Promoting Efficiency and Equity within CMS Program: Request for Information
DAA Comments Were Submitted via an Online Portal on November 4, 2022.

https://www.cms.gov/request-information-make-your-voice-heard

Submitting Comments

Note: *CMS did not permit attachment of letters or other documents; instead, comments had to be submitted via an online portal. The DAA chose to comment on two sections of the CMS Request for Information (RFI), highlighted below in yellow.*

1. Accessing healthcare and related challenges
2. Understanding provider experiences
3. Advancing health equity
4. Impact of the COVID-19 public health emergency waivers and flexibilities

Section 1. Accessing healthcare and related challenges

CMS wants to empower all individuals to efficiently navigate the healthcare system and access comprehensive healthcare. We are interested in receiving public comment on personal perspectives and experiences, including narrative anecdotes, describing challenges individuals currently face in understanding, choosing, accessing, paying for, or utilizing healthcare services (including medication) across CMS programs.

Examples may include, but are not limited to:

- *Challenges accessing comprehensive and timely healthcare services and medication, including primary care, long-term care, home and community-based services, mental health and substance use disorder services.*
- *Challenges in accessing care in underserved areas, including rural areas.*
- *Receiving culturally and linguistically appropriate care (e.g., tailoring services to an individual's culture and language preferences).*
- *Challenges with health plan enrollment.*
- *Challenges of accessing reproductive health services.*
- *Challenges of accessing maternal health services.*
- *Challenges of accessing oral health services and the impact on overall health.*
- *Understanding coverage options, and/or technology to support access to coverage; and,*
- *Perspectives on how CMS can better communicate quality standards and accessibility information to individuals, particularly those with social risk factors.*

The Diabetes Advocacy Alliance (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.

People with prediabetes face many challenges in gaining access to the Medicare Diabetes Prevention Program (MDPP), including: Vastly insufficient number of suppliers available overall; lack of coverage for all modalities of program administration; lack of in-person community-based options in urban and rural areas; low awareness of the program among health care providers, which is associated with low rates of referral of CMS beneficiaries to MDPP programs; and lack of coverage for the A1C blood glucose test, which is commonly used by primary care providers to identify prediabetes and thus patients eligible for referral to the MDPP.

Currently, Medicare covers Medical Nutrition Therapy (MNT) for people with diabetes but does not cover this service for individuals with prediabetes, reducing the options that Medicare beneficiaries with prediabetes have for improving their health. MNT for individuals with prediabetes has been shown in numerous studies to decrease fasting blood glucose, body weight, blood pressure, and waist circumference for patients who received the intervention for at least 3 months.

People with diabetes face challenges in gaining access to comprehensive care and services needed to help them manage their chronic disease, long term, including lack of access to primary care providers and specialists, especially endocrinologists.

Diabetes Self-Management Training (DSMT) is underutilized for a variety of reasons that can be addressed by updating the Medicare benefit for DSMT including addressing beneficiary cost-sharing, making it easier to refer for the service, ensuring flexibilities around how the benefit is utilized, and aligning Medicare Quality Standards for DSMT with current standards of care.

Lack of primary care provider referrals to DSMT is a major reason for underutilization of these services by beneficiaries with diabetes. One study published in 2021 in the *American Journal of Managed Care* (Brown-Podgorski et al. June 2021, Volume 27, Issue 6) examined electronic health records and a statewide health information exchange database to review encounters with primary care providers (PCPs). A total of 8,782 adult patients with diabetes with a total of 356,631 encounters were included. The researchers found that while most patient encounters indicated at least one type of need for DSMT, **less than 7% of those encounters** in which there was a documented need for DSMT resulted in a provider referral.

CMS points out in its CY 2023 Medicare Physician Fee Schedule that “despite Medicare Nutrition Therapy (MNT) being endorsed by the American Diabetes Association, American College of Cardiology and the National Kidney Foundation, less than 1 percent of the estimated 14 million eligible Medicare beneficiaries have accessed MNT.” (p423). Also, in 2013, the Renal Dietetic Practice Group of the Academy of Nutrition and Dietetics surveyed its members regarding the provision of the Medicare Part B benefit to patients with non-dialysis-dependent CKD and found that only 43.9% of renal RDNs indicated they receive physician referrals for their MNT services.

People with obesity at risk for developing diabetes and people with obesity and diagnosed diabetes face challenges in accessing treatment for their obesity. Treating obesity has been shown to lower the risk of developing type 2 diabetes in people with prediabetes and reduce blood glucose, blood pressure, and cholesterol levels in people with diabetes. Yet Medicare does not currently cover anti-obesity medications (AOMs) for the treatment of obesity, even though other federal programs do offer this coverage (the Veterans Administration and Federal Employee Health Benefit Plans). We also note that the American Medical Association recognizes obesity as a disease.

CMS also has recognized that intensive behavioral therapy (IBT) is a high value service and is potentially underutilized. The goal of the Medicare IBT for Obesity benefit is to treat beneficiaries with obesity and reduce the rates of obesity comorbidities among older adults. As CMS has indicated, this benefit is not being utilized to its full potential, thus falling short of the goal. As of 2019, only 2.16% of the more than 7.6 million Medicare FFS beneficiaries with obesity received IBT for obesity. Primary care physicians (PCPs) report a variety of barriers that include limited time per clinical visit, inadequate training, lack of transparency on patient out-of-pocket costs, and reimbursement. Limiting the IBT for Obesity benefit to the primary care setting is a significant barrier.

- **(New comment box)** *Recommendations for how CMS can address these challenges through our policies and programs*.

For people with prediabetes: MNT for individuals with prediabetes has been shown in numerous studies to decrease fasting blood glucose, body weight, blood pressure, and waist circumference for patients who received the intervention for at least 3 months. CMS should add coverage for MNT for prediabetes.

With the MDPP, CMS can increase the number of MDPP providers and healthcare provider referrals and increase awareness and uptake of the underutilized MDPP benefit through these actions:

1. CMS should cover all proven-effective modes of delivery (including in-person, online, and distance learning [telehealth]) for evidence-based interventions in the MDPP that produce successful participant outcomes that meet or exceed those of the CDC's National Diabetes Prevention Program quality standards. DAA members believe that CMS has the authority under section 3021 of the Affordable Care Act (and as established by section 1115A of the Social Security Act) to expand the model test such that fully virtual programs that have met the CDCs National DPP standards can apply to become MDPP providers. Access to fully virtual programs is especially needed in urban and rural areas where no in-person MDPP sites are available, or where travel to such in-person sites is not feasible due to lack of travel options or travel expense, lost income due to missed work, and fear of COVID.

2. CMS should approve the MDPP as a permanent covered benefit regardless of delivery modality and eliminate the "once per lifetime" limit on participation. This idea in included

among the recommendations in the Biden-Harris Administration's recently released National Strategy on Hunger, Nutrition, and Health.

3. CMS should provide coverage for the A1C test without a deductible when used to screen for prediabetes. In a study reported in 2019 in the *Journal of the American Board of Family Medicine* (March 2019, 32 (2) 209-217; doi.org/10.3122/jabfm.2019.02.180259), which examined 107,000 US office visits between 2012-2015, the data showed physicians are equally likely to screen for diabetes with the A1c test as the fasting plasma glucose test. Study authors suggest lack of coverage for the A1C test is likely leading to inequities and missed opportunities for Medicare beneficiaries with prediabetes to be identified and referred to the MDPP.

4. CMS should test new payment models that allow for greater upfront payments and more equitable risk-sharing between CMS and MDPP program delivery organizations and increase payment levels to MDPP program delivery organizations to make MDPP programs financially sustainable.

5. CMS should eliminate requirements regarding submission of social security numbers and other personally identifiable information by volunteer board members of community-based nonprofit organizations, such as the YMCA of the USA, a DAA member, that apply for participation in the MDPP.

For people with diagnosed diabetes, CMS should change regulations related to Diabetes Self-Management Training (DSMT) to improve access, address inequities, and engage more people with diabetes:

1. Allow the initial 10 hours of DSMT to remain available beyond the first 12 months from diagnosis until fully utilized.
2. Allow for six additional hours (instead of two hours) of DSMT, if necessary.
3. Allow MNT and DSMT to be delivered on the same day.
4. Eliminate copays and deductibles (cost sharing) for DSMT.
5. Make it easier for providers to refer for DSMT. Allow community-based sites to provide DSMT.
6. Standardize the data collection required to simplify the process and ensure consistency across DSMT programs. CMS should ensure that all relevant partners including claims adjudicators follow a consistent approach throughout the audit and oversight processes to ensure better alignment with the purpose and scope of high-quality DSMT programs of all types and sizes.

People with obesity at risk for developing diabetes and people with obesity and diagnosed diabetes face challenges in accessing treatment for their obesity. Current CMS guidance does not permit coverage for drugs that treat obesity under Part D, on the grounds that such drugs are excluded under the Part D statute as agents "used for anorexia, weight loss, or weight gain." The DAA believes that the CMS Part D policy, which currently denies coverage of "weight loss" drugs, has the unintended effect of creating and perpetuating an unnecessary gap in

access to an important standard of care. It also ignores that obesity is now recognized as a disease where evidence-based medications may be warranted. The DAA urges CMS to change its current policy to allow the full continuum of obesity treatments for beneficiaries.

CMS has stated that intensive behavioral therapy (IBT) for obesity is an underutilized benefit. Barriers faced by PCPs include inadequate time to spend with patients and training for counseling. CMS should change its regulations to expand the IBT for obesity benefit beyond the primary care setting.

Section 4. Impact of the COVID-19 public health emergency waivers and flexibilities

(CMS wants to understand the impact of waivers and flexibilities issued during the COVID-19 PHE, such as eligibility and enrollment flexibilities, to identify what was helpful as well as any areas for improvement, including opportunities to further decrease burden and address any health disparities that may have been exacerbated by the PHE.)

Examples may include, but are not limited to:

- *Impact of COVID-19 PHE waivers and flexibilities and preparation for future health emergencies (e.g., unintended consequences, disparities) on providers, suppliers, patients, and other stakeholders.*

Preamble. The DAA notes that during the ongoing COVID-19 PHE, diabetes and obesity have emerged as significant risk factors for COVID complications, hospitalization, and death. (*Diabetes*. 2021 May;70(5):1061-1069. doi: 10.2337/db20-0671) (*Diabetes Metab Res Rev.* 2021 eb;37(2):e3377. doi: 10.1002/dmrr.3377). Other research has shown that overweight, obesity, and diabetes are associated with admittance to intensive care units, thereby increasing the risk for poor health outcomes. (*Clin Obes*. 2020 Dec;10(6):e12414. doi: 10.1111/cob.12414). These facts make it imperative that CMS make permanent the waivers and private insurance policy changes that have made telehealth services available for people with prediabetes, diabetes, or obesity and diabetes during the pandemic public health emergency (PHE). However, the current CMS waivers do not solve some ongoing issues with DSMT, diabetes prevention programs, and diabetes and obesity treatment, and these insufficiencies need to be addressed.

DAA Overall Comments. The CMS definition of "telehealth" is too narrow to support the healthcare needs of people with diabetes and prediabetes. The DAA views what is statutorily defined as "telehealth" as one component of the broader area of digital health care.

The DAA recognizes two overarching equity policy issues that affect the ability of many patients with diabetes and prediabetes to access telehealth/e-health services – the lack of universal broadband availability in rural areas and in some urban areas as well, and for those individuals

with primary internet access via Web-enable cell phones, the cost of minutes of use for telehealth appointments.

Regarding diabetes prevention: CMS waivers have allowed Medicare Diabetes Prevention Programs (MDPP) that began pre-PHE to switch to virtual group sessions for program completion. However, CMS is still requiring any new MDPP program that would start during the PHE to hold its first session in person, which was not possible in most of the U.S. due to prohibitions of in-person educational gatherings. Even where MDPP programs might now be allowed by their states and counties to begin MDPP in-person programs again, the DAA believes many if not most Medicare beneficiaries would likely not wish to attend due to being at high risk of serious COVID-19 complications. The DAA requests that CMS, on a permanent basis, make virtual MDPP programs an equal option to in-person programs for beneficiaries with prediabetes.

Regarding diabetes care: For people with diagnosed diabetes, CMS's telehealth expansion has been piecemeal regarding diabetes self-management training (DSMT). Beneficiaries can access DSMT benefits via telehealth, but only when provided by *some* health care providers in *some* practice settings. For example, any DSMT provider in an FQHC/RHC can provide DSMT via telehealth to patients in their homes. CMS has recently allowed clinical staff, like nurses and pharmacists, to provide DSMT in the hospital outpatient setting to the patient in their home; however, RNs and pharmacists are not on the list of eligible telehealth providers outside those practice settings, so a DSMT program lead by a pharmacist in a pharmacy setting would not be eligible. CMS also does not cover DSMT when provided asynchronously through a virtual DSMT program, even if the virtual program is accredited or recognized by one of the National Accrediting Organizations for DSMES.

During the COVID-19 PHE, diabetes health care providers have worked under expanded statutory and regulatory telehealth flexibilities to provide diabetes care to Medicare beneficiaries. These flexibilities have included the delivery of diabetes self-management training (DSMT), clinical diabetes management services, and services that support the use of diabetes technologies, such as continuous glucose monitoring (CGM) and insulin pumps. The telehealth flexibilities afforded during the PHE, including the ability for providers to deliver telehealth services to beneficiaries in their homes and the use of audio only communications, have helped ensure that many Medicare beneficiaries with diabetes and prediabetes receive essential support and care during this critical time. The DAA urges CMS to make these flexibilities permanent to ensure that Medicare beneficiaries with diabetes have improved access to critical services via telehealth.

The DAA also views what is statutorily defined as "telehealth" as one component of the broader area of digital healthcare. This category can include a combination of synchronous telehealth visits, remote patient monitoring, or asynchronous interaction with a healthcare professional or licensed specialist via internet-based services. To date, this mode of digital care has been applied for virtual diabetes prevention programs (DPP), as well as diabetes self-management

training (DSMT). It has also been utilized for remote monitoring of patient blood glucose and blood pressure levels, and medication management.

- **(New comment box)** *Recommendations for CMS policy and program focus areas to address health disparities, including requested waivers/flexibilities to make permanent; any unintended consequences of CMS actions during the PHE; and opportunities for CMS to reduce any health disparities that may have been exacerbated by the PHE.*

For people with prediabetes: The DAA requests that CMS, on a permanent basis, make virtual MDPP programs an equal option to in-person programs for beneficiaries with prediabetes. CMS waivers have allowed Medicare Diabetes Prevention Programs (MDPP) that began pre-PHE to switch to virtual group sessions for program completion. However, CMS is still requiring any new MDPP program that would start during the PHE to hold its first session in person, which was not possible in most of the U.S. due to prohibitions of in-person educational gatherings. Even where MDPP programs might now be allowed by their states and counties to begin MDPP in-person programs again, the DAA believes many if not most Medicare beneficiaries would likely not wish to attend due to being at high risk of serious COVID-19 complications.

Virtual-only options are also beneficial for individuals living in rural, sparsely populated areas where it can take months for enough individuals living in that area to be diagnosed with prediabetes and referred to an MDPP to amass an in-person class large enough that it's financially feasible to run. Virtual options would reduce this wait time for participants.

For people with diabetes: DSMT programs were added to the list of eligible telehealth providers temporarily during the pandemic and we request this change be made permanent. Under the current Medicare benefit for DSMT, DSMT can only be provided and reimbursed through an accredited or recognized DSMT program. These programs exist across many diverse practice settings, including hospital outpatient departments, pharmacies, provider offices, independent clinics, FQHCs, RHCs, etc.

DSMT services are furnished by different provider types across these practice settings. DSMT programs bill Medicare as an entity rather than at the individual provider level and the current regulatory and statutory telehealth flexibilities do not comprehensively address the eligibility of all DSMT providers to furnish telehealth services in all practice settings, hence the request that DSMT programs be added to the list of eligible telehealth providers at the entity level. We recognize that congressional action is required to expand the list of eligible telehealth providers and encourage CMS to work with the Secretary of HHS to ensure DSMT programs are included as the policies are finalized. We also urge CMS to consider allowing virtual only DSMT providers to deliver DSMT services to Medicare beneficiaries. This will help to expand the reach of this service to more beneficiaries.

For people with obesity and diabetes: The PHE has made the need for treatment options for patients with obesity and diabetes very clear. CMS telehealth waivers have helped increase access to medical professional for these patients and the DAA recommends these waivers be

made permanent. However, current CMS guidance does not permit coverage for drugs that treat obesity under Part D, on the grounds that such drugs are excluded under the Part D statute as agents "used for anorexia, weight loss, or weight gain." The DAA believes that the CMS Part D policy, which currently denies coverage of "weight loss" drugs, has the unintended effect of creating and perpetuating an unnecessary gap in access to an important standard of care. It also ignores that obesity is now recognized as a disease where evidence-based medications may be warranted. The DAA urges CMS to change its current policy to allow the full continuum of obesity treatments for beneficiaries.

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