June 16, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: File Code: CMS-0042-NC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Request for Information (RFI); Health Technology Ecosystem

On behalf of the Diabetes Advocacy Alliance (DAA), we appreciate this opportunity to provide information in response to this RFI on the health technology ecosystem. DAA members believe that diabetes prevention and care should be core elements of this administration's efforts to combat chronic disease and are more critical than ever before, as approximately 136 million American adults[1] are now living with either prediabetes (97.6 million) or diabetes (38.4 million), and diabetes-related costs are currently $413 billion per year.[2]

This RFI calls for input on how CMS and ASTP/ONC "can help achieve the potential of digital health technology, and feedback on which elements of today's digital health ecosystem are working, which are working inconsistently and need improvement, and which are impeding rapid progress." **One challenge that needs addressing involves Medicare beneficiary access to fully digital diabetes prevention programs.**

The Medicare Diabetes Prevention Program (MDPP) is an evidence-based behavior change prevention program that can support Medicare beneficiaries in making changes to their daily eating and levels of physical activity, with a goal of achieving quantified weight loss targets. Research shows that even modest weight loss of 3-5 percent can prevent the development of type 2 diabetes or substantially slow down the progression of prediabetes to diabetes.[3] This benefit can also save money: for example, the MDPP Pilot saved $2,650 in Medicare expenditures over 15 months for each senior who completed the program.[4]

Currently, MDPP regulations do not allow organizations that provide fully virtual-only, evidence-based diabetes prevention programs to participate in the MDPP. CMS's most recent updates to the MDPP rules allowed in-person suppliers to add distance-learning virtual programs, and this may have slightly increased the availability of MDPP. However,

CDC fully recognized suppliers that are only virtual are not allowed at all to register as Medicare suppliers. This limitation suppresses the supply of MDPP. Fully virtual providers could drastically increase access to the MDPP services, especially in rural and other communities that presently lack suppliers of MDPP in-person services.

There are many organizations that could apply to be program providers of the MDPP, but do not do so, because Medicare's requirements for the MDPP are different from and harder to implement than those of the CDC's National Diabetes Prevention Program (National DPP). This lack of alignment means MDPP providers are subject to many different rules and regulations, often requiring differing internal accounting and reporting systems.

In addition to the barrier in Medicare to covering virtual MDPP, other challenges include:

- The MDPP is not aligned with the National DPP on risk-reduction metrics. To reduce burden on both suppliers and beneficiaries, the MDPP should align with National DPP metrics, which include not only weight-reduction measures, but also include measuring participant's physical activity minutes and hemoglobin A1C reduction.
- Current CMS regulations require nonprofit and charitable organizations to provide the Social Security numbers of all members of their Boards of Directors, which stops many such groups from applying to be Medicare providers.
- Travel to and from in-person facilities is difficult for many older adults, yet MDPP regulations prohibit participant make-up sessions delivered by fully virtual means, a modality that would ease provider and participant burden. As mentioned earlier, delivery of MDPP via fully virtual communication modes (such as laptops, tablets, and apps on smartphones) would also ease in-person participation challenges for beneficiaries by providing options for those who prefer these modes or are unable otherwise to attend in-person programs.
- With in-person MDPP programs, beneficiaries are weighed on on-site scales. However, because MDPP is limited to in-building programs for the most part, participants currently cannot report their weight to their program coaches via digital apps or scales, although these are allowed in CDC fully recognized programs. Allowing the use of digital apps or scales for the purpose of reporting weight changes to MDPP coaches would remove another barrier to this important program and bring this program further in-line with the use of mainstream digital health products.

Diabetes Self-Management Training and Diabetes Devices

Many Medicare beneficiaries living with diabetes will need education on how to use new and innovative diabetes technologies while others will not, either because they are technologically savvy or because they have used innovative diabetes technologies before enrolling in Medicare. In any event, **all** beneficiaries living with diabetes will benefit from (1) improving the diabetes self-management training (DSMT) benefit; and (2) ensuring

beneficiaries can access educational resources for automated insulin delivery (AID) systems and insulin pumps.

DSMT is a proven and effective intervention that teaches individuals how to use diabetes technologies, administer medications, and implement healthy lifestyle changes that allow them to better manage their diabetes. Accordingly, the American Diabetes Association (ADA), in its 2025 Standards of Care[5], recommends that "all individuals with diabetes should be advised to participate in developmentally and culturally appropriate diabetes self-management education and support (DSMES)." (*Note: DSMES is now the preferred term of diabetes educators, and in practice, is synonymous with DSMT.*) Given the demonstrated effectiveness of this intervention, any unnecessary barriers to DSMT must be removed.

Individuals continue to face numerous barriers in accessing DSMT care, which in turn can hinder access to diabetes technologies, as individuals often rely on DSMT in the set-up and training to use these technologies. First, we wish to re-emphasize that diabetes is a highly personalized disease and that expanded access to a wide array of diabetes care is necessary not just for technologies, but also for diabetes education. However, regulations place rigid requirements on DSMT, such as requiring that the overwhelming majority of the initial DSMT benefit be given in a group setting in a building, disallowing DSMT and medical nutrition therapy (MNT) to be delivered on the same day, and capping initial trainings at up to ten hours of DSMT within a continuous 12-month period and in subsequent years, receive up to two hours of DSMT.

These requirements fail to provide the needed flexibility that should be afforded to individuals with diabetes, considering that some individuals might benefit from receiving their DSMT in a different modality (i.e., a more personalized experience, via such modes as synchronous video sessions, or via virtual/ asynchronous programs, so long as these types of other modalities meet statutory standards for quality, specified in 42 USC 1395x(1395 x[s)] and (qq))),[g,g]). Individuals living with diabetes also might need more hours of DSMT throughout their lives to manage this lifelong disease.

Additionally, CMS's requirements on referral orders for DSMT (which require the provider to provide onerous details and duplicative information) and on program accreditation (which imposes administrative burdens that prevent new DSMT providers and existing programs to grow) create unnecessary barriers to accessing the DSMT benefit. We urge CMS to provide as much flexibility as possible to ensure all individuals can receive DSMT in the modality and at the frequency that both the beneficiary and their provider agree is best for the beneficiary's needs.

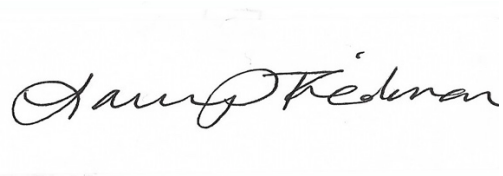
Additionally, while there is a payment mechanism for continuous glucose monitoring (CGM) set-up and training, there is no separate acknowledgement or reimbursement for providers who perform insulin pump set-up and training. Thus, individuals with diabetes must use their limited and front-loaded DSMT hours to obtain insulin pump training or

providers must furnish this training without reimbursement. Without proper education on these technologies, beneficiary interest in these products could remain stagnant thereby suppressing beneficiary access to diabetes technologies. Therefore, DAA urges the agency to ensure that DSMT and other diabetes care and education services are as flexible as necessary to support a wide array of diabetes-related training and educational services spanning the multiple technologies available today and in the future.

Finally, to make DSMT truly accessible and appropriately used to address all forms of diabetes, especially given the epidemic of type 2 diabetes, CMS should consider whether the coinsurance that is currently required by statute is a barrier to self-management of diabetes.

We appreciate this opportunity to provide comments, as we believe adding a fully virtual option to the MDPP would greatly benefit Medicare beneficiaries, as well as making changes to DSMT rules that we mentioned above. We would welcome the opportunity to speak with CMS and ASTP/ONC leadership about how improving Medicare's MDPP and DSMT benefits is critical to making America healthier. DAA Co-Chairs can help facilitate scheduling meetings: Katie Adamson, YMCA of the USA (katie.adamson@ymca.net) or Laura Friedman, American Diabetes Association (lfriedman@diabetes.org).

Sincerely,



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References:

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[2]https://diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetes-in-the-U-S-in-2022
[3]https://www.nejm.org/doi/full/10.1056/NEJMoa012512
[4]https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf
[5]https://diabetesjournals.org/care/issue/48/Supplement_1