

May 19, 2021

Kara Elam, PhD, MPH, MS
Designated Federal Officer
National Clinical Care Commission
U.S. Department of Health and Human Services
200 Independence Ave. SW, 7th Floor
Washington, DC 20201

RE: Draft Recommendations of the National Clinical Care Commission

Dear Dr. Elam:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments on the National Clinical Care Commission's (NCCC) draft recommendations for treating and preventing diabetes. The COVID-19 pandemic highlights the need to address diabetes with a coordinated strategy that includes system and structural changes to health care.

Overall, the AMA supports the comprehensive approach in the Commission's report draft. The AMA appreciates the recognition by the Commission that addressing health equity should be a component of any new or revised Federal agency policy related to diabetes. The AMA recommends that the health equity lens be applied broadly to diabetes and diabetes prevention policies and programs. High rates of diabetes and prediabetes among Black, Latinx, and Indigenous Americans are associated with historical structural barriers and biases. Federal agencies need to assess and improve the impact of their policies and/or regulations on diabetes care and prevention strategies to better serve marginalized communities.

We appreciate the Commission's inclusion of several recommendations that the AMA outlined in its February 3, 2020 response to the NCCC's solicitation for public comments on specific questions related to the Commission's charge. The AMA supports the Commission's inclusion of the AMA's prediabetes quality measures. The AMA is supportive of additional recommendations in the final report draft, including expanded Medicare coverage for screening laboratory tests to identify patients with prediabetes, ongoing research into other evidence-based interventions to prevent type 2 diabetes, strengthening the Medicare Diabetes Prevention Program, continuation of public awareness efforts, and ensuring that health equity provisions, including consistent data collection, will be used to assess and improve the impact of the diabetes care and prevention strategies. The balance of this letter outlines the AMA's specific comments on the draft recommendations.

ACTIONS RELATED TO DIABETES CARE

Commission Recommendations: Team-Based Care

The AMA supports a team-based care approach for both diabetes care and prevention but recommends the Commission add "physician-led" and adopt the AMA policy definition. It is important to have the team led by a physician to ensure consistent adherence to diagnosis and treatment plans. The AMA's Structure and Function of Interprofessional Health Care Teams policy defines physician-led team-based

care as the provision of health care services by a physician-led team of at least two health care professionals who work collaboratively with each other and the patient and family to accomplish shared goals within and across settings to achieve coordinated, high-quality, patient-centered care.

Commission Recommendations: Digital Divide/Connectivity

The AMA agrees with the draft recommendation calling for continued coverage and payment for virtual visits beyond the COVID-19 public health emergency. The AMA asks the NCCC to be more specific in its recommendation and clearly state its support for removing the geographic and originating site restrictions that prevented most patients from being able to access telehealth services before the pandemic. In addition, it is critically important that continued access to telehealth services include audio-only services and not be limited to audio-video services. Allowing for the use of audio alone instead of requiring video addresses the lack of connectivity based on geography as well as lack of the needed technology or ability to use it. The allowance for the use of telehealth—video and audio—visits approved during COVID-19 should be made a permanent option for patient care and communications with physicians and clinical care teams. Physicians have told the AMA that these visits have been particularly useful in talking with patients about a prediabetes and diabetes diagnosis while also having the opportunity during a video visit to see a patient in their home environment. The AMA supports advancing solutions in this area that are physician-led and that take social determinants and social needs into consideration. The AMA also supports eliminating barriers to diabetes self-management training to help patients better manage their condition at home and prevent complications and exacerbations.

ACTIONS RELATED TO DIABETES PREVENTION

Commission Recommendations: Create Awareness

The AMA supports the continuation of a national awareness campaign that includes awareness for prediabetes and effective preventive interventions such as the CDC-recognized diabetes prevention lifestyle change program. The AMA recommends that an awareness campaign is incorporated into the larger framework that contributes to improving health outcomes. In addition to awareness, a comprehensive approach includes improving clinical processes, increasing coverage for all evidence-based preventive interventions, and improving access to evidence-based preventive interventions in community and clinical settings. The AMA also recommends the creation of a clinical awareness campaign that includes input from the medical community.

Commission Recommendations: Expand Screening Coverage

The AMA would like to reiterate its support for Medicare coverage of hemoglobin A1c tests for screening and monitoring of prediabetes. In its previous communications with the Centers for Medicare & Medicaid Services (CMS), the AMA has stressed the importance of this coverage in order to align with clinical guidelines and with the clinically preferred screening laboratory test. The new draft U.S. Preventive Services Task Force (USPSTF) recommendation about Screening for Prediabetes and Type 2 Diabetes Mellitus details the benefits to clinicians and patients of using the hemoglobin A1c test to screen for abnormal glucose.

Commission Recommendations: Adopt Utilization of Clinical Quality Measures

The AMA appreciates the recommendation to include the AMA's prediabetes quality measure for screening, but screening alone is insufficient to prevent diabetes among at-risk individuals. The AMA created an electronic clinical quality measure (eCQM) set which includes three inter-related quality measures: 1) Screening for Abnormal Glucose; 2) Intervention for Prediabetes; and 3) Retesting of

Abnormal Glucose in Patients with Prediabetes. Adoption of the screening measure is a component to preventing type 2 diabetes. Without implementation of the intervention and retesting measures, there is little incentive for physicians and clinical teams to invest in engaging their patients with prediabetes in effective preventive interventions, including referral to CDC-recognized diabetes prevention lifestyle change programs, metformin, medical nutritional therapy, and annual laboratory monitoring.

In addition, the AMA prediabetes quality measure set would provide those federal agencies that deliver direct health care a standardized method to identify patients at risk for or those already meeting criteria for prediabetes and to refer them to appropriate preventive interventions.

Commission Recommendations: Improve Access to and Utilization of Evidence Based Effective Type 2 Diabetes Prevention Interventions

The Commission recognizes the current benefits of off-label use of metformin and recommends research on the benefits of metformin particularly in population subsets to have data to provide to the Food and Drug Administration (FDA) for off-label approval. This research recommendation would be duplicative as the data currently exist. The evidence summary conducted by the USPSTF includes an analysis of metformin, including in population subsets. The AMA recommends that the Commission present the current available data, including the more than 20 years of data analyzed by the original Diabetes Prevention Program Outcomes Study to the FDA.

The AMA believes that there is opportunity to collaborate and share between federal agencies, but creating another inter-agency coordinating body may not be the most efficient way to accomplish the goals and objectives.

The AMA recommends clarification of the recommendation that reads, “Promote coverage for all proven modes of delivery for evidence-based interventions that produce successful patient outcomes consistent with the National DPP quality standards in delaying or preventing type 2 diabetes.” AMA enthusiastically supports the promotion of coverage for all proven modes of delivery for evidence-based interventions that reduce the risk of developing type 2 diabetes. However, the recommendation goes on to state that it is for those interventions that produce successful patient outcomes consistent with the National DPP quality standards. The National DPP does not currently support other interventions beyond the specific lifestyle change program modeled after the intervention in the DPP randomized controlled trial. In addition, patient outcomes tracked by the National DPP do not include delayed or prevented cases of type 2 diabetes but rather weight loss, physical activity minutes, and attendance. The AMA suggests re-wording the recommendation and eliminating the reference to consistency with CDC quality standards. The AMA instead urges the Commission to recommend that the CDC Division of Diabetes Translation establish a system to track the outcomes of all evidence-based interventions for delaying or reducing the risk of developing type 2 diabetes. Also, this recommendation says “promote” coverage. The recommendation should read that all commercial and public insurers should cover evidence-based interventions.

Commission Recommendations: Streamline CDC Recognition Process and Address MDPP Utilization Barriers

The Commission recommendation implies that one of the barriers to enrolling MDPP suppliers is due to the CDC DPRP standards, which is not the case. There are many barriers to becoming a MDPP supplier and to utilization of the service, but the CDC DPRP is not a barrier to supplier or participant enrollment. The AMA recommends that the Commission address the program eligibility differences and duration. The fasting plasma glucose range for MDPP eligibility is different from the CDC lifestyle change program eligibility range. The higher MDPP range is in conflict with clinical guidelines, which results in an added clinical burden. The MDPP service is two years while the CDC lifestyle change program is one year. This

represents another challenge for clinical teams who have to be prepared to have different discussions for Medicare and non-Medicare patients at the point of diagnosis and referral.

The AMA strongly supports the Commission's recommendations to approve MDPP as a permanent covered benefit instead of an expanded model test, lift the "once in a lifetime" limit on participation in the MDPP, and expand coverage to include virtual delivery. The AMA also agrees with the problems that the NCCC has identified in other features of the current MDPP model. Program delivery organizations are definitely under-resourced and cannot be expected to cover the upfront costs to participate in this model. Payment rates are not sufficient to cover the costs of delivering the services and are even lower than the rates in the pilot program. Medicare claims data have shown the utilization of the expanded model is only a fraction of the pilot model. In making the MDPP a permanent program, the flaws in the current expanded model test need to be corrected. It is not necessary, however, to conduct additional model tests. The AMA does not agree with the recommendation to provide funding for testing of new models with greater up-front payments and equitable risk sharing. Many MDPP supplier organizations are pulling out of the program due to inadequate payments and lack of risk-adjusted payments to serve patients at high risk. The AMA believes that CMS can fix a number of ongoing problems that threaten the existence of the MDPP through the Medicare Physician Fee Schedule process or via statute.

Medicaid coverage of all evidence-based interventions is needed in order to address the high rates of prediabetes in the Medicaid population. There are some states that cover the CDC-recognized diabetes prevention lifestyle change program, but there are inconsistencies on the payment structure and inclusion of other evidence-based interventions. The AMA agrees with the recommendation but feels it could be stronger by setting a standard for Medicaid coverage.

Commission Recommendations: Research Funding for Prevention Interventions

The AMA supports the recommendation for more research on options for sustaining weight loss and/or other metrics associated with reducing the risk of developing type 2 diabetes. This type of research could be useful for all interventions including existing and emerging medications associated with weight loss and not just lifestyle programs.

Since the majority of adults with prediabetes and type 2 diabetes are overweight or obese, the AMA believes that access to the full continuum of care to treat obesity would be another important tool to reduce new cases of type 2 diabetes and to help adults sustain weight loss throughout their lives. Even though clinical guidelines recommend treatment of obesity through intensive behavioral therapy (delivered by all modalities: community, online and telephonic), pharmacotherapy, and/or surgery, Medicare does not cover the full spectrum of interventions for obesity, which are also important to curbing cases of prediabetes and type 2 diabetes. The COVID-19 pandemic has clearly shown and reinforced the urgent need to address diabetes and obesity, as these two conditions are major risk factors for severe disease resulting in hospitalization and death from COVID-19.

The AMA believes that more research funding is needed to better understand who benefits from which type(s) of evidence-based preventive interventions. The AMA also suggests the Commission recommend more funding for research about how we can better leverage new technologies to engage people in lifestyle change solutions that are not structured exactly like the DPP. Health care organizations would benefit from research that examines the impact of lifestyle change on other health conditions since these systems are seeking interventions that address obesity and other conditions and risk factors for diabetes and cardiovascular disease. The fact that the CDC-recognized diabetes prevention lifestyle change program is limited only to people with prediabetes has always been a barrier to more widespread adoption.

PREVENTION IN THE GENERAL POPULATION

There are several policies, systems, and environmental changes that are needed to successfully reach the general population and improve population health, which could potentially lower the incidence of prediabetes. These strategies often support behavior changes over a period of time, happen at the community level, and address systemic or structural barriers.

The AMA supports modernizing the SNAP program to recognize changing dietary patterns and food availability by providing the needed incentives for healthier choices and not limiting those incentives to SNAP but expanding them to other food access initiatives.

According to the 2015-2020 Dietary Guidelines for Americans, sugar sweetened beverages account for almost half of the intake of added sugars in American diets. The AMA supports the Commission's recommendation to reduce consumption of sugar sweetened beverages.

The AMA is encouraged that the Commission went beyond diet in addressing other behaviors associated with diabetes. The 50th Anniversary of the U.S. Surgeon General Report on Tobacco identified smoking as a cause of type 2 diabetes. The AMA agrees with the Commission's recommendation to expand availability of tobacco cessation programs.

HEALTH CARE DELIVERY AND PAYMENT MODELS TO IMPROVE DIABETES CARE

It is essential that the report include only those recommendations and quality measure concepts for which there is clear evidence that the structure or process can impact patient outcomes, are appropriate for performance measurement (particularly for accountability purposes), and are feasible to collect and report. Therefore, we recommend the quality recommendations encourage the adoption of the following eCQMs developed by the AMA:

- Prediabetes: Screening for Abnormal Blood Glucose;
- Intervention for Prediabetes; and
- Retesting of Abnormal Blood Glucose in Patients with Prediabetes.

The other measurement approaches or concepts recommended have not been sufficiently evaluated, nor adequately discuss the barriers to the development and implementation of the measure concepts and are better suited for internal improvement.

The NCCC has offered a number of draft recommendations on payment and delivery reforms to better support care for patients with diabetes, many of which the AMA supports. We strongly support the NCCC recommendations for payment reforms that would lead to improved financial and organizational support for:

- Use of physician-led team-based care;
- Flexibility to integrate telehealth, audio-only visits, and digital health tools into care delivery;
- Use of patient-physician shared decision-making tools;
- Education about patient self-management of their condition;
- Integration of behavioral health services;
- Use of monthly care management payments to support practice redesign;
- Provision of timely and actionable data feedback to physicians to help them improve care;
- Payment models with longer on-ramps before downside risk; and
- Providing sufficient support to practices treating marginalized patients to facilitate improvements in health equity.

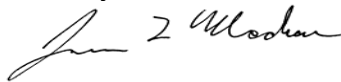
For physicians to successfully redesign the delivery of care, it is important to remove the barriers in the current payment system. The AMA disagrees with the Commission's characterization of value-based care requiring more "incentives" to physicians. Rather, it requires lowering the barriers that practices face in delivering value-based care. An excellent example of this was the rapid and dramatic adoption of telehealth in 2020. No one had to provide any incentives to physicians to adopt telehealth.

Before COVID-19, there were significant barriers to telehealth adoption. Telehealth was only covered by Medicare if the patient was in a rural area and, even then, patients had to go to a facility to receive telehealth services; they could not get them in their homes. Payments for telehealth services were about 30 percent below payments for in-person services. Few services were on the Medicare telehealth list, and some that were had strict frequency limits. Smart phones and mobile apps could not be used for telehealth. Immediately after Congress passed the CARES Act, Medicare made telehealth services available to patients all over the country, not just in rural areas; allowed patients to receive services in their homes and physicians to deliver telehealth from their homes; increased payment rates to equal in-person visits; started paying for audio-only visits; lifted frequency limits and added more than 150 services to the Medicare telehealth list; and allowed use of smart phones and mobile apps.

Once the barriers to telehealth adoption were removed, physicians embraced this innovation with enthusiasm. Other payment innovations face the same barriers. Physicians who deliver preventive services that keep their patients healthier and prevent those with chronic conditions from getting worse will face lower revenues from providing fewer services. Emergency physicians cannot be paid for the transitional care management and support services that are needed to prevent inpatient admissions and allow patients to be safely discharged to their community. There is no payment for developing treatment plans or leading a multidisciplinary team. Patient self-management education coverage is not related to the patient's needs and cannot be provided on a regular basis as often as the patient's condition, treatment plan, and circumstances may require. Practices are not paid for providing standby availability after hours to reduce the need for patients to seek urgent or emergency care, nor can they receive compensation for hiring nurse care managers to do proactive outreach to patients in between visits to help manage their care. Adoption of alternative payment models designed by frontline physicians who know what the barriers are so that needed services are appropriately compensated and barriers are removed is the most effective strategy for achieving more value-based care. Large performance-based payments, global budgets, and shared losses on the other hand are likely to force more of the remaining independent practices to look to large health systems and private equity firms for help to meet capital requirements.

The AMA welcomes the opportunity to discuss our comments with the Commission and identify other areas that would benefit from the inclusion of organized medicine.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD