

February 3, 2020

Ms. Linda Harris
Designated Federal Officer
National Clinical Care Commission
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Disease Prevention and Health Promotion
1101 Wootton Parkway, Suite 420
Rockville, MD 20852

Dear Ms. Harris:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments in response to the U.S. Department of Health and Human Services (HHS) questions from the National Clinical Care Commission (NCCC) on diabetes prevention. The AMA has been addressing prediabetes screening and management since 2012 in collaboration with local and national health, medical, government, and community organizations. This work has included developing, testing and implementing clinical strategies and tools to increase prediabetes screening and referral to evidence-based treatment. We partnered with the YMCA of the USA on its Center for Medicare and Medicare Innovation (CMMI) award to measure the cost savings associated with the Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (DPP) lifestyle change program on the Medicare population, which resulted in Medicare covering the DPP for its beneficiaries. We have been working with the Diabetes Advocacy Alliance and the Centers for Medicare & Medicaid Services (CMS) to increase utilization of this benefit and to identify areas of improvement. To address clinical gaps, the AMA developed three prediabetes quality measures and completed testing in January. The AMA is seeking endorsement of these measures from the National Quality Forum and inclusion into Medicare payment programs.

In response to Docket ID: HHS-OS-2019-0015, the AMA is attaching the following documents:

- Letter to CMS re: Coverage of A1C lab test for prediabetes screening; and
- AMA's Prediabetes Quality Measures.

**Solicitation for Public Comments on Questions from the National Clinical Care Commission
Docket ID: HHS-OS-2019-0015 Agency: Department of Health and Human Services**

- 1. Context: What social, economic, and/or environmental factors have the greatest impact on health care in general—and also on prevention (Type 2) and/or management of diabetes (both Type 1 and Type 2)? What can be done by the federal government to address those social/economic/environmental factors?**

The AMA has been engaged in an initiative to prevent type 2 diabetes in the U.S. since 2012. Our initiative includes a partnership with the CDC's National DPP, as well as partnerships with other key stakeholders. Given the AMA's deep expertise in diabetes prevention, our comments primarily address issues in preventing type 2 diabetes, although some aspects may also be relevant to the management of diabetes.

Preventing type 2 diabetes requires a multi-layered approach that addresses social, economic, and environmental factors. Healthy behaviors are critical to preventing the development of prediabetes and type 2 diabetes. Risk of developing type 2 diabetes is often associated with social determinants of health and economic and environmental access to interventions to improve health behaviors. There are many reasons why Americans struggle to adopt and sustain healthy behavior changes, but the simple answer is that it is confusing and challenging, and the environment does not support healthy behaviors.

First, the average person's understanding of healthy behaviors is poor. The scientific evidence is conflicting, incomplete, and continually changing. Physicians and experts in this field struggle to remain abreast of the current evidence, so it is understandable that lay individuals would struggle further. The confusing state of scientific evidence is compounded by significant misinformation in the public sphere. There are numerous diets discussed in the media or advertised on social media that have weight loss claims. Several products (e.g., supplements) make unsubstantiated claims about achieving weight loss with minimal effort on the part of a consumer. Additionally, consumers are being bombarded with messages about digital apps and physical activity trackers on phones and watches, but the benefit of most of these solutions is questionable at best. Clear, accurate, and trustworthy information about healthy behaviors is difficult for most Americans to obtain.

Even when people have understandable, accurate information about healthy behaviors, implementing and sustaining these behaviors is challenging for any individual. A recent study in *JAMA* suggests that a growing number of Americans are overweight and have obesity despite an increase in the number of people who are trying to lose weight. During the study period the percentage of people reported trying to lose weight went from 34.3 percent to 42.2 percent. But, participants' average weight and body mass index (BMI) increased regardless of whether they tried to lose weight. When one tries any number of these and does not see the rapid weight loss promised, the motivation to keep trying wanes, and self-efficacy is diminished.

Losing weight is a complex behavior change. It is not just a matter of eating less or eating more nutrient-dense foods. According to a 1998 [study](#) in the *Journal of the American Dietetic Association*, factors that predict adult eating habits include taste, cost, nutrition, convenience, pleasure, and weight control. Successful policy and program interventions need to take one or more of these into consideration. In addition to these factors, people have [emotional connections](#) with food that determine choices and quantities. For some people, eating food is a reaction to a situation or feeling. People overeat when they are depressed or under undue stress. For others, these situations result in loss of appetite and weight loss without adopting a healthier diet. Helping people make lasting lifestyle change must start with an understanding of why people, on an individual level, overeat or make poor choices. Given this, it is worth noting that the CDC's National DPP lifestyle change program does address individualized causes of unhealthy habits, stress, and the need for support mechanisms and coping strategies.

The environment in which one lives has a major influence on our eating habits. Much has been studied on food deserts and lack of access to fresh fruits and vegetables. Even in environments where access is not

an issue, the food environment is often supportive to overeating and poor dietary choices. Fine dining restaurants offer entrees that exceed daily calorie requirements. Retailers position calorie-dense nutrient-poor foods near the front of the store. Unhealthy choices make up the bulk of items sold in most stores and are frequently sold at a lower price than healthier options. Our built environment discourages or limits people's ability to walk, bike, and be more physically active. Today's workplaces and types of work require less physical activity and demand more sedentary behavior. The healthier choice is rarely the easier (or more pleasant) choice in today's environment.

The above factors are all issues that impact people with prediabetes directly. There are also many factors that limit physicians' and care teams' abilities to deliver effective preventive care. One major barrier is lack of consistent insurance coverage for evidence-based preventive interventions like the National DPP lifestyle change program. Also, physician practices and health care organizations frequently lack the infrastructure to systematically identify and connect patients to interventions that extend beyond the traditional clinical care environment. They struggle to identify which community-based organizations or digital health companies offer high-quality programs or solutions. Once they have identified preferred referral partners, physicians do not have ready access to seamless and secure information-sharing systems to send and receive referral information. Establishing this prevention infrastructure requires significant time and financial resources which are difficult to allocate given competing priorities driven by payment programs and associated requirements for quality measurement. Financial incentives cannot even be developed without methods for measuring the quality of preventive care. Until the AMA released quality measures for diabetes prevention this month, no such measures existed. These measures are not yet incorporated into payment programs, so physicians are not incentivized to discuss prevention with patients beyond a brief intervention.

2. Policies: What policies should the federal government implement to improve diabetes prevention and/or management? What is the evidence to support those?

Institutional, regulatory, and legislative policies that create environments supportive of making the healthier choice the default choice are proven to provide lasting and sustainable lifestyle changes. Policies, Systems, and Environmental changes (PSEs) go beyond programming to create the structures in which we work, live, and play. PSEs work hand-in-hand. For example, an environmental change may be furthered by a policy or system change. Similarly, a policy could be put in place that results in additional environmental changes. The process is not linear. This has been proven with tobacco control. Increases in tobacco excise taxes and enacting clean indoor air laws not only encouraged people to quit using tobacco products but reduced youth initiation. While both are technically considered policy changes, clean indoor air laws created environments that send a message to the public: no smoking is allowed here.

The successful PSE approach that has resulted in preventing diseases associated with tobacco use is also being applied to prevent diseases associated with obesity. Consumption of sugar-sweetened beverages (SSBs) and fast food have been significant contributors to increased caloric intake and higher body weight. SSBs have been identified as the leading source of added sugar and calories in the American diet. Taxes on SSBs have resulted in decreased consumption and an increase in revenue to support prevention programs. The data on health outcomes—fewer cases of diabetes and hypertension—are limited; however, they all conclude that there is a direct link to reduction in weight which is a risk factor for cardiovascular disease. Examples of environmental interventions include placement of fruits and vegetables near the registers in retail establishments and in school cafeterias, resulting in an increase in consumption.

Additionally, HHS should consider several specific policy changes that will improve the delivery of health care services intended to prevent diabetes, including:

Update the Medicare Diabetes Prevention Program set of services to include the following modifications:

- Eliminate onetime benefit provision;
- Cover all program delivery modalities including virtual/online;
- Align program length and lab values with CDC National DPP standards;
- Under Medicare Part B, expand coverage of Hemoglobin A1c testing to include screening for abnormal glucose metabolism (i.e., prediabetes and type 2 diabetes screening) to align with clinical care guidelines;
- Incorporate AMA's Prediabetes Quality Measure set in Medicare payment programs;
- Develop a MIPS Value Pathway (MVP) for diabetes prevention, inclusive of the AMA Prediabetes Quality Measure Set and the Glycemic Screening Services and Glycemic Referring Services Improvement Activities; and
- Under Medicare Part B, expand Medicare coverage of Medical Nutrition Therapy to be a service covered for people with prediabetes (i.e., not only people with type 2 diabetes).

3. Effectiveness: What specific recommendations do you have for federal agencies to be more effective and/or to collaborate better to prevent and/or help manage diabetes? What is the basis for your specific recommendations?

Federal agencies can create barriers or implement facilitators that impact how physicians and care teams deliver preventive services. Frequently, different federal agencies have misaligned requirements or incentives, and at times, implemented completely conflicting requirements or incentives. To the extent that agencies can align their requirements and incentives, this will significantly eliminate confusion and barriers to delivering evidence-based preventive care.

One specific example is the case of hemoglobin A1c (HbA1c) testing, which is a test commonly used to screen for abnormal glucose metabolism (i.e., prediabetes and diabetes) and to monitor people with abnormal glucose metabolism. Current evidence-based clinical guidelines from organizations such as the United States Preventive Services Task Force (USPSTF) and the American Diabetes Association recommend that patients with specific risk factors undergo regular screening for abnormal glucose metabolism. These organizations state that a HbA1c test is an appropriate test to use for glucose screening. The CDC uses Hb1c as an eligibility criterion for participation in the National DPP, and Medicare uses HbA1c as an eligibility criterion for the Medicare DPP. Additionally, clinical quality measures use HbA1c for both numerator and denominator criteria. Nevertheless, Medicare does not cover HbA1c for the indication of screening for prediabetes and diabetes. Thus, it is very difficult for health care organizations to implement systematic screening of their populations. This misalignment can be rectified with the policy change we proposed in Question 2.

The AMA recommends that there should be better alignment strategies that coordinate with similar agencies and divisions within HHS that are trying to accomplish the same goal. This alignment would allow for greater recognition and promotion of all the evidenced-based strategies for preventing type 2 diabetes.

4. Promising Practices: What are the best and/or most promising practices to prevent diabetes and/or to improve diabetes outcomes? What is the evidence to support them?

The evidence base describing effective preventive interventions is fairly extensive, and numerous clinical guidelines and recommendations—e.g., from the USPSTF, the Community Preventive Services Task Force (CPSTF), and others—encourage the use of specific interventions and services that are known to be effective. One excellent example is the CDC National DPP which provides participants with the information and skills needed to sustain lifestyle behavior changes. Early in AMA's diabetes prevention work, we partnered with the YMCA of the USA, as part of a CMMI demonstration project, to develop, implement, and evaluate innovative quality improvement strategies to increase routine screening, testing, and referral of Medicare patients with prediabetes to a CDC-recognized diabetes prevention program at local YMCAs. This partnership resulted in an economic model confirming the CMMI findings that enrolling Medicare beneficiaries would save CMS \$2650 per beneficiary over 15 months. The AMA/YMCA partnership resulted in CMS covering the lifestyle change program for all Medicare beneficiaries.

Since the CMMI demonstration, the AMA continues to collaborate with CDC and its public health partners on scaling its National DPP lifestyle change program. The AMA specifically has focused its resources on system level changes in clinical practice, including improving prediabetes screening and referral to the DPP. As a result, the AMA has been offering technical assistance to health systems that want to implement their own DPP and syncing it with care coordination. The most successful approach we have observed is when the clinical team utilizes the following strategy:

- Query the electronic health record to identify patients due for screening (per the USPSTF guideline for screening for abnormal glucose);
- Implement standing orders for screening labs;
- Engage with patients using brief counseling interventions and shared decision-making;
- Enter an electronic referral to a DPP provider;
- Outreach to the patient and enrollment is conducted by the DPP provider; and
- Reports on participant progress are transmitted to the referring clinical team.

The AMA's method for implementing diabetes prevention strategies in health care organizations is available at <https://amapreventdiabetes.org/>. This digital experience guides clinical champions and program leads through the necessary steps to build infrastructure to support systematic screening of patients with prediabetes and enrollment in CDC-recognized lifestyle change programs.

The AMA has now supported dozens of health care organizations in implementing diabetes prevention strategies that include referrals to CDC-recognized lifestyle change programs. Some specific examples of success include Intermountain Healthcare's diabetes prevention strategy, which is multi-layered, and patients are offered options for lifestyle change interventions. These options consider location, time, delivery mode, and patient preference. This approach has also resulted in increased engagement in their entire range of diabetes prevention offerings, including in the most intensive intervention, the DPP. The health care system has shown cost savings and reduced incidence of type 2 diabetes using this approach. The AMA has also partnered with Henry Ford Health System to implement a prediabetes registry, clinical decisions support, and other functionalities to optimize their electronic health record for diabetes prevention. The result was a seven-fold increase in referrals (over one year) to Henry Ford's

CDC-recognized lifestyle change program, and this referral rate has continued to grow almost exponentially in the year since.

Outside of our role directly supporting physicians and care teams in connecting patients to CDC-recognized lifestyle change programs, the AMA recognizes the role that media play in promoting health and generating engagement. The AMA, CDC, and the American Diabetes Association partnered with the Ad Council to create the first national public awareness campaign on prediabetes. Now in its fourth year, the campaign has been successful in raising awareness but also in viewers completing a risk assessment that provides them with information to share with their physician. In 2019 alone, more than 600,000 people completed the risk assessment.

5. Limitations and gaps: What are the greatest limitations or gaps in federal programs to prevent diabetes and/or to improve diabetes outcomes? What could the Federal government do to close the gaps? Are there specific research needs? Are there specific research needs or programs that would benefit from new or increased collaboration across federal agencies?

Despite the evidence base and inclusion in clinical guidelines for lifestyle intervention to treat prediabetes, there are several barriers to access. All evidence-based programs are not equally accessible or implementable. Smoking cessation programs are readily covered by public and private insurance companies, but similar behavior change interventions like the DPP struggle to gain universal attention. Program providers like the YMCA must subsidize the program costs or identify grant dollars to cover program operations and to avoid charging participants. The DPP has demonstrated cost savings to health systems like Medicare, as well as to families. Medicare's own estimates show a cost savings of \$2650 per Medicare beneficiary enrolled in the DPP. Yet, the rate of private insurance coverage is not keeping pace with the rise in new cases of prediabetes and type 2 diabetes.

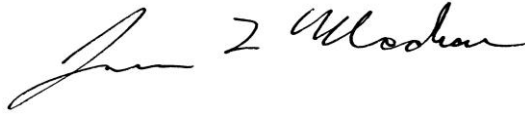
This screening and referral strategy are most successful when there is ongoing use of technology to communicate with the DPP program provider, clinical team, and program participants. This applies even if the DPP provider is a community-based organization such as the YMCA. Lacking in this strategy is a universal system or method to facilitate information-sharing across all stakeholders, so these stakeholders are forced to deal with multiple communication systems that do not interface with each other.

There are multiple interventions proven to be effective to prevent type 2 diabetes, most notably the National DPP, which has the strongest evidence for reducing the risk of developing type 2 diabetes. There are other interventions that are proven to be effective, such as certain medications and medical nutrition therapy. The AMA supports giving patients and physicians access and choice. In addition, there are many Federal agencies that address and promote lifestyle behavior change to prevent type 2 diabetes and cardiovascular diseases. There may be gaps in creating pathway(s) to surface and support the intervention(s) that demonstrate outcomes for reducing the risk of developing type 2 diabetes. The AMA supports physicians and care teams in partnering with their patients with prediabetes to discuss their condition and the best options for management. The AMA urges the Commission to align the agencies to create a mechanism that supports ongoing research of the evidence and promotes the latest evidence in programs and interventions that demonstrate or improved outcomes.

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Thank you for considering our views. If you have any questions, please contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, sweeping initial "J".

James L. Madara, MD