AMA
AMERICAN MEDICAL ASSOCIATION

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Jeffrey Zirger
Lead
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-D74
Atlanta, GA 30329

RE: AMA Comments on Updated Standards for the Centers for Disease Control and Prevention's Diabetes Prevention Recognition Program, (Docket No. CDC–2020–0070)

Dear Mr. Zirger:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am pleased to offer our comments to the Centers for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP), regarding Docket No. CDC–2020–0070. The AMA has been partnering with health care organizations and clinical teams to implement diabetes prevention strategies. Overall, the CDC DPRP standards provide a framework for ensuring program fidelity and collecting relevant program data. There are some areas of the DPRP where the AMA recommends changes, as set forth below, that eliminate any barriers to clinical referrals and program enrollment while providing the needed structure for program delivery.

Section A: Participant Eligibility

Item #3 a: "A blood test result within one year of participant enrollment. Blood test results may be self-reported for CDC recognition purposes. Participants enrolled in a Medicare Diabetes Prevention Program (MDPP) cannot self-report blood test results; lab results must be provided."

In reviewing the MDPP final rule it does not require the beneficiary to provide the DPP program with a report or paper result from a physician. MDPP allows for self-reported lab results as long as the test was performed within 12 months of the first class. When referencing the MDPP, CDC DPRP Standards should include the same language and directives.

Item #3a highlights that without a relevant lab test, a participant 65 and older is not eligible for the MDPP. The AMA has long been concerned about the eligibility differences between CDC DPP and MDPP, primarily regarding the fasting glucose ranges: CDC eligibility 100–125 mg/dL vs MDPP eligibility 110-125 mg/dL. This is confusing for clinicians when making the referral order and for the DPP provider who might be turning people away or charging participants at different rates. This is a problem and makes the program unnecessarily complex for both suppliers and patients. The AMA recommends that the CDC work with the Center for Medicare & Medicaid Services (CMS) to resolve these disparate eligibility requirements.

Item #6. The AMA supports self-referrals to the DPP as stated, but the AMA recommends that the bolded sentence below be added so that number 6 read as follows:

A health care professional may refer potential participants to the program, but a referral is not required for participation in a CDC-recognized program. **Even if self-referred, participants are encouraged to coordinate enrollment in the DPP with their primary care provider.**

Section K: Requirements for Pending, Preliminary, and Full Recognition

The standards recognition eligibilities are clearly defined in the proposed 2021 standards. However, given the need to increase access to the program, the AMA was concerned to see that organizations with full recognition that do not meet the requirements for full recognition at the 36-month mark will lose recognition and are required to wait six months before reapplying. We recommend that the CDC consider allowing organizations that lose full recognition to revert to preliminary recognition during that waiting period if the organization meets requirements for preliminary recognition.

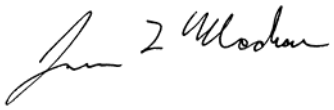
The AMA is supportive of setting up a mechanism that allows for participants to achieve program goals through any of several different outcomes, all of which are generally meaningful/important outcomes, not just weight loss. It would be helpful to know how the CDC arrived at the full recognition requirement that 60 percent of participants must achieve one of the three outcomes metrics (i.e., 5 percent weight loss, 4 percent weight loss plus physical activity, or decreased HbA1c). Does the CDC have data indicating that 60 percent is a reasonable benchmark for these combined metrics?

It is not clear how the CDC arrived at the Option B outcome marker for achieving full recognition of 4 percent weight loss combined with 150 minutes of physical activity. The CDC's own data (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6682852/) shows that while 5 percent is a modest weight loss, there are certain variables that limit certain populations from achieving this milestone. There are studies that show improved health with any amount of weight loss and even a reduced risk of developing type 2 diabetes (https://care.diabetesjournals.org/content/29/9/2102?ijkey=349f14be5261b3ddc5a78275a0d162e27755c09a&keytype2=tf_ipsecsha). Further explanation or citations would be helpful especially for those program providers that address populations at risk.

The AMA is supportive of including a biometric goal as one of the three options (option C, at least 0.3 percent reduction in HbA1c), but our recommendation is to change this to simply: "no increase in HbA1c." A difference in HbA1c of 0.3 percent is within the range of error on some HbA1c tests, particularly point-of-care tests, so a patient may or may not achieve a 0.3 percent reduction in HbA1c purely due to chance. Furthermore, what justification is the CDC using to say that a 0.3 percent decrease in HbA1c is a reasonable goal or a clinically meaningful outcome? In results from the original DPP trial, the lifestyle change group had an average baseline HbA1c of ~5.9 percent, which decreased to an average HbA1c of ~5.8 percent at one year. The placebo group's average HbA1c changed from ~5.9 percent at baseline to ~6.0 percent at one year. So, even in the original trial, HbA1c did not decrease by an average of 0.3 percent over one year. Last, a drop of 0.3 percent in HbA1c is not a clinically meaningful outcome for an individual patient; it does not translate to a clear reduction in diabetes complications or other clinical benefits. The DPP is about preventing or delaying the onset of diabetes, so the outcome should be focused on HbA1c not increasing, rather than HbA1c decreasing.

Thank you for considering the AMA's comments. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,



James L. Madara, MD