January 31, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9898-NC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Request for Information: Essential Health Benefits [CMS–9898–NC] [RIN 0938-AV14]

Dear Administrator Brooks-LaSure:

On behalf of the Diabetes Advocacy Alliance (DAA), I am writing in response to a Request for Information [CMS—9898—NC] on issues related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (the Affordable Care Act or ACA). **We appreciate the opportunity to submit comments regarding the scope of coverage of benefits in health plans subject to the EHB requirements of the ACA, and coverage of prescription drugs**.

The DAA is diverse in scope, with our 29 members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. (www.diabetesadvocacyalliance.com) The DAA advocates for the interests of three populations of people served by CMS programs: People with prediabetes; people with diabetes; and people with obesity that impacts their risk for developing diabetes or complicates the successful treatment of their diabetes. Health disparities and inequities are common in these populations.

Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic, and more recently, the epidemic of overweight and obesity. We are committed to advancing person-centered policies, equitable, practical models, and legislation that can improve the health and well-being of people with prediabetes, diabetes, and obesity-complicated diabetes. An essential component to our goal is combatting health disparities and addressing social determinants of health. Our advocacy to policymakers highlights key strategies to prevent, detect and manage diabetes and obesity and care for those people affected by these diseases. Our educational outreach also illustrates the health equity implications of existing or new policies, regulations, and legislation, and provides alternatives to address the drivers of these inequities.

1. Scope of Coverage of Benefits in Health Plans Subject to the EHB Requirements of the ACA

The DAA has comments on several items in the list of essential health benefits, as well as pointing out some omissions of critical care for people with diabetes, prediabetes, and obesity-complicated diabetes. Our overarching concern is that EHB standards are misaligned with current USPSTF A and B recommendations, and for those with diabetes, prediabetes, or with obesity (a major risk factor for development of type 2 diabetes and a complicating factor in treating most cases of type 2 diabetes), EHB policy does not reflect the standard of care that is essential for preventing and helping people control diabetes.

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." 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.

The DAA 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, the DAA suggests that the EHB policy clearly state that for those with prediabetes, the USPSTF recommended intervention and services must be covered.

Even though health care professionals know that the same tests are used to screen for type 2 diabetes and prediabetes, it would be helpful to consumers to have prediabetes listed as part of this essential health benefit. Also, the DAA notes that, in Medicare, CMS continues to decline to cover HbA1C testing for screening for type 2 diabetes and prediabetes, which continues to cause problems at the health care provider level and is a barrier to provider referral of Medicare beneficiaries to evidence-based diabetes prevention programs. The DAA asks, once again, for CMS to extend its coverage of screening tests to include coverage of the use of the HbA1C test for screening for type 2 diabetes and prediabetes and as a preventive service, since the HbA1C test is commonly used in the United States and most primary care providers prefer this test for its convenience for patients.

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 in the previous section) or adults with cardiovascular disease risk factors (November 2020), specify the provision of 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 DAA believes the EHB language of "diet counseling" is vague and insufficient instruction for health plans as to what constitutes an effective intervention as determined by

the USPSTF's extensive evidence review. The DAA 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. **The DAA believes that National DPP and MDPP programs, delivered by any recognized modality, should be listed as essential preventive health services that marketplace plans should be required to offer as preventive 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. **The DAA 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.*)

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 by the tri-caucus in 2015 that are clear as to what must be covered:

"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
- 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**." The DAA recommends that CMS modify the current vague language in the EHB for "obesity screening and counseling" to "obesity screening and provision/coverage of intensive, multicomponent behavioral interventions for those with obesity," as per the USPSTF recommendation of September 2018, linked above. The DAA believes this 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, or the National DPP or MDPP diabetes prevention programs for people with prediabetes.

DAA would also like to raise a concern about the summary of benefits and coverage (SBC) in which weight loss programs and bariatric surgery are listed as "other covered services (with exceptions)" in the Excluded Benefits section of the SBC. (See Blue Cross© Premier PPO Gold Plan SBC for 2023 as one example.) This language implies to a consumer that weight loss and metabolic surgery, the very services recommended by USPSTF and core pieces of the evidence-based standard of care for those with obesity or weight related chronic disease, are not covered. We urge CMS to carry through these EHB policy updates into its sample SBC form and to warn plans that exclusion of weight loss programs or metabolic surgery is not permitted.

Diabetes Self-Management Training

The DAA 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.

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.

The National Standards for DSMES are updated every 5 years through a collaboration between the Association of Diabetes Care & Education Specialists (ADCES) and the American Diabetes Association (ADA) (both DAA members) and are then approved by CMS; these standards exceed CMS Quality Standards. These standards are the industry recognized markers 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.

It would certainly be helpful to align EHB baseline requirements 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 Affordable Care Act (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 in fact that DSMES is an accredited service across all modalities of care, not just the in-building programs covered by Medicare Part B. However, CMS should be careful not to overwrite or preempt state benefits coverage rules that make DSMES more widely available than the Medicare-defined benefit.

There are 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 thus preventing emergency department visits and inpatient hospitalizations. 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.[1] We see disparities in access to DSMES by age, sex, race, language, geography, and the availability of DSMES providers and programs.[2] 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 barriers for both referring providers and beneficiaries.[3] The COVID-19 pandemic has further exacerbated challenges to beneficiary access to this critical service.[4]

To help address this gap in access and awareness, we recommend that EHB-benchmark plans align with the Medicare DSMT benefit as a baseline for coverage. While as noted by the National Clinical Care Commission in its January 2022 Report to Congress, there are many factors that contribute to the underutilization of the Medicare DSMT benefit,[5] consistency in the description and coverage of DSMT would "heighten consumer understanding of plan options and may facilitate consumers' abilities to make choices that better suit their needs, as intended by CMS." Further, accredited DSMES programs struggle with overly complex referral and reimbursement rules that are inconsistent across Medicare, Medicaid, and Commercial payers. Such factors impact the overall sustainability of local DSMES programs resulting in a lack of these services in certain geographic areas that have the highest prevalence of diabetes.[6] Aligning with the nationally standardized Medicare DSMT benefit would reduce friction for DSMES services getting started in areas of highest need.

In addition to aligning diabetes education services with at least the Medicare DSMT benefit, the DAA 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 accepted in 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 a national campaign starting in 2023 led by the CDC, ADA and ADCES to increase familiarity with and improve access to DSMES services and standardization across a larger number of payers would only bolster those efforts.

Medical Nutrition Therapy

[1] 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/

[2] 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/

[3] 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

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

[5] National Clinical Care Commission Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications. 77-79. 2021 Jan. https://health.gov/sites/default/files/2022-01/NCCC%20Report%20to%20Congress.pdf

[6] Youssef GA. 2019 Health Care & Education Presidential Address: It's All About Access. *Diabetes Spectrum*. American Diabetes Association. https://spectrum. diabetesjournals.org/content/diaspect/33/1/82.full.pdf

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 prescribed by a physician and furnished by a qualified provider. The most appropriate and accepted definition for qualified providers of MNT 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 have fallen through the cracks and are unable to access medically necessary nutrition 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 as consistently and explicitly detailed as that of other specialist services, such as physician specialists and physical/occupational/speech therapy services. The DAA 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 (HHS) to specifically determine whether a base benchmark plan meets the required minimum coverage of MNT and other nutrition services. The DAA and the Academy believe HHS must provide this additional guidance to states to clarify the extent of nutrition services.

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

Overweight and obesity are the key risk factors for identification of asymptomatic people with prediabetes and undiagnosed type 2 diabetes, and there is clear evidence that weight loss is associated with prevention or delay of onset of type 2 diabetes. Also, 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 Affordable Care Act (ACA) plans to

[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.

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. USP-DC did not exist at the time that the original EHB guidance was written. DAA members urge CMS to replace the current USP classification with USP-DC.

Also, the DAA would like to point out that the U.S. Office of Personnel Management (OPM), in a federal employee health benefits (FEHB) program carrier letter, dated February 17, 2022, states clearly that plans cannot exclude anti-obesity medications:

- "OPM is clarifying that FEHB Carriers are not allowed to exclude anti-obesity medications from coverage based on a benefit exclusion or a carve out. FEHB Carriers must have adequate coverage of FDA approved anti-obesity medications on the formulary to meet patient needs and must include their exception process within their proposal."

The February 17, 2022, OPM letter mentions that such discrimination has not been permitted since OPM issued a program carrier letter in 2014:

- "In 2014, OPM issued Carrier Letter 2014-04 clarifying that it is not permissible to exclude weight loss drugs from FEHB coverage on the basis that obesity is a 'lifestyle' condition and not a medical one or that obesity treatment is 'cosmetic.' The landscape of pharmaceuticals available to treat obesity continues to evolve and there are currently a variety of FDA approved medications available with different mechanisms of action. The FDA indications for anti-obesity medications reinforce that nutrition and physical activity regimens should accompany drug treatment of obesity. Treatment with anti-obesity medications is highly individualized and will depend on the individual's comorbidities, their current medication regimen, and the potential for adverse effects."

Summary

The DAA appreciates this opportunity to provide comments on the proposed rule regarding Essential Health Benefits under the ACA. In closing, we urge CMS to:

- Modify the language for the essential health benefit for screening for type 2 diabetes to align with the USPSTF revised diabetes and prediabetes screening recommendation of 2021. The DAA suggests that language be expanded to include "screening for type 2 diabetes **and prediabetes**" and that the applicable age range be modified to "35 to 70" from "40 to 70," to align with the USPSTF's 2021 recommendation. In addition, the DAA suggests that the EHB policy clearly state that, for those with prediabetes, the USPSTF recommended interventions and services must be covered.
- Add HbA1c to the EHB list of acceptable measurements for determining a diagnosis of prediabetes or diabetes.
- Modify the current vague language in the EHB for "diet counseling for adults at higher risk for chronic disease" to become: "Diet counseling via intensive, multicomponent behavioral interventions for adults with prediabetes, obesity, or overweight who are at higher risk for chronic disease."
- Modify the current vague language in the EHB for "obesity screening and counseling" to "obesity screening and provision/coverage of intensive, multicomponent behavioral

interventions for those with obesity," as per the USPSTF recommendation of September 2018. The DAA believes this 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 and the National DPP or Medicare DPP for people with prediabetes.

- For people with prediabetes at risk for type 2 diabetes, the DAA believes that National DPP and MDPP programs, delivered by any recognized modality, should be listed as essential preventive health services that marketplace plans should be required to offer as preventive services.
- Provide specific guidance to states to clarify the extent of nutrition services. The DAA supports the Academy of Nutrition and Dietetics in its belief that both health plans and consumers would benefit from greater specificity of medical nutrition therapy (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.
- Align EHB-benchmark plans with the Medicare DSMT benefit as a baseline for coverage, with reference to the fact that DSMES is an accredited service across all modalities of care and not just the in-building programs covered by Medicare.
- Encourage states to update language in plan descriptions to align with current science and practice by using the term DSMES. DSMES has been accepted in the medical community and public for over a decade. Aligning EHB plans' minimum coverage criteria with at least the level of coverage provided by the Medicare DSMT benefit and using the term DSMES as is used outside of the Medicare program, would reduce friction for DSMES services getting started in areas of highest need and would help consumers access more diabetes education services more consistently across payers.
- Recognize obesity as a complex and chronic disease and require EHB plans to cover all evidence-based treatment services under the appropriate EHB categories. 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.
- Provide guidance to state EHB plans that mirrors the OPM language to Federal Employee Health Benefit (FEHB) plans, which ensures coverage of FDA approved anti-obesity medications.
- Address the discriminatory benefit design language surrounding obesity preventative care services by modifying Medicare Model Guidelines (MMG) to use the United States Pharmacopeia (USP) USP-DC drug classification as the standard for state EHB benchmark plans to determine "must-cover" medications. Currently, 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.

We stand ready to provide more information and are available to discuss if you have any questions about our comments. Please feel free to reach out to us if we can provide further assistance. Thank you again for the opportunity to comment on this important issue.

Sincerely,

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Director of Advocacy, Association of Diabetes Care & Education Specialists
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