February 3, 2020
Linda Harris, Ph.D.
Designated Federal Officer
National Clinical Care Commission
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 420
Rockville, MD 20852

RE: Solicitation for Public Comments on Questions for the National Clinical Care Commission (HHS-OS-2019-0015)

Submitted via Regulations.gov

Dear Dr. Harris,

As co-chairs of the Diabetes Advocacy Alliance (DAA), we are submitting this letter and attached documents in response to the Commission's solicitation for public comments on behalf of the DAA, a coalition of 24 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations. (See attached letter of October 23, 2018, for more on the DAA.)

While the DAA has a wide variety of advocacy priorities in the areas of diabetes prevention, detection, and care, the DAA believes the Commission could make recommendations in the following five areas and have considerable impact on diabetes prevention and control. (See attached letter from the DAA to the Commission dated June 12, 2019 for additional information.) **Our comments are most applicable to the Commission's question areas #2 (Policies), #4 (Promising Practices), and #5 (Limitations and Gaps).**

Current Misalignment of Agencies in Diabetes Prevention (Area #2, Policies and Area #5, Limitations and Gaps). The DAA urges the Commission to better align the standards of the Medicare Diabetes Prevention Program (MDPP) with the CDC's National Diabetes Prevention Program (National DPP) and its Diabetes Prevention Recognition Program (DPRP) guidelines. Better alignment would help MDPP suppliers, currently hampered by having to conform to two different and complex sets of standards. There is misalignment in a number of areas, summarized here (also see attached DAA letter, 6/12/19):

- Currently, the MDPP's required length is 24 months while National DPP recognized programs are 12 months in duration. As even 12 months can be too long for optimal patient participation, the DAA urges the Commission to recommend outcomes research to explore whether similar outcomes could be achieved in programs of shorter duration.

- The DAA strongly urges the Commission to work with CMS to rescind the once-per-lifetime MDPP limit and similar to Medicare coverage of obesity counseling and tobacco cessation, provide beneficiaries with additional opportunities to participate in and benefit from MDPP. Rescinding the limit would 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.

- Our organizations strongly support allowing virtual DPP providers to participate in MDPP. While CDC's National DPRP recognizes virtual DPP providers (which include the programs delivered in any of the following modes permitted by the CDC DPRP - online, distance learning, and combination), these providers are excluded from reimbursement under the MDPP benefit. In-person MDPP suppliers do not have the capacity to serve millions of seniors; allowing virtual providers to participate in MDPP would ensure that Medicare beneficiaries have access to MDPP in the format of their choosing, regardless of where they live. 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. The DAA urges the Commission to work with CMS and the CMS Actuary to consider data that 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. 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.

- In addition, the DAA would like to call out that the MDPP has a higher weight loss threshold (9%) than the threshold in the CDC's DPRP as well as what is 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. The two different blood glucose values serve as a barrier to clinical practices adhering to evidence-based screening guidelines. We encourage the Commission to address both of these issues and help further align the MDPP with the CDC DPRP standards in these areas.

- The DAA also has recommendations for modifications to MDPP reimbursement levels to cover reasonable costs, and encourages CMS to provide targeted solutions for special populations. (See attached DAA letter, dated 6/12/19).

Medical Nutrition Therapy for Prediabetes (Area #4, Promising Practices and Area #5, Limitations and Gaps). 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 improving their health. 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.[1] [2] [3] Increased frequency of MNT visits correlated with greater improvements in these metrics. 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.[4] [5] The DAA encourages the Commission to review the body of literature on the effectiveness of medical nutrition therapy for treating prediabetes.

Diabetes Self-Management Training (DSMT) (Area #2, Policies and Area #4, Promising Practices). Although the evidence base for DSMT is very strong,[6] [7] [8] and 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.

Experimentation Using Medicare Advantage (Area #2, Policies, and Area #4, Promising Practices). The DAA urges the Commission to use Medicare Advantage programs to experiment with coverage of SDOH-related items such as transportation to

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[1] Parker, A.R., Byham-Gray, L., Denmark, R., Winkle, P.J. 2014. The Effect of Medical Nutrition Therapy by a Registered Dietitian Nutritionist in Patients with Prediabetes Participating in a Randomized Controlled Clinical Research Trial. J Acad Nutr Diet 114(11): 1739-48

[2] Academy of Nutrition and Dietetics. 2014. Prevention of Type 2 Diabetes Evidence-Based Nutrition Practice Guideline. Evidence Analysis Library. http://andeal.org/topic.cfm?menu=5344&cat=5210.

[3] Raynor, H.A., Davidson, P.G., Burns, H., Hall Hadelson, M.D., Mesznik, S., Uhley, V., and Moloney, L. Medical nutrition therapy and weight loss questions for the Evidence Analysis Library Prevention of Type 2 Diabetes project: Systematic reviews. J Acad Nutr Diet. 2017; 117: 1578–1611

[4] Balk, E.M., Earley, A., Raman, G., Avendano, E.A., Pittas, A.G., and Remington, P.L. Combined diet and physical activity promotion programs to prevent type 2 diabetes among persons at increased risk: A systematic review for the Community Preventive Services Task Force. Ann Intern Med. 2015; 163: 437–451

[5] Briggs Early, Kathaleen et al. 2018. Position of the Academy of Nutrition and Dietetics: The Role of Medical Nutrition Therapy and Registered Dietitian Nutritionists in the Prevention and Treatment of Prediabetes and Type 2 Diabetes. Journal of the Academy of Nutrition and Dietetics, Volume 118, Issue 2, 343 – 353

and from community-based organizations to increase participation in DPP and DSMT programs.

Regulatory Reforms to Encourage Innovation (Area #2, Policies). The DAA urges regulatory reforms that would allow CMS flexibility to cover innovative diabetes technologies and services, so that as new diabetes technologies and services are approved by the FDA, there is a coverage pathway in Medicare for them. 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.

Thank you for the opportunity to submit these comments to the Commission. As the Commission moves forward with its critically important work to improve patient care, we offer the DAA and our member organization as resources for information and expertise. If you have any questions related to our comments or would like further information, please do not hesitate to reach out to one of the co-chairs. Thank you.

Sincerely,

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[6] Powers, M.A., Bardsley, J., Cypress M., et al. Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Care 2015;38:1372–1382.

[7] Chrvala, C.A., Sherr, D, Lipman R.D. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient Education and Counseling 99 (2016) 926–943.

[8] McCay, D., Hill, A., Coates, V., O'Kane, M., McGuigan, K. Structured diabetes education outcomes: looking beyond HbA1c. A systematic review. Practical Diabetes 2019; 36(3): 86–90.