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August 2, 2024

Honorable Diana DeGette
2111 Rayburn House Office Building
Washington D.C. 20515

Honorable Larry Bucshon
2313 Rayburn House Office Building
Washington D.C. 20515

RE: 21st Century Cures Request for Information

Submitted electronically to *cures.rfi@mail.house.gov*

Dear Representatives DeGette and Bucshon:

The Academy of Nutrition and Dietetics ("the Academy") appreciates the opportunity to provide comments in response to the Request for Information (RFI) on the evolving Cures package that builds upon the achievements and support the advancement of healthcare.

The Academy represents over 113,000 registered dietitian nutritionists (RDNs), nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists—the largest association of credentialed nutrition and dietetics practitioners worldwide. We are dedicated to enhancing global health, addressing food and nutrition security, and understanding its impacts on health and well-being.

The 21st Century Cures Act provided a significant shift in the way Americans experience health care, from improving funding for biomedical research, to improving mental health services, and making giant steps forward in improving interoperability. While each of these advancements plays a crucial role in shaping a more dynamic, patient-centered heath care system, driving research, and improving treatment options, there remain significant gaps and opportunities for improvement in future Cures initiatives.

The Academy recommends actions that address the following:

1. **Increase access to preventive services for chronic diseases in modernizing Medicare coverage**
2. **Broaden home infusion therapy and home-based care providers and services**
3. **Direct CMS to include language that supports nutrition care provided by RDNs into interoperability and value based-care models**
4. **Clarify the role of MNT in advancing healthcare & innovations**
5. **Expand access to providers that can support patients and caregivers.**

We call attention to the fact that our nation continues to pay the prices for overlooking the importance of nutrition in the prevention and treatment of chronic diseases. In the well-intended and necessary efforts to increase access to novel therapeutics, we have lost sight of the critical and necessary services at the most basic level to address lifestyle changes. The system supports higher-cost interventions without supporting low-cost high value interventions such as medical nutrition therapy that improve the effectiveness of other elements of care. MNT is a therapeutic approach to managing chronic conditions and diseases through evidence-based nutritional interventions. MNT is **both** a preventive service and a treatment for those with chronic disease and other health conditions.

This therapy involves personalized dietary planning and counseling provided by RDNs, the only healthcare providers highly trained in nutrition interventions, to help manage conditions such as diabetes, cardiovascular disease, and chronic kidney disease. It works by addressing specific nutritional needs, improving dietary habits, and supporting overall health goals. MNT has been shown to significantly improve health outcomes, such as lowering HbA1c levels in diabetes patients[1] and reducing cardiovascular risk factors.[2]

Recommendation 1: Include bill language or direction to increase access to preventive services for chronic diseases to support novel therapeutic approaches or as stand-alone services as part of modernizing Medicare.

Clinical practice guidelines for diabetes care and cardiovascular disease emphasize the vital role of Medical Nutrition Therapy (MNT) in managing these conditions comprehensively. Although guidelines recommend MNT for chronic diseases and evidence supports its effectiveness, many Americans, especially those on Medicare, face limited access. Medicare's current coverage is restrictive by statute, providing benefits only for diabetes, chronic renal insufficiency (Stage 3 and 4), and post-kidney transplant, and requires a physician referral. It does not cover prediabetes, obesity, or other chronic conditions where MNT is proven beneficial.

MNT is underutilized, with fewer than 2% of eligible beneficiaries accessing these services,[3] in part due to both provider and patient confusion around conditions of coverage to use the benefit[4] and restrictive referral requirements. Without access to RDNs, nutrition care is either delivered by non-qualified providers or omitted altogether thus bypassing a lower cost high value service and defaulting to pharmacology or other higher-level interventions.

In addition to limitations on services like MNT, many seniors struggle to access preventive care from qualified providers and programs. For example, the Medicare Diabetes Prevention Program (MDPP) is a

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[1] Academy of Nutrition and Dietetics Evidence Analysis Library. DM: Diabetes Type 1 and 2 Systematic Review (2013-2015). https://www.andeal.org/topic.cfm?menu=5305&pcat=5491&cat=5161. Accessed July 20, 2024.

[2] Sarah A. Johnson, Carol F. Kirkpatrick, Nicole H. Miller, Jo Ann S. Carson, Deepa Handu, Lisa Moloney, Saturated Fat Intake and the Prevention and Management of Cardiovascular Disease in Adults: An Academy of Nutrition and Dietetics Evidence-Based Nutrition Practice Guideline, Journal of the Academy of Nutrition and Dietetics, Volume 123, Issue 12, 2023, Pages 1808-1830, https://doi.org/10.1016/j.jand.2023.07.017.

[3] FR 39259 through 39261: MNT participation remains under 2 percent of eligible beneficiaries. Based on an analysis of Medicare claims data from 2018, 2019, 2020, we identify the utilization rate of MNT services among eligible beneficiaries to be between 1.5 and 1.8 percent.

[4] Jimenez EY, Kelley K, Schofield M, Brommage D, Steiber A, Abram JK, Kramer H. Medical Nutrition Therapy Access in CKD: A Cross-sectional Survey of Patients and Providers. Kidney Med. 2020 Nov 11;3(1):31-41.e1. doi: 10.1016/j.xkme.2020.09.005. PMID: 33604538; PMCID: PMC7873758.

structured, 16-week group intervention designed to prevent type 2 diabetes in individuals with prediabetes. The level of care provided through the MDPP programs is educational only, it is not a clinical intervention provided by a health care provider. There are seniors that would benefit from alternative interventions due to educational, medical or social factors. Currently, MDPP is not available in all areas or appropriate for all Medicare beneficiaries, many of whom have other chronic conditions in addition to prediabetes and who would benefit from personalized MNT services.

Suppliers of MDPP programs and services face structural and financial barriers that hinder the delivery and sustainability of viable programs. Congress should continue to monitor evidence emerging from the CMS Innovation Center to determine if additional supports are necessary to sustain the program.

Specific actions Congress can take to support increased access to evidence-based nutrition care include:

- **Statutorily expand Medicare coverage of medical nutrition therapy to include preventive services for chronic diseases for which there is clinical evidence.**
  Language from the Medical Nutrition Therapy Act could be incorporated into future Cures language. CMS has explicitly suggested that they lack the authority to expand the coverage although a 2012 Congressional Research Service report suggests that the Secretary of Health and Human Services does have the authority to make modifications to existing covered services such as MNT[5]. Congress could require CMS to act on Section 4105(a) of P.L. 111-148, the Patient Protection and Affordable Care Act (PPACA) to modify coverage as noted in the report.

- **Strengthen Chronic Disease Programs by increasing funding and incentives for the Medicare Diabetes Prevention Program (MDPP) and other support services**
  The steps would boost adoption, accessibility and sustainability. Congress should identify and implement cost and clinically effective technology solutions and modalities such as telehealth and asynchronous learning to increase access and utilization.

Recommendation 2: Broaden Home Infusion Therapy and Home-Based Care Providers and Services to include evidence-based nutrition care

1. *Access to Evidence-based nutrition care in the home-based setting*
   For many Medicare beneficiaries, accessing continued care after leaving the hospital or a skilled nursing facility is crucial for recovery and well-being. Home health services provide a range of offerings, such as outpatient care and medical supplies, to ensure patients receive the support they need. This continuity of care often includes essential therapies like physical therapy, occupational therapy, and speech-language pathology.

   When it comes to nutrition services, the situation is notably different. There are individuals whose nutrition needs extend past discharge as identified during discharge planning. This includes those who are post-surgical, need wound healing, nutrition support, hydration, or management of malnutrition and complications to prevent readmission. Despite the crucial role nutrition plays in recovery and long-term health, most Medicare beneficiaries find that access to nutrition care providers ends at discharge. Despite its importance in whole-person care and well-

[5] Legal Analysis of the Authority of the Secretary of HHS to Add, Modify or Eliminate Certain Preventive Services Under Part B of Medicare. https://crsreports.congress.gov. Congressional Research Service, Report dated: February 21, 2012.

documented benefits, nutrition care remains inaccessible for those who are discharged to home or community settings outside of long-term care. Past legislative and policy decisions have excluded nutrition care services from core offerings. The perception that nutritional needs can be managed without specialized support may have contributed to these decisions, creating a significant gap in care for those who need it most.

2. *Home-Infusion Therapy*
   Under the Social Security Act § 1861(s)(8), parenteral and enteral nutrition therapies are categorized under the prosthetic device benefit and reimbursed under Durable Medical Equipment (DME). Under the Social Security Act § 1861(s)(8), parenteral and enteral nutrition therapies are categorized under the prosthetic device benefit and reimbursed under Durable Medical Equipment (DME). This classification is problematic because it does not provide access to the professional services of the RDN, essential for the effective provision of parenteral nutrition. While Section 1861(iii)(2) of the Act defines home infusion therapy to include professional services, training and education (not otherwise included in the DME payment), remote monitoring, and other monitoring services furnished by a qualified home infusion therapy supplier in the patient's home, RDNs are not included. This discrepancy needs to be addressed to ensure that patients receiving parenteral nutrition therapy can access the necessary professional support services, like those available under the home infusion therapy benefit.

Specific actions Congress can take to increase access to increase access to evidence-based nutrition care in Home-health services:

- **Conduct a Legislative Review and Reform Outdated Policies**
  Congress should conduct a thorough review of past legislative and policy decisions that have led to the exclusion of nutrition care services from core Medicare offerings. By reforming outdated policies, Congress can prioritize whole-person care and recognize the essential role of nutrition in patient recovery and wellness.

- **Align Reimbursement Policies**
  Ensure reimbursement policies provide comprehensive support, including professional services, training, and monitoring, for patients receiving parenteral and enteral nutrition therapy by amending the Social Security Act § 1861(s)(8) to include access to professional services for parenteral nutrition therapy, like those covered under home infusion therapy in Section 1861(iii)(2).

Recommendation 3: Direct CMS to include language that supports evidenced- based nutrition care into interoperability standards and value based-care models

A key tenet in the 21st Century Cures Act focused on promoting interoperability of health information technology systems to strengthen and improve the exchange of health information. The goal was to ensure that health information can be shared easily and securely among providers, patients, and other stakeholders. Additionally, the Act also aimed to strengthen the certification requirements for health IT products, ensuring they meet certain standards for functionality, security, and interoperability. This includes requirements for using application programming interfaces (APIs) to facilitate data exchange and interoperability.

While the Act did place emphasis on the use of interdisciplinary healthcare teams and supported the continued development of patient-centered care, many of the promoting interoperability programs that followed failed to support non-physician providers thereby hindering their ability to adopt, implement and demonstrate meaningful use of a certified electronic health record.

The CMS Quality Payment Program (QPP) is primarily designed with a physician focus, which poses challenges for non-physician providers, including RDNs, to participate effectively. RDNs were granted eligible clinician/qualified Alternative Payment Models (APM) participant status in the QPP in 2019[12] however, to date many RDNs continue to face significant barriers to participating[13]. RDN practices were not included in the EHR Incentive Program, which was designed to make access to health information technology and interoperability among all providers a reality. Like many other non-physician providers, RDN practices continue to rely on manual reporting and data collection which can make it difficult to near impossible to participate in quality reporting. Member feedback reveals that while there is interest in participating in the QPP, the complexities of the program prove to be too burdensome.

In addition to technology barriers, many RDNs have expressed concerns when selecting which measures to report, and meeting participation thresholds. It is crucial that APMs, such as the QPP, include relevant measures for non-physician providers who participate. Addressing these issues by incorporating incentives for utilizing subspecialties like RDNs and designing APMs that include relevant measures for non-physician providers is crucial.

A recent publication from America's Health Insurance Plans[6] emphasizes that integrating quality performance into Value-Based Care (VBC) models aims to drive long term health improvements, even if immediate returns are not apparent. It highlights the need to limit administrative burdens and ensure quality, performance and other reportable measures are clinically meaningful[7]. Without such measures, there's little incentive to integrate RDN services into primary and chronic care effectively. To improve care, payment models should include incentives for subspecialties like RDNs, and design measures that allow non-physician providers to participate fully. Evidence-based nutrition care must be part of payment models to ensure access and quality, promoting comprehensive care and better health outcomes.

It is imperative that the intersection between providers' ability to implement necessary health technology to support interoperability and the design of payment models that support appropriate care for managing chronic disease be effectively managed. When these elements are misaligned, the quality of care falls short of its intended goals.

Specific actions Congress can take to increase access to supports nutrition care into interoperability and value based-care models:

- **Expand Support for Non-Physician Providers in Interoperability Programs**
  We urge Congress to ensure that future interoperability programs explicitly support non-physician providers, including RDNs. This includes providing resources and incentives to

[6] AHIP: A playbook of voluntary best practices for VBC Payment arrangements" 2024
[7] ibid

facilitate the adoption, implementation, and meaningful use of certified electronic health records (EHRs) by these providers, overcoming existing barriers to effective participation.

- **Incorporate evidenced based nutrition in value-based care**
  Congress should direct CMS to include language that supports evidenced-based nutrition care in value-based payment models. This should involve creating clinically meaningful measures relevant to non-physician providers, enabling RDNs to contribute effectively to patient care and quality improvement.

Recommendation 4: Clarify the Role of MNT in Advancing Healthcare & Innovations

Emerging health technologies, such as new diabetes and weight management drugs, are more effective if complemented by evidence-based lifestyle behavior modification and MNT. RDNs provide crucial education and support that optimize the use of these medications, helping patients integrate nutrition into their daily lives effectively and sustainably. However, without appropriate coverage, only those with sufficient resources can access this critical support needed to optimize health outcomes. For Medicare beneficiaries, the lack of coverage for comprehensive nutrition care means that many are unable to benefit from the full range of available treatments and technologies.

1. *Nutrition Care Outside of Medical Nutrition Therapy*

   MNT is the primary service offered by RDNs to Medicare beneficiaries, but they are not able to directly bill Medicare for other services within their scope, such as Intensive Behavioral Therapy (IBT) for Obesity, Caregiver Services, and Remote Monitoring.

   - *IBT for Obesity:* The Centers for Disease Control and Prevention reports a dramatic increase in obesity rates, with nearly 14 million Medicare beneficiaries living with either overweight or obesity[8]. Obesity is associated with chronic diseases like cardiovascular conditions and diabetes. Unfortunately, the current IBT benefit fee-for-service (FFS) is outdated and limited. The service is limited to the primary care setting and is not based current evidence-based recommendations[9,10,11]. Under current rules, RDNs provide IBT under general supervision of the primary care provider in their office and bill incident to the physician. This results in a higher-cost intervention than if the RDN were allowed to provide and directly bill for the service. With the rise of anti-obesity medications, updating policies to reflect current literature, best practices and care delivery is essential.

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[8] An Estimated 1 in 4 Medicare Beneficiaries With Obesity or Overweight Could Be Eligible for Medicare Coverage of Wegovy, an Anti-Obesity Drug, to Reduce Heart Risk. Accessed at https://www.kff.org/medicare/press-release/an-estimated-1-in-4-medicare-beneficiaries-with-obesity-or-overweight-could-be-eligible-for-medicare-coverage-of-wegovy-an-anti-obesity-drug-to-reduce-heart-risk/#:~:text=Based%20on%20KFF%20research%2C%20about,risk%20of%20serious%20heart%20problems. Accessed July 12, 2024

[9] Medical Nutrition Therapy Interventions provided by Dietitians for Adult Overweight and Obesity Management: An Academy of Nutrition and Dietetics Evidence-Based Practice Guidelin**e.** *J Acad Nut Diet 2023:23(3):520-545.* doi: https://doi.org/10.1016/j.jand.2022.11.014

[10] Barton, Mary & Miller, Therese & Wolff, Tracy & Petitti, Diana & LeFevre, Michael & Sawaya, George & Yawn, Barbara & Guirguis-Blake, Janelle & Calonge, Ned & Harris, Russell. (2007). How to Read the New Recommendation Statement: Methods Update from the U.S. Preventive Services Task Force. Annals of internal medicine. 147. 123-7.

[11] National Coverage Determination for Intensive Behavioral Therapy for Obesity. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=353. Accessed July 22, 2024

Most primary care providers do not have RDNs on site in their offices making it challenging to refer under the current rule. Physicians have also recognized that RDNs are the preferred provider for delivering services[12] and have expressed frustration with the way the benefit is restricted.

- *Caregiver Training Services*: Caregiver Training/Caregiver Behavior Management Services are designed to support patient treatment plans by educating caregivers, particularly when the patient is unable to follow the plan themselves. For many older adults with chronic conditions or disabilities, nutrition care interventions often need to be delivered to the caregiver to ensure adherence to the nutrition care plan. However, CMS has explicitly stated that RDNs are statutorily limited to bill for only care that falls within the scope of MNT, restricting their ability to offer this crucial caregiver training.

- *Remoting Monitoring Services*: Remote monitoring involves the use of technology to efficiently support patient care, physiologic data (e.g. serum glucose, body weight, and blood pressure) are key markers that influence nutrition care management and can be reported through monitoring devices. Again, RDNs are restricted to only directly bill for care services provided within the scope of MNT, limiting their ability to use technology effectively to improve care.

2. *Clarifying the Confusion Around Nutrition Services*

MNT and food and nutrition security programs are essential components to building and maintaining a robust healthcare system. While there are many conversations regarding Food as Medicine, a clear definition, model and approach are lacking. It is important to recognize that Food as Medicine initiatives attempt to bridge complimentary services. MNT is a carve out of the practice of medicine as is specifically designed to prevent, treat and manage chronic diseases and conditions through personalized nutritional strategies. There is often confusion between nutrition services aimed at addressing food insecurity and providing medical nutrition interventions. While addressing food and nutrition security is important for ensuring access to adequate and nutritious food, it does not replace the need for MNT.

Food as medicine initiatives aim to support overall health and prevent disease through providing broad access to nutritious foods that are tailored to meet the needs of those living with chronic conditions. MNT should play an integral role in food as medicine initiatives to ensure meals and groceries are medically tailored when an individual has specific medical conditions or diagnoses, or such personalization is otherwise indicated. Policies are needed to aid in proper delivery of each service as well as support providers best suited to deliver each.

Specific actions Congress can take to support comprehensive nutrition care through policy and innovation:

- **Support Policy Initiatives to Integrate MNT with Emerging Health Technologies & Innovation**

[12] Bleich S, Bennett W, Gudzune K, Cooper L. National survey of US primary care physicians' perspectives about causes of obesity and solutions to improve care. BMJ Open. 2012;2(6):e001871. doi:10.1136/bmjopen-2012-001871

Develop policies that integrate MNT with emerging health innovations, such as IBT for Obesity, caregiver training services, and remote monitoring.

- **Address statutory language limiting RDN Practice that prevents them from practicing within their full scope of practice.** Currently, RDNs cannot bill Medicare for these services, despite their importance in comprehensive care. Updating policies to reflect current evidence-based practices and expanding RDN capabilities will enhance patient care and outcomes,

- **Develop Policies for Comprehensive Nutrition Care:**
  Create policies that provide greater clarity around services offered in comprehensive nutrition care, ensuring that MNT, nutrition assistance programs, and 'food as medicine' initiatives are well-defined and integrated within the broader healthcare and food systems. This will enhance support for each service and ensure they complement each other effectively.

In closing, the Academy firmly believes that integrating the above recommendations into future Cures legislation will enhance care by modernizing and expanding Medicare's coverage for evidenced-based nutrition care for chronic conditions, broaden access to home-based nutrition services, and allow credentialed nutrition providers, such as RDNs to work within their full scope. Congress can bridge gaps in care and promote a more inclusive, patient-centered healthcare system.

Thank you for considering our comments. We look forward to working with you to address these gaps and advance the integration of nutrition care into the healthcare system by providing additional resources and language recommendations. Please contact Jeanne Blankenship at jblankenship@eatright.org with any questions.

Best Regards,

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