May 19, 2021

Dear Members of the National Clinical Care Commission:

The Diabetes Advocacy Alliance (DAA) has appreciated the many opportunities that the National Clinical Care Commission (NCCC) has afforded us to provide input for your deliberations and feedback to your ideas and questions. We applaud your efforts and the monumental amount of work that has been done to get to the point where you have generated a draft report of your recommendations to Congress. We thank you giving us the chance to provide comments ahead of your next meetings on June 1 and 22.

As a reminder, the DAA is a coalition of 27 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 with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat this potentially devastating chronic disease.

The DAA recognizes that addressing prevention and management of chronic disease is difficult and often impossible if we do not address social determinants of health (SDOH). The DAA commits to advancing legislation and policies to improve the health and well-being of people with and at risk for diabetes, and ensuring that these policies combat health disparities and SDOH. Through our work, DAA members will continue to advocate for diabetes prevention, screening, detection, and care, while always being mindful of the foundational need for food security; access to safe opportunities for physical activity; access to health care, medications, and equipment; improved air quality; access to transportation; and other SDOH.

Overall Comments

Since we have provided the Commission with input via letters and in-person testimony over the past few years, we will keep these comments relatively brief. After reviewing your draft report, we were very pleased to see how comprehensive your recommendations are, covering not only diabetes prevention, screening, detection, and care, but also health equity, diabetes technology, team-based and virtual care, access to health insurance and medications, quality measures, coverage and payment models, the digital divide, coordination among federal agencies, food supply, sugar-sweetened beverages, food labelling, and housing, among other topics.

Because your report is so comprehensive and extensive, **the DAA recommends that the Commission's final report to Congress be organized to emphasize and reflect a hierarchy of needs, beginning with the most urgent recommendations**. The DAA also suggests that the Commission **consider a format that would separate program-related recommendations from research-related recommendations, as these types of changes are often handled by different committees in Congress**. We also want to ensure that Congress understands that, while there

may be research gaps that need to be filled, the many urgent policy changes put forth by the Commission do not need to be delayed.

DAA Perspective on What Is Most Urgent for Congress to Address

The DAA has reviewed the draft recommendations and has offered comments in response to certain recommendations as they apply to serious, ongoing issues for which the DAA has long advocated in its interactions with members of Congress and federal agencies. The DAA offers our strong support for many of the recommendations and has provided additional feedback in other areas for the Commission's consideration.

The DAA respectfully suggests that these recommendations be emphasized in your final report to Congress, as they apply to serious, ongoing issues for which the DAA has long advocated in its interactions with members of Congress and federal agencies:

<u>Health Equity (p.1)</u>
The DAA supports thus recommendation (CMS and other agencies including VA, HRSA, IHS, DoD, BoP):
"Health equity as a component of any new or revised policy related to diabetes.
For any new or revised policy related to diabetes, the relevant federal agency will consider and evaluate the impact on health disparities. Federal agencies will ensure collection of appropriate and relevant data and will use such data to assess and improve the impact of their policies and/or regulations on health disparities among persons with diabetes."

<u>Actions to Increase Uptake of DSMES/DSMT (pp. 1-2)</u>
The DAA supports all of these recommendations:

- "Expand access and reduce barriers to delivery of DSMT
- Reduce administrative burden regarding standards and documentation requirements for DSMES programs
- Create a task force with the authority to update the Medicare Quality Standards (1997) that govern DSMT
- Establish a process for ongoing timely review, updating and revision with input from external stakeholders
- Prioritize funding for innovative research to explore factors that affect referrals to and patient uptake of DSMES, such as: patient, clinician, and systemic-level barriers, quality measures and incentives, and patient reported outcomes and perspectives
- Telehealth waiver for DSMES/DSMT made permanent"

<u>Actions Related to Diabetes Prevention</u>
Focus Area 1. The DAA supports recommendation #2 (p. 4): "Expand coverage for screening/diagnostic tests used to confirm prediabetes. Recommendation: CMS should provide coverage for hemoglobin A1c testing when used to screen for prediabetes."

Focus area 1, Recommendation #3 (p. 4): "Establish a new clinical quality measure for screening of abnormal blood glucose. Recommendation: Endorsement and promotion of the 2019 AMA-proposed prediabetes quality measure related to screening for abnormal blood glucose by all federal agencies that directly deliver or influence the delivery of care." The DAA agrees with the

Commission's rationale and supports the American Medical Association's proposed quality measure.

Focus Area 2, Recommendation #2 (p. 6): "Identify or establish a federal inter-agency coordinating body within HHS to review, support, promote, and implement proven evidence-based programs shown to be effective in preventing or delaying type 2 diabetes." **While the DAA supports the establishment of a federal interagency coordinating body, we do so in the sense of fulfilling a need for such a body to coordinate on all aspects of federal work related to diabetes, obesity, and other metabolic disorders. We disagree with the Commission in presenting this recommendation narrowly on the prevention of type 2 diabetes.** Also, the Commission, when discussing evidence-based diabetes prevention programs, should be specific and cite the two evidence-based federal programs that currently exist: the National Diabetes Prevention Program (National DPP) that is administered by the CDC, and the Medicare Diabetes Prevention Program (MDPP) expanded model at CMMI/CMS, that specifies that its suppliers must be recognized by the CDC's Diabetes Prevention Recognition Program (DPRP), which is a core component of the National DPP.

[The DAA wishes to share some background information about the CDC's National DPP and its DPRP to provide important context to the NCCC. The CDC has set up the DPRP in a manner that permits and encourages innovation and can recognize evidence-based innovative diabetes prevention service models. The DPRP allows programs/providers to apply to be recognized through provision of data that support their content and delivery models and does not require use of the CDC developed content and approach. Thus, there are two pathways to be recognized by the DPRP: 1) Use of the CDC content with delivery on the CDC frequency schedule; OR 2) Delivery of a program in a different way or on a different schedule with CDC content OR different content, as long as pilot or randomized controlled trial data are provided to CDC showing that the program delivers the same outcomes.

The CDCs flexible approach has been key to development of virtual DPP, and it is also what allowed for WW (formerly Weight Watchers and a DAA member) to achieve recognition of a continuous enrollment model (WW also does not use the CDC content but operates with WW content). The CDC's approach recognizes, encourages, and embraces innovation and provide additional reasons why the DAA believes the Commission should specify the CDC's National DPP as the federal evidence-based program for prevention of type 2 diabetes.]

Focus Area 2, Recommendation #3 (p. 7): "Promote coverage for all proven modes of delivery (in-person, asynchronous, and synchronous/video) for evidence-based interventions that produce successful patient outcomes consistent with the National DPP quality standards in delaying or preventing type 2 diabetes." The DAA suggests the addition of the content highlighted in yellow.

Focus Area 2, Recommendations #4, 5, 6 (pp. 7-8): "Continue efforts to streamline the CDC recognition process and CMS payment process for the National DPP while maintaining quality." **The DAA suggests splitting this one recommendation into two because it addresses policy changes at two separate agencies**. We suggest the first recommendation be, "Continue efforts to streamline the CDC recognition process and data reporting requirements." The DAA agrees with the Commission's rationale made in support of this recommendation.

For the second recommendation statement, the DAA suggests: “Improve CMS payment policies for the MDPP.” There are significant problems with the current CMS payment amounts and processes for the MDPP expanded model that are largely due to the fact that CMMI deviated from the National DPP protocol and made the MDPP expanded model a two-year program versus the National DPP’s one-year program. Payments to suppliers of the MDPP are inadequate to cover costs of a two-year program. Also, payments come only after weight loss milestones have been achieved, and many program suppliers are community-based nonprofit organizations and cannot float the upfront costs to deliver the MDPP. These suppliers have decided that the MDPP does not make economic sense for them. Also, because CMMI/CMS has designated MDPP suppliers as “high risk,” these suppliers see legal and other risk issues associated with this designation. The net results are that many of the most vulnerable high-risk Medicare beneficiaries have few or in many cases no options for participating in a diabetes prevention program, which is exacerbating health inequities.

Focus area 2, Recommendation #7 (p. 9): “Provide funding to support the testing of new models that allow for greater up-front payments and more equitable risk-sharing between payers and MDPP program delivery organizations. (CMS)” **The DAA believes that CMS can fix a number of ongoing problems that threaten the existence of the MDPP through the Medicare Physician Fee Schedule process**, therefore negating the need for new models. While the DAA agrees with the need for “greater up-front payments and more equitable risk sharing,” the DAA does not believe that additional models are the answer; rather, **the DAA has strongly urged CMMI/CMS to immediately implement the 1-year model that they originally tested** with the YMCA of the USA, evaluate progress, and only then consider additional models. The Commission has well-articulated the problems that urgently need to be fixed in the MDPP and CMS already has the data needed from the original CMMI pilot to realign the MDPP payment scheme with a 1-year program.

Recommendation (NIH, CDC) on p. 10: “The NCCC recommends more research on the number, frequency, and content of “booster” doses (i.e., lifestyle intervention sessions) needed, to effectively sustain weight loss and type 2 diabetes prevention in the longer-term, after successful completion of a (1 year) diabetes prevention intervention.” **While the DAA believes this type of research could be useful, we also believe that programmatic changes do not necessarily have to wait for the completion of research**. There should be no lifetime cap until research demonstrates there are significantly diminishing/zero returns after X times through the program. Most other similar benefits are treated this way and such an approach would be in line with the spirit of the Affordable Care Act’s elimination of lifetime benefit caps.

The DAA also notes that, in addition to lifestyle, there are other interventions that have evidence to support their use for diabetes prevention and sustaining weight loss – evidence-based interventions for obesity. Clinical guidelines recommend treatment of obesity through intensive behavioral therapy (delivered by all modalities: community, online and telephonic), pharmacotherapy, and/or surgery, but Medicare and private payers do not currently cover the full spectrum of interventions for obesity – interventions that are also important to curbing cases of prediabetes and type 2 diabetes.

Focus Area 4, Background type 2 diabetes prevention research (p. 11). Recommendation: “The NCCC recommends funding:

1. to promote widespread implementation of the most effective in-person and virtual diabetes prevention programs.
2. to study impediments to participation in effective diabetes prevention programs for the communities of greatest need.
3. to disseminate new knowledge about effective diabetes prevention programs both in-person and virtual.
4. To study and develop new medications that delay or prevent the onset of type 2 diabetes and its complications."

The DAA agrees with all four recommendations. Regarding #4, to study and develop new medications that delay or prevent the onset of type 2 diabetes and its complications, the DAA urges the Commission to consider that such medications already exist.

Since the majority of adults with prediabetes and type 2 diabetes are people with overweight or obesity, we believe 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 in the longer term. 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 currently cover the full spectrum of interventions for obesity – interventions that 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 have been shown to be major risk factors for hospitalizations and death from COVID-19.

<u>Prevention, General Population</u>
Recommendation #1 (pp. 12-13): "The NCCC recommends the creation of the Office of National Diabetes Policy (ONDP) in the Domestic Policy Council of the Executive Branch (akin to the Office of National AIDS Policy) to develop and facilitate a national diabetes strategy that leverages and coordinates the work of relevant federal departments and agencies as outlined in the NCCC report. The NCCC also recommends that a new federal program be created within the Office of the Secretary of HHS to work with the ONDP to foster broad, trans-agency collaborative work aimed at positively changing the social and environmental contexts that are promoting the type 2 diabetes epidemic. In addition to departments and agencies within DHHS, this entity should include, but not be limited to, the Departments of Agriculture, Transportation, Education, Justice, Defense, Labor, as well as the Federal Trade Commission, Environmental Protection Agency and the Bureau of Indian Affairs."

The DAA commends the Commission for including this recommendation and urges that it be positioned as a priority recommendation in the Commission's final report. This recommendation captures the spirit of something many members of the diabetes community have wanted since the late 1990s – a national, across-agencies focus on diabetes, similar to what transpired in the wake of the HIV/AIDS crisis. However, as we mentioned in our comments to Focus Area 2, Recommendation #2 (p. 6), we suggest that the Commission broaden the language in this recommendation from "a national diabetes strategy" to a strategy that takes into account diabetes, obesity, and other metabolic disorders.

The DAA also suggests that the Commission examine this recommendation and Focus Area 2, Recommendation #2 (p. 6) where interagency coordination is also mentioned. These two recommendations could potentially be combined to reduce redundancy in the final report.

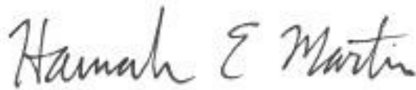
Background Type 1 Diabetes Prevention Research

The DAA supports this recommendation (p. 12): "The NCCC recommends funding the special diabetes program in five-year increments so that new, innovative research can effectively be developed." The DAA has consistently advocated for the special diabetes program and agrees with the Commission that a five-year versus two-year period of authorization makes more sense for the reasons the Commission has cited.

In conclusion, we again thank the Commission for its work and for providing the opportunity for comment. DAA representatives will attend upcoming NCCC meetings on June 1 and June 22, and we look forward to hearing from you about the feedback you receive to your draft report. As always, we would be happy to elaborate upon or clarify any points in this letter of special interest to the Commission.

Members of the DAA greatly appreciate the Commission's efforts and we believe your work will make a difference for people with and at risk of diabetes.

Sincerely,



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