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January 31, 2023

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1770-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Request for Information; Essential Health Benefits: CMS-9898-NC

Dear Administrator Brooks-LaSure,

The Association of Diabetes Care & Education Specialists (ADCES) appreciates the opportunity to offer comments in response to the *Essential Health Benefits (EHB) Request for Information (RFI).*[1] ADCES is an interdisciplinary professional membership organization dedicated to improving prediabetes, diabetes, and cardiometabolic care through innovative education, management, and support. With more than 12,000 professional members including nurses, dietitians, pharmacists, and others, ADCES has a vast and diverse network of practitioners working to optimize care and reduce complications. ADCES supports an integrated care model that lowers the cost of care, improves experiences, and helps its members lead so better outcomes follow.

ADCES acknowledges the Centers for Medicare & Medicaid Service's (CMS's) efforts to improve health equity and access to care for Marketplace beneficiaries. As detailed in our comments below, ADCES remains committed to working with CMS to ensure that all Marketplace beneficiaries with diabetes, prediabetes, obesity, and other cardiometabolic conditions have access to high-quality, equitable care.

Within the comments below are recommendations to improve coverage and specificity in EHB-benchmark plan documents for diabetes self-management education and support (DSMES), medical nutrition therapy (MNT), obesity screening and counseling, intensive behavioral counseling for adults at higher risk for chronic disease, and screening for abnormal blood glucose in adults. ADCES also offers comments in support of coverage of anti-obesity medications in ACA plans.

1. **Improving Coverage and Specificity in EHB-benchmark Plan Documents**

Intensive Behavioral Counseling for Adults at Higher Risk for Chronic Disease and Effective Preventive Interventions

EHB policy indicates that all marketplace health plans must cover "**diet counseling** for adults at higher risk for chronic disease." However, USPSTF recommendations, for those with prediabetes (described below) for adults with cardiovascular disease risk factors (November 2020), specify the provision of

[1] 87 *Fed. Reg.* 74097 (Dec. 2, 2022).

intensive behavioral counseling as the effective service. Further, USPSTF has defined intensive behavioral counseling very clearly as 12 to 26 sessions with diet, physical activity, and lifestyle modification counseling. The EHB language of "diet counseling" has proven to be vague and insufficient instruction for health plans as to what constitutes an effective intervention as determined by the USPSTF's extensive evidence review. **ADCES recommends using this language instead: "Diet counseling via intensive, multicomponent behavioral interventions for adults with prediabetes or obesity/overweight, who are at higher risk for chronic disease."**

For people at risk of diabetes with prediabetes, the CDC's National Diabetes Prevention Programs (National DPP) and the CMS Medicare Diabetes Prevention Programs (MDPP) provide intensive behavioral counseling that meets the USPSTF specifications for effective preventive treatment, but these programs are not listed as required services for marketplace plans to offer. **ADCES recommends that National Diabetes Prevention Programs or Medicare Diabetes Prevention Programs, delivered by any CDC-recognized modality, should be listed as essential health services that marketplace plans must cover as preventive health services**.

For people with diabetes, "diet counseling" should come in the form of evidence-based care from qualified professionals and programs such as diabetes self-management education and support (DSMES) and medical nutrition therapy (MNT). Neither of these evidence-based services is listed as an essential preventive health service, but both are vital to successful management of diabetes. **ADCES believes that DSMT and MNT should be listed by CMS as essential services that marketplace health plans must cover as preventive health services.** (*See below for more information on DSMT and MNT.*)

Diabetes Self-Management Education and Support

ADCES applauds CMS in their continued collaboration to reduce barriers to timely and critical diabetes self-management education and support (DSMES) services, one of several underutilized services proven to improve health equity. DSMES is also referred to as diabetes self-management training (DSMT) under the Medicare program. There is substantial data showing that DSMES services (and Medicare's DSMT benefit) lower the overall burden and improve outcomes for people with diabetes. DSMES reduces the risk of diabetes complications, thereby preventing emergency department visits, inpatient hospitalizations and rehospitalizations.[2] Despite the undisputed benefits of DSMES for people with diabetes (lower hemoglobin A1C, weight loss, improved quality of life, healthy coping skills, and reduced healthcare costs) only an estimated 6.8 percent of people with diabetes and commercial insurance had access to and utilized DSMES services.[3] We see disparities in access to DSMES by age, sex, race, language, geography, and the availability of DSMES providers and programs.[4] According to CMS, fewer Black and Hispanic beneficiaries reported knowing about Medicare coverage policies for diabetes testing supplies and self-management education compared to White beneficiaries, indicating awareness

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[3] Strawbridge LM, Lloyd JT, Meadow A, Riley GF, Howell BL. Use of Medicare's Diabetes Self-Management Training Benefit. Health Educ Behav. 2015 Aug;42(4):530-8. doi: 10.1177/1090198114566271. Epub 2015 Jan 23. PMID: 25616412. https://pubmed.ncbi.nlm.nih.gov/25616412/

[4] Strawbridge LM, Lloyd JT, Meadow A, Riley GF, Howell BL. Use of Medicare's Diabetes Self-Management Training Benefit. Health Educ Behav. 2015 Aug;42(4):530-8. doi: 10.1177/1090198114566271. Epub 2015 Jan 23. PMID: 25616412. https://pubmed.ncbi.nlm.nih.gov/25616412/

barriers for both referring providers and beneficiaries.[5] The COVID-19 pandemic has further exacerbated challenges to beneficiary access to this critical service.[6]

As stated in the RFI, the EHB-benchmark plan approach was designed to "allow States to build on coverage that is already widely available, minimize market disruption, and provide consumers with familiar products**." In our review of the national benchmark plans, this was not applied consistently to DSMES. Each state uses different terms to refer to diabetes education services, putting consumers at risk of lower quality or unqualified services, undermining the true benefits of evidence-based DSMES and causing confusion for consumers, providers, and billers.**

One option to improve and standardize coverage would be to align EHB baseline requirements for diabetes education services with the Medicare benefit for DSMT, so long as those become the baseline, and not the benefit maximum. This would help CMS fulfill its statutory obligation of the ACA to periodically review and update for gaps in coverage or change in the evidence base. Indeed, this is already occurring with the CMS Quality and Oversight Group for the DSMT benefit through monthly reporting, annual reports and audits and maintenance of certification for accrediting organizations every six years. **What would be even more helpful is if the EHB baseline requirements reflected the fact that DSMES is an accredited service that extends beyond the DSMT programs covered by Medicare Part B. For this reason, CMS should be careful not to overwrite or preempt state benefits coverage rules that may make DSMES more widely available than the Medicare-defined benefit.**

The National Standards for DSMES are updated every 5 years through a collaboration between the ADCES and the American Diabetes Association (ADA) and are then approved by CMS; these standards exceed CMS Quality Standards. These standards are the industry recognized marker of quality such that even providers of DSMES who do not choose to or are unable to bill Medicare, such as virtual and telehealth providers, seek ADCES accreditation as a marker of meeting standards for clinical quality. ADCES accredits virtual, synchronous video-based DSMES, and in-person programs. An added benefit for accredited organizations is that they gain a network of peers, experts and mentors to share best practices and learn about current and updated guidelines, evidence and practice as well as being able to promote that they achieved accreditation by meeting National Standards for quality diabetes care and education.

In addition to aligning diabetes education services with at least the Medicare DSMT benefit, ADCES recommends that CMS encourage states to update language in plan descriptions to align with current science and practice by using the term DSMES. DSMES has been the accepted terminology among the medical community and public for over a decade. Aligning EHB plans' minimum coverage criteria with the Medicare DSMT benefit and DSMES accreditation standards and using the term DSMES (as is used outside of the Medicare program) would help consumers access more diabetes education services more consistently across payers. There is also a national campaign starting in 2023 led by the CDC, ADA and ADCES to increase familiarity and improve access to DSMES services, and standardization in language across a larger number of payers would only bolster these efforts.

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[5] 2012 Medicare Current Beneficiary Survey, sponsored by the Centers for Medicare & Medicaid Services (CMS). https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data-highlights/disparities-in-diabetes-prevalence

[6] https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18

Medical Nutrition Therapy
Medical nutrition therapy 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.[7] MNT is 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.

MNT is medically necessary for chronic disease states in which dietary adjustment has a therapeutic role when it is furnished by a qualified provider. The most appropriate and accepted definition for qualified providers of medical nutrition therapy are registered dietitian nutritionists (RDN) or other qualified nutrition professional as defined by the Social Security Act §1861 (vv).

Access to evidence-based nutrition care by qualified providers remains at the mercy of the vague and ill-defined nature of some of the EHB categories. Four of the top six leading causes of death can be influenced and ameliorated by cost-effective nutrition and diet counseling and interventions by registered dietitians. EHB 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. Even though the ACA guarantees protection from discriminatory health care practices and of EHB coverage, people living with nutrition-related chronic conditions such as diabetes, prediabetes and obesity have fallen through the cracks and are unable to access medically necessary care for their chronic condition.

Many state health plans continue to provide ambiguous and inconsistent coverage for both MNT and nutrition services. While there are health plans that do include specific benefit language related to MNT and/or nutrition counseling, terminology and actual coverage for these nutrition services are not consistently and explicitly detailed. ADCES supports the Academy of Nutrition and Dietetics in its belief that **both health plans and consumers would benefit from greater specificity of MNT in the listed elements of the EHB and it would behoove the Department of Health and Human Services to specifically determine whether a base benchmark plan meets the required minimum coverage of MNT and other nutrition services.**

Obesity Screening and Counseling
The phrase "obesity screening and counseling" is similarly unclear and is insufficient instruction for health plans. Further, it does not reflect the FAQs issued jointly by the Tri-Agencies in 2015, which clearly stated:

"Non-grandfathered plans and issuers must cover, without cost sharing, screening for obesity in adults. In addition to such screening, the USPSTF currently recommends, for adult patients with a body mass index (BMI) of 30 kg/m2 or higher, intensive, multicomponent behavioral interventions for weight management. The recommendation specifies that intensive, multicomponent behavioral interventions include, for example, the following:

- Group and individual sessions of high intensity (12 to 26 sessions in a year)
- Behavioral management activities, such as weight-loss goals

[7] Academy of Nutrition and Dietetics. Effectiveness of Medical Nutrition Therapy. Eatrightpro.org. https://www.eatrightpro.org/-/media/files/eatrightpro/advocacy/mnteffectivenessleavebehind.pdf. Published 2021. Accessed January 31, 2023.

- Improving diet or nutrition and increasing physical activity,
- Addressing barriers to change
- Self-monitoring, and
- Strategizing how to maintain lifestyle changes."

Also, the updated USPSTF recommendation (September 2018) entitled "Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions," is clear and specific in its recommendations that "clinicians offer or refer adults with a body mass index (BMI) of 30 or higher (calculated as weight in kilograms divided by height in meters squared) to intensive, multicomponent behavioral interventions." ADCES echoes the Diabetes Advocacy Alliance's recommendation to **change "obesity screening and counseling" to "obesity screening and provision/coverage of intensive, multicomponent behavioral interventions for those with obesity."** ADCES additionally echoes the Obesity Care Advocacy Network's recommendation that **CMS issue formal guidance that mirrors the Tri-Agencies October 23, 2015 FAQ guidance on weight management services** to ensure that these critical preventive care services are being adequately covered to encompass both the appropriate frequency and intensity of the benefit. This and guidance language would be more helpful to marketplace health plans than "obesity screening and counseling" in specifying the types of therapy that should be covered, such as intensive behavioral therapy (IBT) for people with obesity.

Screening for Abnormal Blood Glucose in Adults (and provision of services for those with high blood glucose levels)

The United States Preventive Services Task Force (USPSTF), in its revised recommendation announced on August 24, 2021, stated: "The USPSTF recommends screening for **prediabetes and type 2 diabetes** in **adults aged 35 to 70 years** who have overweight or obesity. Clinicians should offer or refer patients with **prediabetes** to effective preventive interventions."[8] Also, the USPSTF recommendation further states that those with pre-diabetes be provided (either by primary care provision or referral) **intensive behavioral counseling**, which is shown to reduce risk of diabetes by 60%. As a result, all marketplace health plans must cover screening for blood glucose for this at-risk population, without charging a copayment or coinsurance, among adults ages 35 to 70 years who are overweight or obese. However, current EHB standards only specify "screening for type 2 diabetes." The lack of specificity leaves out a significant at-risk population that should receive screening and does not address coverage for the service associated with reducing type 2 diabetes risk.

ADCES suggests that EHB policy language be expanded to include "screening for type 2 diabetes **and prediabetes**" and that the applicable age range be modified to 35 to 70, to be aligned with the USPSTF recommendation. In addition, ADCES suggests that the EHB policy clearly state that, **for those with prediabetes, the USPSTF recommended interventions and services must be covered**. ADCES also recommends aligning required service coverage with the 2019 American Medical Association-proposed prediabetes quality measures which recommend **people with prediabetes receive a referral to a CDC-recognized DPP, a referral to MNT with a registered dietitian, or a metformin prescription following a prediabetes diagnosis.**

[8] U.S. Preventive Services Task Force. Prediabetes and Type 2 Diabetes: Screening. https://uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes

2. **Coverage of Prescription Drugs Subject to the EHB Requirements of the ACA**

Overweight and obesity are key risk factors for identification of asymptomatic people with undiagnosed prediabetes and type 2 diabetes. There is clear evidence that weight loss is associated with prevention or delay of onset of type 2 diabetes, and there are serious negative health outcomes associated with overweight and obesity among people with both type 1 and type 2 diabetes.

There is growing consensus among health care organizations that people with diabetes need access to the full continuum of available treatments for obesity, since overweight or obesity affects most people with diabetes. Currently, Medicare Model Guidelines (MMG), which are based upon a U.S. Pharmacopeia (USP) medication classification system, are used by ACA plans to determine "must-cover" medications. USP MMG does not include one critical treatment option for many people with prediabetes and diabetes: anti-obesity medications (AOMs). This RFI calls out this omission and notes such omission could lead to coverage gaps for millions of ACA plan beneficiaries. The RFI also describes a newer drug classification system from U.S. Pharmacopeia (USP) called USP-DC, which does include AOMs and did not exist at the time that the original EHB guidance was written. ADCES echoes the Obesity Care Advocacy Network's support for **utilization of the United States Pharmacopeia Drug Classification (USP-DC) as the standard for determining covered drug classes within state EHB benchmark plans** to ensure coverage of AOMs in ACA plans.

Conclusion

ADCES, along with many other stakeholders within the diabetes community, stand ready to support CMS in these efforts. ADCES appreciates the opportunity to provide input to this RFI. We hope to work with CMS to support policies that will improve health equity for people living with diabetes, prediabetes, obesity, and other cardiometabolic conditions. Please contact Hannah Martin at hmartin@adces.org should you have any questions regarding ADCES' comments.

Sincerely,

Matthew Hornberger, MBA, CAE
Chief Executive Officer

Dr. Leslie E. Kolb, DrPH, RN, MBA
Chief Operating Officer