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August 17, 2020

Ann Albright, PhD, RDN
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Re: Docket No. CDC-2020-0070

Dear Dr. Albright,

120 South Riverside Plaza Suite 2190 Chicago, Illinois 60606-6995 800 877 1600

1120 Connecticut Avenue NW Suite 460 Washington, D.C. 20036

The Academy of Nutrition and Dietetics appreciate the opportunity to comment on the proposed revisions to the Diabetes Prevention Recognition Program data collection. Representing more than 107,000 registered dietitian nutritionists (RDNs), dietetic technicians, registered (DTRs), and advanced-degree nutritionist researchers, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation's health through food and nutrition across the lifecycle. Across the country, RDNs and DTRs are involved in the oversite and administration of Diabetes Prevention Programs.

## **Changes to Applicant Form**

We are supportive of the proposed changes to the response options and descriptions for the Delivery Mode, Class type, and Organization Type questions on the applicant form. These changes pose no additional data collection burden to programs and the updated wording of answer choices improves clarity and specificity.

## **Changes to Evaluation Data Elements**

Enrollment Motivation and Enrollment Source

We support the expansion and clarification of response choices to assess both why a participant chose to enroll in the program and, if the reason was a referral from a health care provider, what type of provider. We believe that these two questions could be combined into a single question with 11 answer choices by replacing Motivation response 1 "Health Care professionals" with the provider types identified in the first three answer choices from Enrollment Source. That is, the Enrollment Motivation question would be kept with responses 1 through 3 being "1. A doctor/doctor's office," "2. A pharmacist," and "3. Another healthcare professional," and then with the responses currently designated numbers 2 through 9 being renumbered 4 through 11.

# Participant's Gender

We support the inclusion of a question about participant gender in addition to the longstanding question about participant sex. The inclusion of both in the data collected by DPP follows a steady trend in biomedical research to study these distinct variables and their differing and intersecting effects they have on program outcomes.

#### Participant's reported HbA1c value

We strongly support the addition of the option for programs to report participants' HbA1c values. The HBA1C has several advantages compared with fasting plasma glucose (FPG) and oral glucose tolerance test (OGTT), including greater convenience (fasting not required), greater preanalytical stability, and less day-to-day perturbations during stress, diet, or illness. The use of HbA1c lab values for the diagnosis of prediabetes is also in line with the American Diabetes Association (ADA) Standards of Medical Care in Diabetes, which recommends prediabetes can be diagnosed based on HbA1c lab values.<sup>ii</sup>

Tracking HbA1c, where available, will also help facilitate the future use of this measure of prediabetes in the MDPP. Currently, the MDPP uses the World Health Organization definition of impaired fasting glucose that requires a fasting plasma glucose of 110-125 mg/dl.<sup>iii</sup> This is at odds with the ADA definition of impaired fasting glucose that requires a fasting plasma glucose of 100-125 mg/dl.<sup>iv</sup> Many health systems and medical providers use the ADA standards for diagnosing prediabetes in their patients. It causes confusion and frustration for patients when they are diagnosed with prediabetes based on the ADA standards, referred to MDPP, and then subsequently are refused admission to the MDPP because their disease does not meet the narrower definition of prediabetes used by MDPP. A transition towards using HbA1c as a recognized diagnosis for pre-diabetes in MDPP could help lessen this frustration and confusion.

#### **Data Submission Burdens**

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.

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 needed 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 administrations, 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.

Thank you for the opportunity to provide comment on data collection changes for this important public health program. Please contact either Jeanne Blankenship at 312-899-1730 or by email at jblankenship@eatright.org or Hannah Martin at 202-775-8277 ext. 6006 or by email at hmartin@eatright.org with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS, RDN

Vice President

Policy Initiatives and Advocacy

Academy of Nutrition and Dietetics

Glanne Blankenshija MSRDN

Hannah Martin, MPH, RDN

Hamah & Martin

Director

Legislative & Government Affairs Academy of Nutrition and Dietetics

## References

<sup>1</sup> Clayton JA. Studying both sexes: a guiding principle for biomedicine. FASEB J. 2016;30(2):519-524. doi:10.1096/fj.15-279554

<sup>&</sup>lt;sup>ii</sup> Classification and Diagnosis of Diabetes: *Standards of Medical Care in Diabetes—2020* American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S14-S31 <a href="https://doi.org/10.2337/dc20-S002">https://doi.org/10.2337/dc20-S002</a>

iii Prediabetes diagnosis and treatment: A review <u>World J Diabetes</u>. 2015 Mar 15; 6(2): 296–303. Published online 2015 Mar 15. doi: <u>10.4239/wjd.v6.i2.296</u> Accessed July 18, 2020.

 $<sup>^{\</sup>rm iv}$  Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2020 American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S14-S31  $\underline{\rm https://doi.org/10.2337/dc20-S002}$