October 8, 2019

Dear National Clinical Care Commission members:

The Diabetes Advocacy Alliance (DAA) continues to support the activities of the National Clinical Care Commission (Commission) as evidenced through several letters and oral comments we have provided to the Commission. We write today to highlight several key issues our organizations have identified for consideration by the Commission and offer our expertise to the Commission on these topics. DAA member organizations and their subject matter experts offer to present "deep dives" on any of the topics outlined below at an upcoming Commission meeting. We stand ready to serve as a resource to the Commission as you continue to evaluate and provide recommendations on the coordination and leveraging of federal programs related to complex metabolic or autoimmune diseases that result from insulin-related issues such as diabetes.

As you know, health care is changing at a rapid pace, yet our coverage and payment systems has not advanced in the same way. Much of the care individuals receive, including for people with diabetes and prediabetes, is delivered by allied health professionals and/or delivered outside the physician office. Delivery of care is changing for people with diabetes and prediabetes and our health system, including Medicare, needs to adapt. The DAA would like to note five specific areas of innovation to highlight this point and offer to present a "deep dive" to the Commission to better understand its impact on people with diabetes.

<u>Innovations in Diabetes Prevention Programs</u>

The YMCA has been working with the Centers for Disease Control and Prevention (CDC) to continually innovate the National Diabetes Prevention Program's delivery. Strategies include the utilization of a digital program retention tool to increase the capacity of organizations to retain participants once they have begun the program. Additionally, the Y is piloting three Diabetes Prevention Program delivery projects. These are focused on patient recruitment and retention strategies, health care provider engagement, and piloting a system approach to facilitate an electronic, closed feedback loop (referral and participant progress) between a community-based program and their health care provider's electronic health record system, using the Fast Healthcare Interoperability Resource (FHIR) standards for bi-directional services e-referral (BSeR). Also, the Y is also working with CDC and HealthBegins to improve health equity by training lifestyle health coaches as Community Health Detailers (based off the model employed by pharmaceutical companies to promote drugs) with the goal to increase referrals for individuals and communities with high levels of health-related social needs from the healthcare sectors to evidence-based programs like the Diabetes Prevention Program. The Y is willing to provide the Commission with a detailed overview of how it is working to improve the DPP and share best practices related to recruitment, retention and referral.

Virtual Medicare Diabetes Prevention Program (MDPP) Expanded Model

Half of all Medicare beneficiaries have prediabetes placing them at high-risk of developing type 2 diabetes. In April 2018, Medicare began reimbursing for diabetes prevention through the Medicare Diabetes Prevention Program (MDPP) expanded model. Unfortunately, Medicare prohibits virtual programs from participating in the MDPP expanded model. Because the current geographic distribution of in-person MDPP suppliers is limited, the restriction on virtual providers significantly impacts beneficiary access to diabetes prevention. For example, CMS' website indicates there are currently no in-person MDPP suppliers in the state of Louisiana. However, virtual providers such as Omada Health have served thousands of Louisianans.

Omada Health, a DAA member, is a privately-held healthcare service company focused on chronic disease prevention and management. Omada is the largest CDC-recognized provider in the U.S. of the National Diabetes Prevention Program (National DPP). Omada's digitally-delivered version of the National DPP utilizes human coaches, personalized content approved by the Centers for Disease Control and Prevention (CDC), all other required elements of a fully-recognized DPP, as well as several additional features possible only because of their digital care model. The Omada program is truly cutting-edge and has the potential to benefit thousands of Medicare beneficiaries with prediabetes if only Medicare allowed virtual suppliers to participate in the MDPP expanded model. The DAA encourages the Commission to have Omada present a deep-dive on their program, possibly including a live demo, depending on available technology, to better understand the positive impact it could have for seniors with prediabetes. In addition, we'd like to note that while Omada is the largest, numerous virtual DPPs exist in the U.S. and many are recognized by the CDC and meet appropriate National DPP standards and certification.

Medical Nutrition Therapy for Prediabetes

Medicare covers medical nutrition therapy (MNT) for people with diabetes but does not cover this service for individuals with prediabetes, reducing the options that Medicare beneficiaries have for preventing or delaying the onset of type 2 diabetes. MNT for individuals with prediabetes has been shown in numerous studies to decrease fasting blood glucose, body weight, blood pressure, and waist circumference for patients who received the intervention for at least 3 months. Increased frequency of MNT visits correlated with greater improvements in these metrics. In 2015, a review of 66 programs by the Community Preventive Services Task Force found that programs that combined diet and physical activity counseling decreased diabetes incidence, and that the most intensive programs—primarily led by registered dietitian nutritionists in those studies—were the most effective at obtaining these outcomes. The DAA encourages the Commission to have the Academy of Nutrition and Dietetics present the body of literature on the effectiveness of medical nutrition therapy for treating prediabetes and preventing or delaying the onset of type 2 diabetes.

Diabetes Self-Management Training

The DAA has identified several barriers to utilizing diabetes self-management training (DSMT) in Medicare that we have previously highlighted for the Commission. Even though DSMT is a covered benefit under the Medicare program, only 5% of Medicare beneficiaries with newly

diagnosed diabetes participate in this evidence-based service. CMS has publicly recognized the significant underutilization of DSMT and the DAA has urged the agency through letters and in-person meetings to implement regulatory reforms to expand access to DSMT so Medicare beneficiaries with diabetes can prevent costly complications.

Many serious health complications of diabetes can often be prevented with proper treatment and care, which is why it is critical that people with diabetes have access to a team of health care professionals, medications, devices, and self-management education to help them manage their diabetes successfully. The American Association of Diabetes Educators (AADE) is a member of the DAA. The DAA strongly believes the members of the Commission would benefit from having a diabetes care and education specialist (DCES) (also known as a Certified Diabetes Educator) from AADE attend an upcoming Commission meeting. The DCES could provide a deep-dive on DSMT to help the Commission better understand why improving utilization of this benefit is so important for people with diabetes.

Medicare Coverage of Innovative Diabetes Technologies and Services

In 2017-2018, the DAA worked with the broader diabetes community to successfully resolve a Medicare coverage issue related to beneficiary coverage of continuous glucose monitors (CGMs) used in conjunction with smart devices. While the issue relating to Medicare CGM coverage was resolved, the DAA is concerned that CMS lacks flexibility to cover innovative diabetes technologies as well as approaches to diabetes prevention and self-management through reimbursed health care services. The DAA, working with JDRF, diabetes device manufacturers, and others, has identified an array of issues innovative diabetes technologies and services face in gaining coverage under Medicare. Rapid advances in this space have outpaced Medicare's existing coverage and reimbursement guidelines resulting in overly complicated or even a lack of, access processes for patients, health care professionals and suppliers.

For example, WW (formerly Weight Watchers International, Inc.), a DAA member, has a healthy lifestyle and weight management program for people with type 2 diabetes that is based on a randomized controlled trial (RCT). Participants with diabetes receive the commercially available WW program combined with telephone and email consultation with a Certified Diabetes Educator (CDE). Studies find that individuals showed greater improvements in glycemic control and in weight compared to participants receiving brief standard diabetes nutritional counseling.[1] Unfortunately, the program is currently not delivered in a way that is aligned with Medicare provider types and/or reimbursement rules, so while individuals in the private sector may have access to this innovative approach to diabetes management, Medicare beneficiaries do not because Medicare is currently not reimbursing for them.

The DAA recommends that the Commission explore these areas related to Medicare coverage and reimbursement of innovative diabetes technologies and services and would be happy to

---

[1] O'Neil PM, Miller-Kovach K, Tuerk PW, et al. Randomized controlled trial of a nationally available weight control program tailored for adults with type 2 diabetes. Obesity, November 2016.

have one of our members focused in this policy space brief Commission members at an upcoming in-person meeting.

***

As always, thank you for considering the DAA's comments and recommendations as the Commission continues its work. We stand ready to serve as a valuable resource for the Commission and to assist with providing additional clinical or practical expertise as needed to help facilitate critically important recommendations for new strategies to improve patient care. Should you have any questions, please feel free to contact us.

Sincerely,

Meredith Dyer
Endocrine Society
DAA Co-chair
mdyer@endocrine.org

Karin Gillespie
Novo Nordisk, Inc.
DAA Co-chair
kgil@novonordisk.com

Meghan Riley
American Diabetes Association
DAA Co-chair
mriley@diabetes.org

About the DAA
The DAA is a coalition of 24 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 to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes. The DAA includes the leading diabetes organizations in the U.S. who have come together to advocate for improved diabetes prevention, detection and care.