

June 12, 2019

Dear National Clinical Care Commission members:

The Diabetes Advocacy Alliance (DAA) continues to support the activities of the National Clinical Care Commission (Commission) and we write today to highlight several key issues our organizations have identified for consideration by the Commission. As you know, DAA members led advocacy efforts to introduce and enact the National Clinical Care Commission Act and we strongly believe the Commission will help the nation undertake more proactive and innovative approaches to diabetes and its disease complications, which represent the most significant insulin-related metabolic or autoimmune diseases we face as a nation. We stand ready to serve as a resource to the Commission as you set out 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.

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. The [DAA's priorities](#) are diverse and we urge the Commission to review them as we strongly believe they can serve as a foundation for Commission activities. The DAA's areas of focus are described below.

Medicare Diabetes Prevention Program (MDPP) Expanded Model

More than 30 million Americans have diabetes and another 84 million have prediabetes and are at high risk of developing type 2 diabetes. Prevention of type 2 diabetes is a top policy priority for the DAA because slowing the number of new cases of diabetes is vital to decreasing the human and economic burden of diabetes in America. Scientific research has demonstrated conclusively that type 2 diabetes can be prevented or delayed in adults with prediabetes through both community-based and online settings. The DAA is a long-time supporter of the Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (National DPP) which makes it possible for organizations to get trained and certified as CDC-recognized providers of evidence-based diabetes prevention programs. The DAA has advocated for increased federal funding for the program in addition to expanding coverage for and access to the National DPP.

In addition, the DAA led advocacy efforts for Medicare coverage of diabetes prevention programs which went into effect in April 2018 and was certified by the Centers for Medicare

and Medicaid (CMS) Office of the Actuary that diabetes prevention programs save money and improve health outcomes in seniors in Medicare. The DAA is dedicated to assisting with the implementation and promotion of the MDPP expanded model and in February 2019 we sent a letter to Administrator Verma offering some thoughts about possible modifications that would improve the accessibility and uptake of the MDPP expanded model. Expansion of the National Diabetes Prevention Program (National DPP) to eligible Medicare beneficiaries has the potential to completely transform the trajectory of a pervasive and costly chronic disease. CMS has taken an important step to empower beneficiaries at risk for type 2 diabetes to prevent or delay the disease's onset and reach their full health potential through this program. Successful implementation of this benefit is a top priority for our organizations, and we are committed to working with CMS to ensure that eligible beneficiaries have access to qualified programs that suit their individual needs and drive better health outcomes.

The DAA offered the following recommendations to help increase the number of organizations enrolling as MDPP suppliers as well as increasing the number of Medicare beneficiaries who utilize the MDPP benefit and participate in a diabetes prevention program. The DAA urges the Commission to help implement some of the below recommendations to improve the MDPP expanded model.

Overarching Theme -- Align MDPP services with evidence base & CDC National DPP

During the MDPP rulemaking process, the DAA urged CMS to align with the CDC's Diabetes Prevention Recognition Program (DPRP) guidelines so MDPP suppliers are not hampered by conforming to two different and complex standards. We appreciate that CMS aligned closely with the CDC National Diabetes Prevention Program (National DPP) standards, but we have encouraged CMS to further align with the evidence base where misalignment currently exists. We call out several examples below including the once-per-lifetime limit and coverage of virtual DPPs as areas of inconsistency between the DPRP and MDPP.

In addition, the DAA would like to call out that there is no evidence base for the 9 percent weight loss threshold included in the MDPP; we encourage the Commission to help align with the DPRP on weight loss thresholds as well as those cited in the original Diabetes Prevention Program study. Further, the two programs have inconsistent blood-based screening requirements with a higher value of fasting plasma glucose (FPG) needed in MDPP. We encourage the Commission to address this issue and help further align with the CDC DPRP standards in these areas. The two different values serve as a barrier to clinical practices adhering to evidence-based screening guidelines.

Modify reimbursement to cover reasonable costs

The DAA is concerned that current MDPP reimbursement levels do not cover MDPP supplier reasonable costs. We encourage the Commission to work with CMS to modify MDPP reimbursement to ensure payments for core and maintenance sessions are structured and resourced in a way that supports the patient and enables them to get the services they need. We have urged CMS to consider payment levels that adequately cover the cost of providing core and maintenance session services, respectively. In addition, we have asked CMS to ensure

that MDPP suppliers receive MDPP payments in a timely manner. Small community-based organizations do not have the capital on hand to wait months to receive payments. DAA is concerned about the impact payment delays could have on the ability of some MDPP suppliers to remain part of the program if long waits exist.

The DAA also urged CMS to consider the *distribution* (as opposed to the amount) of payments over the course of the program. For example, most supplier costs (e.g., administrative costs, staffing, beneficiary engagement, recruitment, etc.) are incurred up front or in the initial weeks of the program. This requires MDPP suppliers to amass enough capital to pay for this largely on their own until they receive the first outcomes-based payments. Addressing these capital-related concerns will allow for a greater variety and number of MDPP suppliers (i.e., more community-based suppliers) to offer DPP to Medicare beneficiaries. We recognize and appreciate that CMS has already taken some steps to address this, but we urge the Commission to work with CMS to increase and rebalance reimbursement in the first year in future rule-making.

Provide targeted solutions for special populations

The DAA is concerned the existing MDPP benefit does not allow for targeted solutions for special populations including but not limited to dual eligible beneficiaries. The current payment structure does not consider socioeconomic status. As noted in MDPP rule-making, low-income participants lose, on average, one percentage point less weight than other participants. Given that evidence shows that type 2 diabetes is most prevalent in underserved communities and the CDC has identified this as a priority area of DPP expansion,¹ we strongly urge the Commission to work with CMS to allow for targeted solutions, including but not limited to payment adjustments, for special populations.

Additionally, evidence shows that patients who achieve weight loss of just 2% to 5% reap health benefits including improved glucose, systolic blood pressure, and triglycerides.² DAA is pleased that the CDC has previously acknowledged the impact of socioeconomic status on achieving National DPP goals but specific solutions must be identified for special populations across MDPP and National DPP.

First, we urge immediate, targeted relief from the requirement that each beneficiary achieve 5% weight loss in order for ongoing maintenance sessions to be covered by Medicare. This relief should apply to all dual eligible beneficiaries enrolled in MDPP and to all Medicare beneficiaries receiving MDPP services in low-income or underserved areas.

Additionally, insofar as transportation availability and costs can deter MDPP attendance, we believe CMS should provide supplemental payments to suppliers in underserved areas for the purpose of mitigating transportation for participating beneficiaries. Medicaid diabetes

¹ <https://www.cdc.gov/diabetes/programs/national-dpp-foa/index.html>

² Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care* 2011;34: 1481-1486.

prevention program demonstrations have identified transportation as an acute barrier and we encourage the Commission to work with CMS to address it in the MDPP.

Finally, we urge the Commission work with CMS to continue to align with CDC and the DPRP and to encourage and/or incentivize suppliers, through fully transparent policy, to deliver MDPP in low-income areas.

Remove the once-per-lifetime limit

The DAA is seriously concerned about the once-per-lifetime limit for MDPP. The once-per-lifetime limit punitively denies some beneficiaries the benefits of a program that reduces Medicare expenditures while also improving health outcomes and quality of life for those at risk for diabetes. Research demonstrates that weight loss is extremely difficult and complex, and some beneficiaries may need multiple attempts to be successful.³ The Medicare program publicly acknowledges the science showing the need for repeated use of healthy lifestyle counseling for weight management in its current coverage policy for obesity counseling. Under the Medicare obesity counseling benefit, doctors are allowed to reassess a beneficiary for additional obesity preventive benefits after a six month period if they failed to achieve the original weight loss goal (6.6 lbs).⁴ Smoking cessation is another example of a difficult and dramatic lifestyle change that can require multiple attempts.⁵ In this area too, Medicare coverage policy is aligned with the literature on tobacco cessation and Medicare covers smoking cessation services two times per year for beneficiaries.⁶ The majority of private payers who cover and reimburse diabetes prevention programs consider the intervention an annual benefit and the DPP model test allowed participants to reenroll after the year-long program if they were still eligible.

The DAA strongly urges the Commission to work with CMS to rescind the once-per-lifetime limit and similar to Medicare coverage of obesity counseling and tobacco cessation, provide

³ Wing RR and Phelan S. Long-term weight loss maintenance. *American Journal of Clinical Nutrition* 2005;82:2225-2255.

⁴ Centers for Medicare & Medicaid Services. National coverage determination (NCD) for intensive behavioral therapy for obesity, November 2011. Available online: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&Keyword=obesity&KeywordLookUp=Title&KeywordSearchType=And&bc=gAAAABAAAAA>

⁵ Jones J. *Smoking habits stable; most would like to quit*. Gallup News Services, 2006. <http://www.gallup.com/poll/23791/smoking-habits-stable-most-would-like-quit.aspx> (accessed 21 Aug 2013).

⁶ Centers for Medicare & Medicaid Services. National coverage determination (NCD) for smoking and tobacco-use cessation counseling, March 2005. Available online: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=308&ncdver=1&DocID=210.4&ncd_id=210.4&ncd_version=1&basket=ncd%25253A210%25252E4%25253A1%25253ASmoking+and+Tobacco%25252DUse+Cessation+Counseling&bc=gAAAAgAAAAAA%3D%3D&

beneficiaries additional opportunities to participate in and benefit from MDPP. This will also better align Medicare coverage with the commercial market. The DAA urges the Commission to work with CMS to allow beneficiaries who did not successfully complete the MDPP to reenroll following a six-month waiting period if they meet eligibility criteria. Instituting a six-month waiting period between attempts would align this benefit with the Medicare obesity counseling benefit and address concerns that suppliers might abuse the system by automatically reenrolling participants.

At minimum, the DAA urges that in future rulemaking an exception is allowed for participants who experience a major life event that may impact his or her ability to attend MDPP sessions. We recognize and appreciate that CMS has already taken steps to address some concerns with the allowance for four make up sessions, but we believe there may be circumstances that prevent or derail participation for longer than those four sessions. Examples of major life events may include (but are not limited to): newly-developed health condition (not diabetes-related) by the participant; newly-developed health condition of a loved one; surgery or injury of participant or a loved one; and death of a loved one. We have urged CMS to consider how such an event could impact participation in the core sessions independently from the maintenance sessions and create a viable exception process.

We understand and sympathize with the balance CMS is trying to strike: dis-incentivizing a revolving door approach or “gaming” while simultaneously ensuring Medicare beneficiaries have access to this important preventive service *and* that MDPP suppliers supply cost-effective MDPP services. Yet if CMS leaves the once-per-lifetime rule in place, more guidance is needed to ensure that MDPP suppliers have accurate Part B information before enrolling a beneficiary, especially given the time lag on confirmed Part B enrollment. Until a real-time notification system is established for MDPP suppliers to check beneficiary eligibility for MDPP, when a beneficiary (wittingly or unwittingly) applies to receive the benefit but is later determined to be ineligible based on the once-per-lifetime limit, CMS should supply guidance or payment to MDPP suppliers that would address the costs of services already provided before the MDPP supplier was notified that the beneficiary was determined to be ineligible.

Allow virtual programs to participate in MDPP

Virtual DPP providers (which include the programs delivered in any of the following modes permitted by the CDC DPRP - online, distance learning, and combination) recognized by the CDC are excluded from reimbursement under MDPP benefit. Nearly half of all Medicare beneficiaries – 23 million – have prediabetes and thus are eligible to participate in MDPP (after obtaining a qualifying blood test). Many of these beneficiaries live in frontier and remote, exurban and suburban areas that lack a DPP provider with preliminary or full recognition from the CDC, making those providers ineligible to *apply* to serve Medicare beneficiaries. Additionally, in urban areas providers face challenges in providing sufficient, culturally tailored programming for the large population. When looking at the Medicare population, mobility also becomes a significant issue and represents the most common disability among older

Americans.⁷ This makes getting to medical appointments or weekly in-person DPP sessions especially challenging. Lastly, many seniors consider themselves “snowbirds” and find themselves living in two different locations throughout the year and thus would be unable to complete a year-long in-person diabetes prevention course. A virtual MDPP option would enable them to participate regardless of their location. Qualified virtual DPP providers have the potential to fill gaps in coverage for these beneficiaries.

Without the addition of virtual MDPP suppliers, large rural areas or underserved communities will not have reasonable access to MDPP suppliers. The fundamental value of community-based programs is delivery of needed services where consumers live and work, and the success of DPP programs relies heavily on lowering barriers to participant access. In the final Medicare Physician Fee Schedule (MPFS) rule, CMS estimated enrollment in MDPP for the initial year between 65,000 and 110,000 Medicare beneficiaries with demand leveling to 50,000 participants per year moving forward. The CMS Actuary calculated an estimated savings of \$182 million based on these projections, with greater enrollment directly correlated with higher savings. Lack of widespread access for eligible beneficiaries will not only result in less access for beneficiaries, but decreased cost savings for the Medicare program. The continued exclusion of qualified virtual programs will be felt most by Medicare’s most vulnerable populations.

In the final MPFS rule, CMS stated the Secretary lacked the authority to include virtual programs, as the demonstration project was conducted via in-person DPP. However, this rationale conflicts with the separate decision to include virtual makeup sessions in the expanded model, as virtual makeup sessions were not included in the demonstration. Furthermore, the stated purpose of the demonstration was to test the impact of the CDC-approved curriculum by a recognized DPP provider and layperson health coaches in preventing type 2 diabetes, not to test a specific location or class schedule. Virtual DPP providers recognized by CDC fulfill all these requirements. In addition, virtual DPP programs have installed a range of program integrity safeguards and can be fully audited on a range of participant measures.

Additionally, the data collected from the CDC National DPP now includes information on thousands of Medicare-age participants who have received the DPP from qualified virtual providers. Of the more than 300,000 people who have participated in the CDC’s National DPP, approximately 60 percent of them have used a virtual program. Therefore, our organizations urge the Commission to work with CMS and the CMS Actuary to consider data CDC has already gathered from virtual DPP providers and reevaluate the decision to prohibit virtual delivery of MDPP. The data for virtual DPP demonstrates comparable efficacy to that of the in-person DPP providers in the CDC database and is the same data source CMS relied upon when deciding for expansion of the in-person program. Our organizations strongly support allowing virtual DPP providers to participate in MDPP.

⁷ <https://www.census.gov/newsroom/press-releases/2014/cb14-218.html>

In-person MDPP suppliers do not have the capacity to serve millions of seniors; allowing virtual providers to participate in MDPP will ensure Medicare beneficiaries have access to MDPP in the format of their choosing, regardless of where they live. If CMS believes it necessary to move forward with a separate virtual model test, we strongly advise the agency to move forward with the test this year, and we urge the CMS Innovation Center to work closely with stakeholders to ensure a successful test and future implementation.

Diabetes Self-Management Training

Since the many serious health complications of diabetes can often be prevented with proper treatment and care, the DAA strongly supports policies improving the care of people with diabetes. 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.

One specific area of focus for the DAA has been related to diabetes self-management education and support (DSMES) which is known as diabetes self-management training (DSMT) in Medicare. 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 urges the Commission to work with CMS to implement regulatory reforms to expand access to DSMT so older adults with diabetes can prevent costly complications. The DAA has identified several barriers to DSMT that we urge the Commission to address:

- Extend the initial 10 hours of DSMT covered by Medicare beyond the first year until fully utilized and cover additional hours based on individual need;
- Allow medical nutrition therapy (MNT) and DSMT to be provided on the same day;
- Remove patient cost-sharing;
- Broaden which providers can refer to DSMT beyond the provider managing the beneficiary's diabetes to include other providers caring for the patient;
- Clarify agency policy that hospital outpatient department based DSMT programs can expand to community-based locations, including alternate non-hospital locations; and
- Pilot virtual DSMT through the Innovation Center.

Medicare Coverage of Innovative Diabetes Technologies and Services

In 2017 and 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 and services. We urge the Commission to examine this issue so that as new diabetes technologies and services are approved by the Food and Drug Administration, there is a coverage pathway in Medicare for them.

Thank you for considering the advocacy priorities of the DAA as the Commission continues its work. As previously mentioned the DAA was highly involved in the introduction of the National Clinical Care Commission legislation and passage and is excited for the Commission to tackle some of these important issue in diabetes. 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.

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