September 14, 2020

Mr. Jeffrey Zirger

Information Collection Review Office

Centers for Disease Control and Prevention

1600 Clifton Road NE, MS-D74

Atlanta, Georgia 30329.

Dear Mr. Zirger:

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to offer comments related to the *Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operating Procedures (DPRP Standards).*

The DAA is a coalition of 25 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes.

The DAA offers its recommendations based on the collective experiences of a number of DAA members that offer in-person and fully virtual diabetes prevention programs, and aims to provide 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. The DAA has identified several issues that we believe the CDC should review and address before final DPRP Standards and Operating Procedures are issued.

**Health Equity Lens**

In the past six months, we have seen firsthand the tragic outcome of racial health disparities in our country. According to CDC's own data, African Americans and Latinos in the United States are three times as likely to contract COVID-19 and twice as likely to

die from the disease. The COVID-19 pandemic has highlighted a pre-pandemic reality that those of us working with prediabetes, diabetes, and other cardiometabolic conditions know only too well. The pandemic has also reinforced the urgent need to confront our country's legacy of structural racism, as well as the role of social determinants of health on individual health, well-being, and longevity whether we are talking about a novel coronavirus or a chronic disease like diabetes. Going forward, in the work we do collectively as the DAA, we are committed to considering health equity as a lens through which we can view and shape our efforts and activities to improve the health of people with diabetes and those with prediabetes. As such, in reviewing the DPRP proposed standards, we have considered improvements to the DPRP and the National DPP that could help address health inequities.

**Program Equity, Data Documentation and Incentives to Serve Wider Ranges of Populations**

There are components of the proposed DPRP standards that add unnecessary complexity to National DPP processes and procedures. These components can make it more difficult for some National DPP provider organizations to serve populations disproportionately affected by prediabetes and diabetes and therefore can contribute to furthering health inequities.

**Recognition Criteria**

Weight loss

Approximately two-thirds of National DPP participants do NOT achieve 5% weight loss. An independent analysis of National DPP data by Ely et al[1] found that overall – even with median attendance of 14 sessions – only 35.5% of National DPP participants achieved the 5% weight loss goal, with average weight loss of 4.2% and median weight loss of 3.1%. Coupled with consistent findings that even small amounts of weight loss reduce risk of developing Type 2 Diabetes, the DAA believes the evidence supports revision of the 5% weight loss goal as a program outcome measure. We note that alteration of the 5% weight loss goal would also help reduce health inequities, since the original DPP clinical trial and other studies consistently find that some high risk populations (such as Black women) do not achieve the 5% target even with the same levels of participation.[2]

It would seem that CDC agrees, given that CDC has proposed an alternate outcome measure of a 4% weight loss goal, coupled with 150 minutes of weekly physical activity. However, the CDC has not provided any citations of evidence to support a 4% weight loss coupled with 150 minutes of weekly physical activity goal. If there is evidence to support this alternate outcome measure, the DAA would appreciate CDC sharing these data. From the practical perspective of the DAA's DPP providers, a 4% weight loss goal is a more realistic outcome measure. The 4% weight loss is also a more equitable goal,

given that some high-risk population members, compared with white populations, do not achieve 5% weight loss in National DPP programs.[1] The lower weight loss goal also would be more of an incentive for many National DPP providers to offer a program.

Weight loss and physical activity

The DAA questions coupling this 4% weight loss goal with a goal of 150 minutes of weekly physical activity. While the DAA commends CDC's willingness to look beyond weight loss for metrics as an indicator of program success and participant risk reduction, as CDC well knows, weight loss is the dominant predictor of reduced type 2 diabetes incidence[2,3], with every 2.2 pounds of weight loss yielding a 16% reduction in risk, and that meeting physical activity goals, even in the absence of meeting the weight loss goal, results in a 44% lower type 2 diabetes incidence. However, the research group noted in its conclusions that "in the ILS group, we found no independent effects of increased physical activity or decreased percent fat on diabetes risk after adjustment for weight change when analyzed as continuous variables. This suggests that self-reported changes in physical activity or fat intake did not lead to additional reductions in diabetes risk after accounting for weight loss."[3] Physical activity remains important to weight loss maintenance, but weight loss is critical to type 2 diabetes risk reduction.

Weight loss, largely determined by changes in diet and exercise, is the primary factor resulting in reduced diabetes incidence among those in the ILS group. An increase in physical activity helps sustain weight loss and in- dependently reduces diabetes risk among those who do not lose weight. Interventions to reduce the incidence of diabetes should aim at weight loss

In summary, the DAA believes there is sufficient evidence to lower the weight loss objective from 5%, to a target of 4% or even less, because weight loss at these percentage levels reduces the risk of developing type 2 diabetes. In addition, lower weight loss targets can provide incentives to National DPP program providers that serve populations that struggle to achieve the 5% weight loss threshold. As observed by Delahanty et al in analysis of data from the original DPP clinical trial, every kilogram of weight loss in the first 6 months of the trial corresponded with a 6% reduction in risk of diabetes.[4]

HbA1c

The DAA supports CDC's proposed use of HbA1c as an outcome measurement, but we have a few concerns that require some technical clarification of this outcome measure. First, what evidence demonstrates that a reduction of 0.3 in HbA1c is significant reduction for an adult with A1c in the prediabetic range of 5.7-6.4? The DAA would appreciate the CDC sharing these data. Second, the DAA asks the CDC to reconsider the requirement that HbA1C be reported at the first program session. By providing flexibility to sites, CDC would allow for a new HbA1C test to be administered between the first

session and the fourth session. That data would serve as a more accurate baseline than an HbA1C test administered 6-9 months prior to the program. We agree that a final HbA1C should be administered between months 10-12 and recorded in the participant's final session.

The DAA asks the CDC to provide additional information to better understand how using HbA1c as an outcome measure would work on a day-to-day basis:

- Is self-reported data by participants acceptable? Or does the HbA1c value need to come from a lab source?
- Would all program participants in a provider's program need to use HbA1c data, or would CDC accept a hybrid model of HbA1c and weight data? If so, what would these requirements be?

The DAA urges CDC to work with CMS to achieve consistency between the National DPP and Medicare DPP program standards in how HbA1c is to be reported.

**Unintended Consequences: Do Proposed Standards Provide an Incentive to Stay in Preliminary Recognition?**

The proposed standards note that organizations that do not achieve the standards for full recognition at the 36-month mark will lose status and will need to wait six months before reapplying. The DAA urges CDC to reconsider this stance given that organizations can maintain preliminary status indefinitely and that preliminary may be the only status required for certain health plan coverage of the program.

Because organizations may remain at pending or preliminary status indefinitely, if data are submitted to CDC, DAA finds it counterintuitive that while, on one hand, organizations at full recognition would completely lose recognition, and be asked to leave the DPRP for six months, if they do not achieve the requirements of full recognition, yet on the other hand, providers that are in preliminary recognition status can keep providing services. The DAA points out that National DPP providers may thus have a perverse incentive to remain forever in preliminary recognition status, as there is no additional benefit to full recognition. (Since the MDPP requires full recognition status, this incentive would not apply to program providers that serve both National DPP and MDPP participants.)

This situation may also encourage sites to pick or drop participants to avoid outreach to priority populations with greater challenges in achieving risk reduction markers or physical activity goals due to racial inequity or social determinants of health. Thus, in response, the DAA recommends that fully recognized organizations that fail to achieve the reduction of risk markers be placed in *preliminary recognition* while those who fail to achieve attendance and retention markers be placed in *pending recognition*.

**Umbrella Arrangements**

The DAA has questions related to the section on Umbrella Arrangements:

- The proposed standards mention the following: "Single evaluation of cross-subsidiary aggregated participant data." Would this requirement be a disincentive for umbrella organizations, if many of their subsidiaries could lose their recognition status because one subsidiary is struggling?
- Do those subsidiaries have any recourse? Or does the umbrella organization have any recourse or options for how it would problem-solve with struggling subsidiaries? Should new subsidiaries be given time to acclimate before their data are included in the aggregated analysis?

**Coach Training and Participant Outcomes**

The proposed standards call for linking Coach ID to program evaluation data, to further assess performance. Many programs are facilitated by more than one lifestyle coach and may also have turnover in staff. Although it may be ideal for one lifestyle coach to facilitate the entire year long program, that is not always the reality and basing the success of an individual participant or cohort on the lifestyle coach may not be appropriate. This requirement would add unnecessary burden for some DAA program providers, and the DAA recommends that this requirement be eliminated.

Regarding CDC's notation that the collection of additional organizational information from applicant organizations in order to assess coach performance is an internal responsibility, the CDC states that this will allow CDC to link the Coach ID to evaluation data to further assess performance. However, this does not provide full insight as to what goes into each coach-to-participant interaction. It is important to consider, as a major part of the formula, valuable baseline information for each coach, including where coaches received their education, training and experiences before being trained as a lifestyle coach. From the participant perspective, the participant may or may not have spent one-on-one time with the coach, asked questions, viewed supportive materials, and participated in a specific number of lessons. Will all of this be measured as well?

We understand the proposal to enable the CDC to ensure coaches are trained by a CDC-approved training entity. However, this is already a requirement that is not currently being measured. It makes sense to track this requirement, but it does not seem

appropriate to tie this requirement for coach training, to participant outcomes, per comments stated above.

Regarding the collection of class cohort-level information, this proposed standard would allow the CDC to evaluate outcomes by annual participant cohorts, yet it would remove the individuality of the program participants. There could be participants who do extremely well, and those that do not. This would remove the individual's accomplishments, as well as skew the individual's needs for extra support. We believe the individual outcomes are a vital part of the evaluation statistics, versus the group outcomes.

Regarding the collection of Coach Identifiers by class cohort, the DAA believes that allowing the CDC to link Coach ID to evaluation data is not a fair assessment of cohort performance for quality improvement. Again, placing the data fully on the Coach "characteristics" (defined as place trained and type of training received) is not a true measurement of cohort performance. This places the cohort outcomes fully on the coach, without taking population, culture, socioeconomic status, and any other factors into account. The intensity of desired data surrounding the singular coach and training entity evaluation does not seem appropriate or accurate, to the coach, participants and programs.

**Interaction with Coaches**

**On Page 6, Section II.D.2, this content appears: "***Live Lifestyle Coach interaction is required and should be offered to each participant no less than once per week during the first six months and once per month during the second six months. Emails and text messages do not count as live interaction, but are appropriate for session content reminders, encouragement, weight collection where an automated system (such as a Bluetooth scale) is not available, and/or other logistical information."*

The DAA assumes that this new content is not intended to create problems for currently-approved National DPP providers. However, this language still concerns us, and we seek clarification and certainty that our current providers can continue operating successfully as they have to date in regard this area of participant-coach interactions. The DAA believes that emails, text messages, and "click to chat" sessions that are unique messages created by the coach (and not automated message reminders or chat bots), and are part of behavior change and behavior reinforcement communications between a coach and a participant, are legitimate participant-coach interactions. The DAA also views this issue as one of equity – National DPP providers need to meet the needs of National DPP participants, and need flexibility in how they meet the communication needs of participants. We seek clarification that DAA member providers that are currently recognized by the DPRP can continue to operate as they have in the past in terms of participant-coach interactions.

**Data Submission Burdens**

Program delivery mode

The DAA seeks clarification from CDC as to why the proposed standards continue to require a separate application for each mode of delivery (i.e., in-person, online, distance learning, or combination). This requirement adds a tremendous burden to some National DPP providers, given that a separate data set submission would be required for each mode – that is, data could not be combined. With the coronavirus pandemic, in-person program providers have been conducting sessions online, as is permitted by the public health emergency. The DAA urges CDC to allow such program providers to continue to deliver in both in-person and online modes, and collapse the data into a single modality at least through the public health emergency (PHE) and for one year following the end of the PHE.

The DAA asks if the CDC could divide the data without requiring a separate organization number. The DAA notes that there are huge cost ramifications, especially for small National DPP providers, to modifying data collection systems. For example, requiring a unique organizational code for each delivery mode will result in a significant administrative burden for DPRP organizations and data preparers that are now essentially organizing, cleaning, and submitting data at least four times a year (moving from two per year to four per year when an additional delivery mode is added).

One DAA member, the YMCA of the USA, has said such a new standard would require Y DPP providers to move from submitting 320+ DPRP reports per year to approximately 650 per year by continuing with distance learning beyond the coronavirus public health emergency. The Y has suggested that CDC could use the Delivery Mode data element already captured at the session level to inform separate data analysis. Alternately, the Y has suggested that another approach would be to allow an organization's data to be merged and a single status to be assigned across all delivery modes. The latter route would make it easier for health plans and health care providers to ascertain status information from the DPRP directory about a given organization to make decisions on coverage and referral. CDC and CMS could work together to ensure both agencies have what they need for DPRP and Medicare DPP but minimize the reporting burden to organizations participating in DPRP.

Other onerous data documentation requirements

While the DAA appreciates the CDC's efforts to update its data elements and reporting requirements, we recommend streamlining changes as much as possible. Updating data collection software with additional fields can be a costly and cumbersome process for many programs and sites and may add an additional burden to program participants.

Changes to data platforms require an investment of resources and time, as do the creation of instruments to collect data from program participants such as intake forms that ask for enrollment motivation, HbA1C, and sex assigned at birth. By providing a transitional period for sites, CDC would acknowledge the cost that even minor changes may have on providers while allowing providers the time they need to align with these changes.

In the proposed DPRP data collection change, CDC indicates that the data collection burden for additional participant demographic questions is very low because most of these data points are only collected one time, before or at enrollment, from program participants. While the participants themselves are only asked for most of this information once, programs must submit to CDC all of these data points for every participant at every session. That is, programs must report on static variables such as participants' race and sex for every session just as they have to report on the variables that vary session to session such as weight and activity minutes. Over the course of 26 weeks, 24 pieces of information for 25 participants can results in 15,600 data points being submitted by programs for a single cohort, even though a significant number of those data points are identical for a given participant for every session. Due to the high volume of data reported by programs, the rates of errors can be quite high. Revising errors and resubmitting data is a burden to program administrators and can also use CDC staff resources if programs are not able to fix their errors and need further assistance.

The new DPP data submission portal has improved this process somewhat in that it tells programs immediately if there are suspected errors in their data. This saves a small amount of time for programs by allowing them to immediately correct the data rather than having to go back weeks later. Additionally, it is our understanding that the new portal saves significant time for CDC staff who are no longer having to review raw data with high error rates. However, from the perspective of a program administrator, there remains the high potential for errors upon initial submission, which is not ameliorated by the new portal. Also, the new portal does not indicate where the error is happening, requiring sites to review a checklist of potential errors instead of identifying specific issues.

CDC should consider revising its DPP data submission portal to reduce data submission burdens on programs. There should be a way for programs to report full demographic data on participants at the start of their programs. Then this data, which is tied to the program and participant ID numbers, could be carried over on the back end from week to week so programs only need to submit session data on variables that should or could change from week to week. This type of enhanced system would save significant time for program administrators, particularly those running small programs that do not necessarily have the scale or technological capabilities to utilize more sophisticated software to automatically track data for their programs.

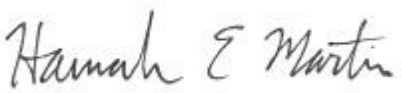
**Transition to 2021 DPRP Standards**

The DAA believes that a reporting grace period, like the one provided in 2018, is necessary to allow current DPRP recognized providers to modify their data collection and reporting systems. The DAA notes that CDC is planning to develop and release a transition plan in early 2021 to support existing organizations in working toward implementation of the new standards by midyear. (See document "SS Part A (DPRP)_5-26-20_Final to OMB"). DAA members would appreciate a transition period that offers grace and provides allowances for organizations migrating to the new standards.

**Summary**

The DAA and its members remain enthusiastic supporters of the National DPP and the DPRP. We recognize that CDC must occasionally review and revise the DPRP Standards, and we appreciate the value that these standards bring to ensuring prevention program quality and effectiveness. We urge CDC to make changes that are necessary but to keep in mind the consequences (and sometimes unintended consequences) of these changes on the very providers that are making diabetes prevention programs more accessible to people at risk of type 2 diabetes across the U.S. We appreciate the opportunity to share our thoughts and recommendations with you.

Sincerely,



Hannah Martin, MPH, RDN
DAA Co-chair
Academy of Nutrition and Dietetics Specialists

Kate Thomas, MA
DAA Co-chair
Association of Diabetes Care & Education

[1] Ely EK, Gruss SM, Luman ET, et al. A National Effort to Prevent Type 2 Diabetes: Participant-Level Evaluation of CDC's National Diabetes Prevention Program. Diabetes Care 2017;40:1331–1341 | DOI: https://doi.org/10.2337/dc16-2099

[2] Diabetes Prevention Program Research Group. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. N Engl J Med 2002; 346:393-403 DOI: 10.1056/NEJMoa012512

[3] Hamman RF, Wing RR, Edelstein SL, et al. Effect of Weight Loss with Lifestyle Intervention on Risk of Diabetes. Diabetes Care 29:2102–2107, 2006

[4] Delahanty LM, Pan Q, Jablonski KA, et al. Effects of Weight Loss, Weight Cycling, and Weight Loss Maintenance on Diabetes Incidence and Change in Cardiometabolic Traits in the Diabetes Prevention Program. Diabetes Care 2014;37:2738–2745 | DOI: 10.2337/dc14-0018