February 13, 2024

Jeffrey M. Zirger
Lead, Information Collection Review Office
Office of Public Health Ethics and Regulations
Office of Science
Centers for Disease Control and Prevention.
1600 Clifton Road NE, MS H21–8
Atlanta, Georgia 30329.

RE: Docket No. CDC–2023– 0096

Dear Mr. Zirger:

The undersigned members of the Diabetes Advocacy Alliance (DAA) appreciate the opportunity to comment on the Centers for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP) – Revision.

Founded in 2010, the DAA is a coalition of 29 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way prediabetes, diabetes, and obesity are viewed and treated in America. DAA members work to increase awareness of, and action on, the epidemics of diabetes and obesity, and improved access to diabetes prevention services and diabetes and obesity treatments and care. The organizations that comprise the DAA share a common goal of elevating prediabetes, diabetes, and obesity on the national agenda.

The undersigned members of the DAA offer the following recommendations based on the collective experiences of several DAA members that offer in-person, distance learning, and fully virtual diabetes prevention programs. We aim to provide you with the following practical feedback meant to help improve the delivery and evaluation of these programs that are so critical to helping prevent or delay the onset of new cases of type 2 diabetes among at-risk adults in the U.S., including changes we support and areas we believe the CDC should review and address in final 2024 DPRP Standards and Operating Procedures.

I. Changes to the 2021 DPRP Standards We Support

DPRP Application Form

The undersigned members of the DAA generally support the changes described for the DPRP Application Form. One change stands out as especially important: allowing organizations that serve populations in

areas that are designated as having high social vulnerability to be fast tracked to preliminary CDC recognition status, and permitting them, if desired, to immediately apply for MDPP status and bill for services that they provide to Medicare beneficiaries. The need for more suppliers of National DPP LCP and MDPP programs is enormous, to serve more of the 98 million U.S. adults with prediabetes, and more suppliers of the MDPP are desperately needed to improve the chances for success of the MDPP model test. A successful model test will enhance the chances of making the MDPP a permanent benefit to serve the 27 million people with prediabetes aged 65 and older.

Requirements for Pending, Preliminary, Full, and Full Plus Recognition

We appreciate and support the new fast-track to Preliminary recognition for suppliers that serve populations in counties designated as high vulnerability according to the Social Vulnerability Index. This new path to recognition should appeal to organizations in these counties where the need for National Diabetes Prevention Program Lifestyle Change Program (National DPP LCP) and Medicare Diabetes Prevention Program (MDPP) suppliers is high. The provision that allows for a path to being able to invoice the Centers for Medicare & Medicaid Services (CMS) immediately should be especially attractive to nonprofit and other community-based organizations in these counties that are considering applying to become a National DPP LCP supplier, thereby expanding the number of suppliers and reach of the program to more individuals.

We also support CDC's proposal to update the DPRP standards with additional evidence-based options for suppliers to achieve full recognition. We question the need for the full plus category of recognition, especially since full plus designation lasts only until the next data submission. If National DPP LCP and/or MDPP suppliers wanted to integrate full plus status into their communication and marketing materials, they would want to know that such designation would last for a longer, defined time, before investing in changes to their marketing. We recommend that CDC either grant full plus recognition for an additional two years or eliminate it as a distinct recognition category.

Language Clarifications

We support proposed language additions intended to provide needed clarity pertaining to recognition requirements and participant eligibility criteria. Specifically, the new language in outcome #2: a combination of a loss of 4% of baseline body weight and at least 8 sessions associated with an average of 150 minutes/week of physical activity, and outcome #3: a combination of a loss of 4% of baseline body weight and at least 17 sessions attended.

Likewise, we appreciate and support additional language that clarifies that participants who develop type 2 diabetes during a National DPP LCP may continue in the program and acknowledge that data on these participants are not to be submitted for purposes of program evaluation. We also support the additional language that clarifies that family members, friends, caregivers, and others offering support for participants may participate in class sessions, at the discretion of the CDC-recognized program.

Participant Safety and Data Privacy

We appreciate and support the additional sentences in the 2024 draft standards that describe how CDC keeps participant data private and safe and unavailable to the public. Participant data privacy is critical to participant trust in specific prevention program staff and processes and to the likelihood of participants

recommending their prevention programs to family members and friends. Data privacy is also critical to compliance with federal and state privacy laws.

Recognition Extensions and Exceptions to Data Submission Requirements

We appreciate that CMS has added examples of what would constitute valid reasons for requesting an extension or exception to data submission requirements, which will help to provide needed clarity for suppliers and reduce the need to clarify on a case-by-case basis, reducing burden on participants and CDC staff.

II. Changes that Could Pose Barriers to National DPP LCP and MDPP Participation

The undersigned members of the DAA believe the following proposed changes to the 2021 DPRP Standards could pose significant barriers for some program suppliers and may impede participation by adults with prediabetes in their programs. **We strongly recommend, in the comments below, that CDC conduct research to assess the impact on program participants and suppliers of the proposed changes to the intake form, before rolling out the proposed modifications.**

Adding HRSN and Disability Questions to Participant Intake Form

We recognize and support CDC's desire and need to collect information to assess participants' disability status/needs and health-related social needs (HRSN), as such information could be useful in addressing health inequities. Likewise, we support and recognize the importance of collecting data to determine disparities between disabled and nondisabled populations, as doing so could be valuable from a research perspective and could contribute to improved program tailoring for individuals with certain disabilities in the future. Gaining insight in these areas could help National DPP LCP suppliers better understand the diverse needs of their participants and adjust their program processes to better serve participants. We agree with CDC that collecting HRSN information is important to efforts to reduce health disparities, and indeed some program suppliers do provide social service navigation services, such as One Degree. However, there are some important considerations to address before moving forward with adding these questions to the intake form.

To start, given the sensitive nature of these questions, adding them will deter program enrollment. At-risk participants may experience survey fatigue or be turned off by the volume of questions. Others may not wish to answer the new questions due to concerns about privacy. Participants with disabilities and/or social needs may be those individuals most likely to not complete the intake form with the additional new questions.

One major concern is whether participants who are willing to answer HRSN questions will then expect programs to help participants address their HRSN needs. **We believe that assessment on its own without action will be ineffective and that CDC should have suppliers collect this information only if the data will be acted upon** (e.g., a referral made). National DPP LCP and MDPP suppliers would need more resources to deploy interventions to overcome HRSN-related barriers to participation in the program. If CDC is asking supplier organizations to serve as navigators or case managers, suppliers would need to be compensated for this work which is not part of current typical DPP reimbursement methods and is not reimbursed by Medicare for MDPP.

Importantly, these benefits or additional resources must outweigh the increase in burden that would result from the lengthened Participant Intake Form to maintain suppliers in the program. Updating data collection software with additional fields can be a costly and cumbersome process, especially when so many DPPs are small, community-based organizations. For some National DPP LCP and MDPP suppliers, formally documenting HRSN risks in their clinical records brings new sensitive data into those records. Such data are often subject to special rules under federal and state law, for instance when individuals indicate that they have a substance use disorder or have experienced intimate partner violence.

Unless they already manage such information through other programs, suppliers, especially small or community-based organizations, may end up having significant new compliance burdens if they collect this information. Moreover, due to the sensitive nature of these questions, if they are asked outside of a context of established trust, they will turn people off from participating.

Some of the undersigned members of the DAA are National DPP LCP and/or MDPP suppliers with direct, relevant experience in the program. We leverage this collective experience to suggest that the CDC make the following recommended changes *before* proceeding to add additional questions related to HRSN and disabilities during participant enrollment:

- **Review current literature and determine impact on program enrollment considering CDC's goals.**
- **Weigh the impact in terms of supplier burden.**
- **Use already collected data from other agencies such as CMS or directly from vendors or proxies (e.g., zip code) rather than requiring additional, duplicative data collection from program suppliers to** minimize both patient and supplier burden, as well as the risk of the data being compromised.
- **Survey a random sample of suppliers from all five modalities identified in the 2024 standards.** This survey would have two purposes: To assess the impact (structural and financial) of a longer Patient Intake Form, and to ask suppliers when, in the onboarding of new program participants, the best time to collect such data might be.
- **Review how to implement data collection post-enrollment (rather than prior to the first session).** We **recommend CDC study how** collecting **a more limited set of data/**information after participants have enrolled, have trust in the process, and are experiencing the benefits of their diabetes prevention program **could meet CDC objectives** while promoting more accurate data collection.
- **Highlight HRSN and disability screenings as best practice for organizations able to directly address participant needs and consider incentivizing through direct reimbursement or additional resources, but do not require them currently so as not to further dissuade smaller, non-profit community-based organizations from participating in the program.**
- **Start by focusing on high-priority domains.** This focus would allow policymakers and stakeholders to advance collection of HRSN data in the highest-impact areas while further studying the positive benefits from the data collection relative to the associated increase in supplier reporting burden.
- **Assess how CDC could incorporate standardized, validated and consensus-driven data elements so data can be collected in a consistent, comparable fashion to be proposed in potential future requirements.** Standardization would allow data to be easily utilized across HHS programs to benefit the participant/patient while minimizing burden, and to regularly

update collection criteria as more information on how to optimize HRSN data collection becomes available.

- **Consider reframing disability questions:** We refer you to this journal article entitled "Rethinking and Updating Demographic Questions: Guidance to Improve Descriptions of Research Samples." We ask that you consider Figure 8 on page 143 of this article, as we find the researchers' question to be potentially simpler, preferable to program participants, and could provide more useful feedback: "Do you have a long-lasting or chronic condition (physical, visual, auditory, cognitive, or mental, emotional, or other) that substantially limits one or more of your major life activities (your ability to see, hear, or speak; to learn, remember, or concentrate)?" Respondents can select "yes," "no," or "prefer not to answer." Follow-up question: "If yes, please indicate the terms that best describe the condition(s) you experience." Respondent fills in or checks "I prefer not to answer."
- **Allow participants to opt-in to being screened** (and be able to subsequently revoke their opt-in).
- **Ensure participants understand the possible social risks that the given screener may detect** (e.g., transportation insecurity, homelessness, victim of domestic abuse, etc.).
- **Inform participants of how their data will be used and stored.**

Online Supplier Requirements

Several of the undersigned DAA member organizations are CDC-recognized online providers of diabetes prevention programs. We have noticed that there are several program delivery requirements in the proposed 2024 standards that apply only to online program providers. The undersigned members of the DAA do not understand why they are being added, or if CDC deems them necessary, why they do not apply to all program suppliers equally.

First, CDC does not cite evidence in the proposed standards that fully recognized, online National DPP LCPs are NOT delivering curriculum content that is comparable to that of in-person programs. Before CDC finalizes any such online-supplier-only specific requirements, we believe that in the interest of transparency, it is vital that CDC provide evidence for imposing new requirements on a subset of program suppliers.

Second, we point out that CDC does receive an attestation from each program, including online programs, subject to federal enforcement for truthfulness. If CDC believes these new program delivery requirements are necessary, then we believe they should be applied to and required of all National DPP LCP suppliers, inclusive of all modalities.

Organizations providing services through online delivery modes should not be held to a different standard than in-person programs. For example, in the following sentences, CDC is requiring proactive outreach only for online programs: *Live Lifestyle Coach interaction is required and should be offered to each participant no less than once per week during the first six months of the program and once per month during the second six months. E-mails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication (i.e., organizations may not simply send out an announcement via text or e-mail and count that as live coach interaction; the participant must have the ability to respond to and get support from the live coach).*" In contrast, an in-person or distance learning program could have live interaction in class but is not required to reach out separately

to a participant who was quiet during or absent from a class.

If CDC believes an applicable proactive outreach minimum is needed, then CDC should make this minimum requirement apply to all program modalities. To achieve the intended goal of increasing active participation in the program, we believe it would be more effective to require all suppliers, regardless of modality, to proactively make participants aware at the start of the course of tools or opportunities through which individuals may request access to coaches, including but not limited to messaging software, email, or regular in-person or virtual office hours.

We believe the current proposed policy of emailing participants weekly will not increase their desire to request one-on-one coaching. Rather, it could be viewed as a nuisance and incentivize them to drop from the program or cause other important messages about the program to get lost. In addition to being more effective, we believe the approach described in the paragraph immediately above will reduce supplier burden and avoid reductions in supplier participation in the program. Importantly, applying this less burdensome standard universally across all suppliers regardless of modality would achieve more widespread positive changes and reach more participating individuals than the originally proposed policy, and promote consistent application of high caliber requirements across suppliers.

In addition, the undersigned members of the DAA support the new language that Artificial Intelligence (AI) or Machine Learning (ML) do not replace the valuable coaching that a human Lifestyle Coach provides, and we believe this requirement should apply to all programs, regardless of modality, to ensure these critical patient protections apply universally to all program participants.

The CDC also proposes coach tracking of lesson completion and proactive reminders to do activities between sessions for online programs only. We again argue that all programs should be held to the same standards for tracking lesson completion and reminding people to do their work between sessions. For example, the standard could instead reflect language like the following: *Programs must keep coaches apprised of participant engagement and completion of their lessons whether online, in distance learning, or in person. Programs must remind participants to complete their tasks in a manner consistent with the modality of care and schedule of coursework. An in-person program would therefore remind people at the next class, or, if it has the technical capability, send between session reminders email or SMS. A distance learning or online program may send reminders automatically. Reminders of this type when sent automatically do not count towards substantive interaction between a coach and a member as otherwise specified in the Guidelines.*

CDC proposes that Online Programs (only) must also be able to confirm accuracy of activity minutes that are self-reported. DAA online National DPP LCP providers are interpreting this to mean that **o**ther non-online programs can record self-reported exercise minutes. If activity minutes are suspect when self-reported, **they are suspect in all programs** and any confirmation requirement should apply to all programs. But again, before advancing with additional requirements on suppliers that would increase burden, we would require CDC to first provide evidence of inaccuracy or continue to rely on its attestation process for all suppliers.

Recording Weight to the Nearest Tenth of a Pound

We are concerned with the addition of tenth of a pound in this evaluation element: “Each time a participant attends a session, his or her body weight should be measured and recorded to the nearest whole tenth of a pound.” We know that recording weight to the nearest whole tenth of a pound will not

be possible for some participants and suppliers, who may not have access to or be using a digital scale. We propose this edit to your sentence: “Each time a participant attends a session, his or her body weight should be measured and recorded to the nearest whole tenth of a pound **if using a digital scale, or to the nearest pound if using an analog scale**.”

Delivery Mode Codes

We appreciate and support the changes made to the categorization of delivery mode #3, in-person with a distance learning component, #4, online (non-live), and #5, combination with an online component. These categories reflect the way National DPP LCP programs are commonly being delivered at the session level, and they give suppliers more flexibility for program delivery, allowing these programs to reach more participants. However, because we are capturing delivery mode at the session level via DMODE, we see it as an unnecessary burden to separate data for delivery mode at the organizational level. **We recommend that this organizational level requirement be removed**.

Full Recognition Requirements

We note that the proposed 2024 standards have changed the required number of program completers from five to 10 eligible participants. The YMCA of the USA, a DAA member organization, knows that several Y’s would drop out of analysis with a threshold set at 10 eligible participants. We recommend lowering the requirement to 6 completers to promote expanded reach of the program and allow suppliers time to ramp up participation in newer programs. As an alternative, CDC could instead consider offering additional resources to suppliers with lower participation rates to boost participation, particularly those serving underserved populations or geographic areas.

Make-Up Sessions

We appreciate the additional clarity added to the 2024 Standards in the new language that appears in the Make-Up Session section. However, we wish to point out that make-up sessions, whether they be individual or small group, are, in practice, usually much shorter than a regular session, because the large group format takes more time to facilitate the same material. Additionally, we urge CDC to work with CMMI/CMS to bring consistency to how makeup sessions can be coded.

There is also a change in how reporting of physical activity minutes is done for a makeup session which is more complicated than what was stated in the 2021 standards. We recommend reverting to the 2021 language*: "If a participant attends a make-up session for a session that has not yet been held, it is up to the discretion of the Lifestyle Coach as to which week the minutes should represent."*

DPRP and MDPP Alignment

Also, as DAA members have mentioned previously in other letters and comments, we strongly urge CDC and CMMI/CMS to work together to align the allowable delivery modes for the MDPP with that of CDC’s DPRP to promote consistency between the two programs and expand access to these critical services for more Medicare beneficiaries, particularly those living in rural and underserved areas.

In Conclusion

We thank you CDC for the opportunity to provide comments on your draft version of the 2024 DPRP Standards. We remain fervent supporters of the National DPP LCP and MDPP, and we look forward to continuing to work with you and others at CDC and CMMI/CMS to continue to refine and improve diabetes prevention programs.

Sincerely,

The undersigned members of the Diabetes Advocacy Alliance

American Medical Association
Association of Diabetes Care & Education Specialists
Black Women's Health Imperative
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Noom, Inc.
Omada Health, Inc.
Teladoc Health, Inc.
WeightWatchers