Decision Memo for Intensive Behavioral Therapy for Cardiovascular Disease (CAG-00424N). Available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=248. Accessed January 15, 2019.

[30] Overview of U.S. Preventive Services Task Force Structure and Processes. Available at https://www.uspreventiveservicestaskforce.org/Page/Name/section-1-overview-of-us-preventive-services-task-force-structure-and-processes. Accessed January 15, 2019. (Emphasis added.)

[31] Final Research Plan for Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Behavioral Counseling. Available at https://www.uspreventiveservicestaskforce.org/Page/Document/final-research-plan17/healthy-diet-and-physical-activity-counseling-adults-with-high-risk-of-cvd. Accessed January 15, 2019.

recommends referral of patients with obesity "to intensive, multicomponent behavioral interventions."[32]

Elsewhere, the Social Security Act explicitly contemplates physician referral to an RDN as a preventive service;[33] the obesity and cardiovascular NCDs should have provided coverage for both the work of the physician and the work of the RDN. The Academy agrees with CMS that care coordination is critical, but the desired coordination is accomplished when a primary care provider refers a patient to an RDN for medical nutrition therapy (MNT)/intensive behavioral counseling. CMS should recognize and adopt the USPSTF's broader understanding that preventive services includes services physically provided outside the primary care setting when driven by a coordinated referral from a primary care physician.[34] **CMS's limitations on the setting in which the IBT benefits can be provided also directly conflicts with the president's directive in Section 7 of the Executive Order emphasizing the importance of "rewarding care for site neutrality."[35]**

Medicare already covers numerous preventive services—including counseling services—recommended by the USPSTF in which a specialist rather than a primary care provider is paid. The Academy strongly encourages HHS to revise these coverage decisions that both dismiss the USPSTF's explicit recommendations and misapprehend the USPSTF's underlying concept of "primary care-relevant" services. In a subsequent revision, we urge CMS to establish coverage consistent with the USPSTF recommendations, thereby enabling beneficiaries to access RDN-provided IBT that is both more cost-effective and demonstrated to produce better outcomes than available under the existing benefit.

C. "Incident-To" Billing Imposes Costly Burdens and Limits Access

As a result of the coverage limitations, only primary care providers can bill for these services and only if the services are rendered in a primary care setting.[36] There remains a very limited, impracticable option for practitioners (such as RDNs, obesity medicine specialists, exercise physiologists, and clinical psychologists—or in fact many others who lack the same relevant training and expertise) to provide IBT services under the supervision of a physician who is able to bill the services as "incident-to." Primary care providers' offices simply do not have the additional functional space for an entirely new

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[32] Archived Final Recommendation Statement Obesity in Adults: Screening and Management. Available at https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/obesity-in-adults-screening-and-management-2012. Accessed January 15, 2019.

[33] Social Security Act, 42 U.S.C. 1395(x)(vv)(1).

[34] *See, e.g.,* USPSTF's assertion that it is clearly not limited to primary care disciplines or the primary care setting ("This Task Force represents primary care disciplines [nursing, pediatrics, family practice, internal medicine, and obstetrics/gynecology], preventive medicine, and behavioral medicine.") accessed 3 January 2012 at http://www.uspreventiveservicestaskforce.org/3rduspstf/behavior/behsum1.htm.

[35] Executive Order, Section 7.

[36] See https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?&NcaName=Intensive%20Behavioral%20Therapy%20for%20Obesity&bc=ACAAAAAAIAAA&NCAId=253 and https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=248

practitioner to setup a separate room for individual or group nutrition and behavioral counseling. Moreover, since RDNs and other non-primary care providers already have existing practices—of which Medicare beneficiaries may comprise merely a part—running back and forth from their own office to that of a primary care provider imposes incredible burdens and unnecessary expense.

Mandating services can only be provided "incident to" is impracticable and fails to reflect how a Patient Centered Medical Neighborhood best operates: fostering an environment of collaboration and coordination without co-location. Given the increased costs associated with incident-to billing for IBT and its impracticability, it is hardly a surprise that utilization rates for the services are under one percent. The Academy appreciates that some of our members have taken advantage of this limited opportunity to bill as auxiliary providers incident to physician services, and we agree with CMS that "preventive services should be furnished in a coordinated approach as part of a comprehensive prevention plan within the context of the patient's total health care."[37] Coordinated approaches accord with both the 5As approach and the process recommended by the USPSTF in which primary care providers refer beneficiaries for covered medical nutrition therapy services. **Referral to RDNs will not only improve outcomes, it would lower costs, because coordinated referrals to RDNs are less expensive than "incident to" billing. RDNs working independently providing the service would be reimbursed 85% of the cost that Medicare would pay physicians billing if they contracted with RDNs to have the services provided "incident to."**

The use of "incident-to" billing also creates "disparities in reimbursement between physicians and non-physician practitioners," which the Executive Order specifically seeks to eliminate.[38] Despite the ability of RDNs to provide more effective care than primary care providers, they are not "reimbursed in accordance with the work performed," but instead solely based upon the clinician's occupation."[39]

Medicare should endeavor to end antiquated reliance on mandated "incident to" billing models that increase costs and deny beneficiaries access to the most effective care. Reform should empower primary care providers to coordinate care with effective specialists, such as RDNs, endocrinologists, and bariatricians, in their respective clinical environments. The current system simply does not facilitate patient-centered care by the right providers in the most logical care settings. In addition, the current benefit's limitation to the primary care setting should be considered ripe for revision in light of the president's directive in the Executive Order to "encourage competition and a diversity of sites for patients to access care."[40]

We are facing a costly, harmful, and explosive chronic disease crisis; it makes no sense to retain arbitrary, burdensome, and financially imprudent limitations restricting the most qualified and effective individuals from helping to solve the problem. To ensure reasonable

[37] *See,* 29 November 2011 CMS NCD on Intensive Behavioral Counseling for Obesity.

[38] Executive Order, Section 5(c).

[39] *Ibid*.

[40] Executive Order, Section 7.

and timely access to Medicare benefits and fulfill the directives and priorities of the president's Executive Order, the Academy urges HHS to remove the 'incident to' requirement for service provision of both IBT benefits.

V. PERMIT DIABETES SELF-MANAGEMENT TRAINING AND MEDICAL NUTRITION THERAPY TO BE PROVIDED ON THE SAME DATE OF SERVICE

The Social Security Act provides, in part, that the determination of the provision of Diabetes Self-Management Training (DSMT)[41] and Medical Nutrition Therapy (MNT)[42] services is deferred to the discretion of the Secretary.[43] In a 2002 national coverage determination, CMS indicated that MNT and DSMT cannot be provided on the same date of service.[44] This current regulation burdens quality and access to care and creates undue hardships for persons with diabetes, particularly those with reduced mobility, limited support networks, or who reside significant distances from providers. Many beneficiaries forego necessary DSMT and MNT care because they cannot schedule services on the same day, and a regulatory change would allow beneficiaries to consolidate often-difficult and increasingly expensive trips to ambulatory care settings to receive care.

The MNT and DSMT benefits act synergistically to improve beneficiaries' quality of care, allowing for individualized and general nutrition planning and blood glucose monitoring by qualified non-physician providers such as registered dietitians. The current regulation limiting same day DSMT/MNT services creates burdensome impediments to quality patient-centered care and increases health care costs at both the individual and systems level. If the 2002 coverage determination were reformed to allow for the provision of same day service for DSMT and MNT in this circumstance, a beneficiary would be more likely to receive ample disease management and education. Associated diabetes education and disease management by non-physician providers saves money and decreases healthcare utilization.[45] Compared to no prevention, self-management reduces a high-risk person's 30-year chances of getting diabetes by about 11%, the chances of a serious complication by

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[41] Diabetes Self-Management Training is defined by section (qq) of 42 USC 1395x as education and training services to an individual with diabetes by a certified providers in an out-patient setting to ensure therapy compliance or to provide the individual with the necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of their condition.

[42] Medical Nutrition Therapy is defined by section (vv) of 42 USC 1395x as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional."

[43] 42 U.S.C. 1395x(s)(2)(V)(i). "Medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who - (i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary . . ."

[44] Centers for Medicare & Medicaid Services. NCD Decision Memo for Medical Nutrition Therapy Benefit for Diabetes & ESRD (CAG-00097N). February 28, 2002.

[45] See Robbins JM, Thatcher GE, Webb DA, Valdmanis VG. Nutritionist visits, diabetes classes, and hospitalization rates and charges: the Urban Diabetes Study. Diabetes Care. 2008;31(4):655-60; Boren SA, Fitzner KA, Panhalkar PS2; Specker, J. Costs and Benefits Associated with Diabetes Education: A Review of the Literature. The Diabetes Educator. 2009;31(1):72-96.

8% and the chances of dying of a complication of diabetes by 2.3%.[46] With the flexibility of having both services available on the same day, the likelihood of beneficiaries maintaining their appointments will increase. Preventive self-management, combined with reduced numbers of no-shows and lost days from work and school will result in significant cost savings to the health care system.

CMS has cited the dual positive impact of both DSMT and MNT Medicare services for qualifying individuals with diabetes, and has acknowledged data indicating that, "provision of both Medicare benefits may be more medically effective for some beneficiaries than receipt of just one of the benefits." The current regulatory limitation improperly conflates these two services and incorrectly assumes that health care professionals providing either DSMT or MNT all have within their scope of practice the ability to provide both services. MNT and DSMT are distinct from each other, but are both necessary for beneficiaries' improved health outcomes. Further, same day provision allows for more effective multidisciplinary care.

These two services are not interchangeable or substitutable for one another due to the scope of practice of the providers who provide each type of service. The list of provider types[47] that can teach DSMT classes includes registered dietitian nutritionists as well as health care professionals (such as registered nurses or pharmacists) whose scope of practice does not include the provision of medical nutrition therapy. Similarly, licensed dietitian nutritionists providing MNT for diabetes can be restricted in some states from providing all aspects of DSMT, such as education on the self-administration of injectable drugs, without maintaining current certification as a Certified Diabetes Care & Education Specialist (formerly a Certified Diabetes Educator or CDE).

The conflation of DSMT and MNT services and the conflation of scopes of practice of DSMT and MNT providers limits access to care for individuals with diabetes who would benefit clinically from receiving both services. It also needlessly requires patients to travel—potentially to the same office—on multiple occasions rather than receiving services in the same day. The statutory preclusion against receiving both services should be removed. In absence of that, the Secretary should exercise his authority to reissue guidance to reduce the amount of time that must occur between these services such that they can be received on the same day.

VI. REVAMP ANTIQUATED TELEHEALTH REQUIREMENTS

Policies regarding telehealth services under the current Medicare program are antiquated and do not adequately address the needs of Medicare patients, providers, and the Medicare program itself. The emergence and rapid growth of telehealth and mobile technologies designed to improve the health of individuals, enhance patient engagement and lower costs should be recognized in this model as it offers new opportunities to increase access to care

[46] *Ibid.*

[47] American Diabetes Association Education Recognition Program. Available at https://professional.diabetes.org/sites/professional.diabetes.org/files/media/erp-recognition-faq-12-18-16.pdf#page=12. Accessed January 15, 2019.

in urban, suburban and rural areas. Time spent by all qualified health care professionals (both physician and non-physician providers) using such technologies for assessment, treatment, evaluation and monitoring functions needs to be recognized in current and emerging payment models. CMS could expand traditional telehealth service policies beyond the current restrictions to incorporate rural Health Professional Shortage Areas (HPSA) or counties outside of a Metropolitan Statistical Area (MSA).

Telehealth and telenutrition practice is firmly within RDNs' professional scope of practice: "RDNs use electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. RDNs use interactive electronic communication tools for health promotion and wellness, and for the full range of MNT services that include disease prevention, assessment, nutrition focused physical exam, diagnosis, consultation, therapy, and/or nutrition intervention."[48] Allowing RDNs to practice at the height of their scope of practice in providing telehealth services in Medicare aligns with the president's directive in the Executive Order to ensure "advances in telehealth services and similar technologies[ ] are appropriately reimbursed and widely available."[49]

Expanding current policies related to telehealth services beyond HPSAs and MSAs will assist Medicare beneficiaries living in urban and suburban areas who have limited mobility and transportation issues. Why not enable beneficiaries to receive health care services amenable to telehealth technology in their homes, taking advantage of the wide range of emerging e-health technology? Home-based access to services becomes even more important with the population's desire to "age in place" as well as the recognition of the cost savings of keeping people at home rather than in expensive institutional settings when possible.

VII. REFORM BURDENSOME LIMITS ON REFERRALS FOR MNT

Building on CMS's Rural Health Strategy to improve rural health and provide reasonable and timely access to Medicare covered benefits in rural health settings, we encourage CMS to leverage partnerships with qualified non-physician providers treating Medicare beneficiaries by expanding the referral base for MNT services to qualified non-physician providers (*i.e.*, clinical nurse specialists, physician assistants, nurse practitioners, and nurse midwives, as appropriate) caring for beneficiaries with diabetes and chronic renal disease in FQHCs and RHCs. At present, patients who receive care at clinics without physicians are simply ineligible for referrals, despite the fact that advanced practice nurses and physician assistants can practice independently in many states.[50] [51] Accordingly, they should also be

[48] Academy of Nutrition and Dietetics Quality Management Committee. Academy of Nutrition and Dietetics: Revised 2017 Scope of Practice for the Registered Dietitian Nutritionist. J Acad Nutr Diet. 2018;118(1):141-165.

[49] Executive Order, Section 5(b).

[50] *See, e.g.,* State Practice Environment. American Association of Nurse Practitioners website. Available at https://www.aanp.org/advocacy/state/state-practice-environment. Accessed January 15, 2019.

[51] *See, e.g.,* Physician Assistants Overview. Scope of Practice Policy website. Available at http://scopeofpracticepolicy.org/practitioners/physician-assistants/ Accessed January 15, 2019.

recognized for referral purposes. This reform would also benefit beneficiaries receiving care in non-rural areas as we're seeing a rise in non-physician providers to meet the primary care physician shortage

VIII. INCLUDE RDNS IN ANY MODEL TREATING PATIENTS WITH NUTRITION-RELATED CHRONIC DISEASES OR MEDICAL CONDITIONS

The Academy strongly believes that RDNs must be part of any complex medical management model focused on chronic disease prevention and treatment and should specifically require MNT by RDNs within any model that includes Medicare beneficiaries with chronic conditions for which MNT is considered a standard part of care based on clinical guidelines. CMS has taken the stand of not dictating specific providers/services within models but rather leaving it up to the organization to determine the most cost-effective way to manage the population. The Academy recommends that CMS define and develop a complex medical management model by focusing on the chronic conditions known to be most prevalent in the Medicare population. As noted in CMS' "Chronic Conditions among Medicare Beneficiaries: 2012 Chartbook," more than half of Medicare beneficiaries have one or more chronic conditions, such as diabetes, hypertension, high blood cholesterol, heart disease and kidney disease.[52]

Heart failure has already been identified as a condition where clinical outcomes, patient quality of life, and health care spending can all be improved with proper medical management and care coordination and thus would also be an appropriate medical condition to include in such a model. Heart failure is the primary cause of hospitalizations among the Medicare population. Hospitalizations are most often the result of non-compliance with medications or diet. Efforts to improve quality of care and control spending in these high cost, high volume populations would significantly advance efforts to achieve CMS's goals of improved patient care, reduced healthcare costs, and improved patient health. Studies on the patient-centered medical home model of care consistently demonstrate significant clinical and financial improvements with care coordination efforts focused on such populations.[53] [54]

MNT provided by RDNs 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. As primary prevention, strong evidence supports optimal nutritional status as a cost-effective cornerstone in the maintenance of health, well-being, and functionality. As secondary and tertiary prevention, MNT is a cost-effective disease

[52] Chronic Conditions among Medicare Beneficiaries: 2012 Chartbook. Available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf. Accessed June 15, 2015.

[53] Proof in Practice: A Compilation of Patient Centered Medical Home Pilot and Demonstration Projects, Patient-Centered Primary Care Collaborative, 2009.

[54] Higgins S, Chawla R, Colombo C, Snyder R, Nigam S. Medical homes and cost and utilization among high-risk patients. Am J Manag Care. 2014:20(3):e61-e71.

management strategy that reduces chronic disease risk, delays disease progression, enhances the efficacy of medical/surgical treatment, reduces medication use, and improves patient outcomes including quality of life.[55]

While not a new service under the Medicare program, recognition of clinically-effective MNT services provided by RDNs would need to expand beyond diabetes and non-dialysis renal disease to include all of the medical conditions included under this model for which such services have been proven to be of benefit and are recognized in national clinical practice guidelines. This list would include, at minimum, hypertension, high blood cholesterol, heart disease, heart failure, obesity, undernutrition/malnutrition and unintended weight loss, metabolic syndrome/pre-diabetes, eating disorders, cancer, celiac disease, HIV/AIDS, and COPD.[56]

These services could be paid for as a fee-for-service payment to the RDN provider or via funds designated for such use as part of a per-patient-per-month payment to the practice (primary or specialty) serving as coordinator of care for the patient's plan of care. A value-based payment model could be utilized that specifically allows the RDN provider (and other non-physician members of the patient's health care team) to share in the savings achieved by the entire care team, as well as incentive payments received by the practice for the quality outcomes achieved. Payment models continue to pose challenges as providers across practice settings who contribute to the care of an individual patient are often faced with the challenge of "carving up the pie" when it comes to bundled payments.

The payment mechanism for this model needs to recognize that health care can effectively be delivered via a medical "neighborhood" or virtual team, meaning the care team of physicians and qualified non-physician practitioners do not all need to be located within the primary care provider's office setting. The care model needs to be designed to go beyond the physical walls of any particular medical practice to allow patients to receive services where they work, live and play; in locations convenient to them; and at hours convenient to them. Payment models need to hold the team accountable for care while providing the flexibility needed to attribute payment equitably among all members of the team, no matter their practice location. While a designated "primary" care provider is essential to achieving effective care coordination, the model needs to recognize that depending on the individual patient and their needs at a particular point in time, leadership in complex chronic care management services may shift amongst members of the care team, including the registered dietitian nutritionist.

Unlike traditional Medicare, Medicare Advantage plans, the Veterans Administration, and other federal government health plans have the flexibility to ensure beneficiaries receive the behavioral and pharmaceutical therapies they need to treat and manage their chronic

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[55] 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."

[56] Gradwell E, Raman PR. The Academy of Nutrition and Dietetics National Coverage Determination Formal Request. *J Acad Nutr Diet.* 2012:112:149-176.

diseases. RDNs and NDTRs are critical members of health care teams and are essential to delivering nutrition-focused preventive services in clinical and community settings, advocating for policy and programmatic initiatives, and leading research in disease prevention and health promotion. The Academy agrees with the American Heart Association and the American College of Cardiology that "[t]he ultimate decision about care of a particular patient must be made by the healthcare provider and patient in light of the circumstances presented by that patient[,]"[57] which manifests the need for qualified, independent practitioners such as RDNs to provide more complex, individualized care when formal intervention programs or protocols may be unavailable, ineffective, or non-indicated. **We urge CMS and HHS to integrate qualified and effective providers, such as RDNs, into all payment and delivery models to ensure beneficiaries have the ability access the right care, at the right time, from the right provider.**

Thus, the Academy strongly recommends that all alternate payments models and all policies aimed to address care of Medicare beneficiaries with nutrition-related chronic diseases in any care setting should routinely require inclusion of RDNs as part of the care team (including virtual teams, meaning RDNs should not have to be directly in a Patient Centered Medical Home building to be a part of the team and help the patients manage their chronic conditions). Payment models should provide funding for the nutrition services provided by the RDN, either through enhanced fee for service, enhanced Per Member Per Month fees, part of a bundled payment for chronic conditions and/or episodes of care, as well as access to shared savings and incentive programs.

IX. CONCLUSION

The Academy appreciates the opportunity to comment on the request for feedback on scope of practice-related Medicare reforms to reduce burdens, enhance access, and improve health. Please contact either Jeanne Blankenship at 312-899-1730 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

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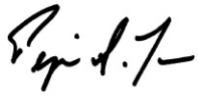

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[57] Eckel RH, Jakicic JM, Ard JD, et al. 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2013 at 6.