AMA
AMERICAN MEDICAL ASSOCIATION

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Adam Boehler
Deputy Administrator for Quality and Innovation
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Room 310G-04
Washington, DC 20201

Dear Deputy Administrator Boehler:

On behalf of the physician and medical student members of the American Medical Association (AMA), we applaud the expansion of the Medicare Diabetes Prevention Program (MDPP) model to Medicare patients. At the same time, we strongly urge the Center for Medicare and Medicaid Innovation (CMMI) to expand the program to include virtual diabetes prevention program (DPP) providers that are recognized by the Centers for Disease Control and Prevention (CDC). We are very pleased that as of last month many Medicare patients will be able to benefit from the MDPP expansion. However, many of the most underserved and vulnerable Medicare patients, as well as those in remote areas, will not be able to access the program without immediate action by the Centers for Medicare & Medicaid Services (CMS) to ensure the inclusion of CDC-recognized virtual DPP providers in the MDPP expansion.

Approximately 27 percent of Medicare patients have diabetes, and half of all seniors over age 65 have prediabetes. Medicare spending on services related to prediabetes and diabetes is projected to cost more than $2 trillion over the next 10 years, including $1.7 trillion in federal spending. Preventing or delaying the onset of type 2 diabetes must be a national priority as the disease is costly and places patients at high risk for severe complications and chronic diseases. The implementation of the MDPP is an essential step forward in a national strategy to improve health outcomes and reverse this alarming growth trend of disease burden and cost. The AMA continues to commit our resources, expertise and reach to prevent type 2 diabetes and to improve outcomes for those suffering from this disease. This includes collaborations with the YMCA of the USA and the CDC, and integrated health systems such as Intermountain Healthcare and Trinity Health, to increase physician screening and testing of patients for prediabetes and referrals of at-risk patients to the National Diabetes Prevention Program as well as advocating for the expansion of the MDPP model for both in-person and virtual DPP providers. **We are concerned that the expansion did not include virtual DPP providers despite substantial evidence that virtual programs deliver positive patient health outcomes that meet or exceed the CDC program goals.**

Virtual DPP and the CDC National DPP Data

The AMA strongly urges CMMI to consider all of the new data submitted by the CDC-recognized virtual DPP providers to the CDC National DPP after the CMS Chief Actuary certified the MDPP. The certification was provided in March 2016, yet the data from CDC-recognized virtual DPP providers were not available for review by the CDC until April 2016 because of the CDC's previous recognition

standards. The CDC data now include information on thousands of Medicare-age participants who received the DPP from CDC-recognized virtual providers. There are no statutory or regulatory prohibitions that prevent the CMMI from considering data that are currently available that establish improved patient health outcomes and cost savings associated with the virtual DPP providers. The data submitted by the virtual DPP providers to the CDC demonstrate clinical efficacy consistent with CDC and MDPP program goals. This is the same data source that was relied upon to expand the in-person program because it was relevant to evaluating patient health outcomes and overall efficacy. Based on these data, CMMI is able to expand MDPP coverage to include virtual DPP providers.

Virtual DPP and the Literature

The AMA also strongly urges CMMI to consider clinical literature that establishes clinical efficacy and cost savings or cost neutrality for virtual programs:

Source	Summary
Diabetes Prevention Programs: Effectiveness and Value Final Evidence Report and Meeting Summary July 25, 2016, Institute for Clinical and Economic Review	A Markov based model with a 10-year time horizon was used to compare DPP participants with propensity score-matched community controls with prediabetes. The simulation found a breakeven point at three years, with a positive savings of $1,565 at five years. Smith *et al.* assessed the cost-effectiveness of the Canary Health Virtual Lifestyle Management (VLM) DPP using a Markov model with a 10-year time horizon. Costs and changes in weight came from a pre-post study of the VLM intervention, which estimated an incremental cost of $458 and incremental gain of approximately 0.06 quality average life year (QALYs) compared to usual care in a hypothetical cohort without diabetes. Estimated that the intervention would cost approximately $7,800 per QALY gained from a health system perspective. Using a $100,000 per QALY threshold, the intervention was found to be cost-effective in over 95% of model iterations in a probabilistic sensitivity analysis. However, it should be noted that these results are based on data from one study using a one-year before/after design in 50 patients, 14 of whom already had diabetes.
Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease. Chen F, Su W, Becker SH, Payne M, Castro Sweet CM, Peters AL, et al. (2016), *PLoS* ONE 11(10): e0163627.doi:10.1371/journal.pone.0163627	Participants in the digital IBC intervention, the DPP program, included 1,121 overweight or obese seniors with additional risk factors for diabetes or heart disease. Weight changes were objectively measured via participant use of a networked weight scale. Participants averaged 6.8% reduction in body weight within 26 weeks, and 89% of participants completed 9 or more of the 16 core phase lessons. Markov-based microsimulation model was used to simulate the impact of weight loss on future health states and medical expenditures over 10 years. Cumulative per capita medical expenditure savings over 3, 5 and 10 years ranged from $1,720 to $1,770 (3 years), $3,840 to $4,240 (5 years) and $11,550 to $14,200 (10 years). The range reflects assumptions of weight re-gain similar to that seen in the DPP clinical trial (lower bound) or minimal weight re-gain aligned with age-adjusted national averages (upper bound). The estimated net economic benefit after IBC costs is $10,250 to $12,840 cumulative over 10 years. Simulation outcomes suggest reduced incidence of diabetes by 27±41% for participants with prediabetes, and stroke by approximately 15% over 5 years.
Outcomes of a Digital Health Program With Human Coaching for Diabetes Risk Reduction in a Medicare Population. Castro	A virtual DPP provider conducted a retrospective analysis of Medicare-aged adults' participation in their virtual DPP. The study included 500 Medicare Advantage participants with prediabetes or metabolic syndrome as determined through claims and/or lab data. The results demonstrated that 92% of

Sweet CM, Chiguluri V, Gumpina R, Abbott P, Madero EN, Payne M, Happe L, Matanich R(2), Renda A, Prewitt T, J Aging Health. 2017 Jan 1:898264316688791.	participants completed 9 or more lessons. Among all participants, the average weight loss at 6 months was 8.0% of body weight. Among those completing a full year of the program (86% of participants), the average weight loss at one year was 7.5% of body weight. Among the 69 participants for whom hemoglobin A1C data were available, a 0.14% absolute decrease in A1C was observed at 6 and 12 months. A statistically significant decrease in total cholesterol was observed, as were improved scores on the WHO-5 well-being index and PHQ-4.
Engagement and outcomes in a digital Diabetes Prevention Program: 3-year update. Sepah SC, Jiang L, Ellis RJ, McDermott K, Peters AL, BMJ Open Diabetes Res Care 2017;5:e000422	A virtual DPP provider recently reported 3-year weight loss and glycemic outcomes from a longitudinal study of 187 Omada participants who completed at least 4 sessions of the virtual DPP. The participants were adults of any age (including 65 years of age and older) with prediabetes. The observed weight loss at 16 weeks, one year, and 3 years 5.0% of body weight, 4.7%, and 3.0%, respectively. Change in hemoglobin A1c at three years was a 0.31% percentage point decrease from baseline.
Usefulness of a Novel Mobile Diabetes Prevention Program Delivery Platform With Human Coaching: 65-Week Observational Follow-Up. Michaelides A, Major J, Pienkosz E Jr, Wood M, Kim Y, Toro-Ramos T., JMIR Mhealth Uhealth 2018;6(5):e93	A virtual DPP provider has published the results of a pilot study of 140 adults age 18-75 years with prediabetes. Among participants who completed at least 4 sessions of the program, mean weight loss was 6.15% of body weight at 65 weeks.
Successful weight reduction and maintenance by using a smartphone application in those with overweight and obesity. Sci Rep. 2016;6:34563.	This study included 15,376 users of their mobile app who logged in at least twice. This study was not limited to individuals with prediabetes, but findings from this study are consistent with the smaller study noted above. In this analysis, 68.52% of the app users lost at least 5% of their body weight.

The literature establishing the effectiveness of virtual DPPs is extensive. The following is a list of additional citations for your consideration:

1. Wilson MG, Castro Sweet CM, Edge MD, et al. Evaluation of a Digital Behavioral Counseling Program for Reducing Risk Factors for Chronic Disease in a Workforce. J Occup Environ Med 2017;59:e150-e155

2. Michaelides A, Raby C, Wood M, Farr K, Toro-Ramos T. Weight loss efficacy of a novel mobile Diabetes Prevention Program delivery platform with human coaching. BMJ Open Diabetes Res Care 2016;4:e000264

3. McTigue KM, Conroy MB, Hess R, et al. Using the internet to translate an evidence-based lifestyle intervention into practice. Journal of Telemedicine and e-health 2009;15:851-858

4. Cha E, Kim KH, Umpierrez G, et al. A feasibility study to develop a diabetes prevention program for young adults with prediabetes by using digital platforms and a handheld device. Diabetes Educ 2014 Sep-Oct;40:626-37

5. Wijsman CA, Westendorp RG, Verhagen EA, et al. Effects of a web-based intervention on physical activity and metabolism in older adults: randomized controlled trial. J Med Internet Res 2013 Nov 6;15:e233

6. Fukuoka Y, Gay CL, Joiner KL, Vittinghoff E. A novel diabetes prevention intervention using a mobile app: a randomized controlled trial with overweight adults at risk. Am J Prev Med 2015;49:223-237

7. Block G, Azar KM, Romanelli RJ, et al. Diabetes Prevention and Weight Loss with a Fully Automated Behavioral Intervention by Email, Web, and Mobile Phone: A Randomized Controlled Trial Among Persons with Prediabetes. J Med Internet Res 2015;17:e240

8. Fischer HH, Fischer IP, Pereira RI, et al. Text message support for weight loss in patients with prediabetes: a randomized clinical trial. Diabetes Care 2016;39:1364–70

9. Vadheim LM, McPherson C, Kassner DR, et al. Adapted diabetes prevention program lifestyle intervention can be effectively delivered through telehealth. Diabetes Educ 2010;36:651–6

10. Weinstock RS, Trief PM, Cibula D, Morin PC, Delahanty LM. Weight loss success in metabolic syndrome by telephone interventions: results from the SHINE study. J Gen Intern Med 2013;28:1620-1628

11. Azar KM, Aurora M, Wang EJ, Muzaffar A, Pressman A, Palaniappan LP. Virtual small groups for weight management: an innovative delivery mechanism for evidence-based lifestyle interventions among obese men. Transl Behav Med 2015;5:37-44

12. Fontil V, McDermott K, Tieu L, et al. Adaptation and Feasibility Study of a Digital Health Program to Prevent Diabetes among Low-Income Patients: Results from a Partnership between a Digital Health Company and an Academic Research Team. J Diabetes Res 2016;2016:8472391

13. Napolitano MA, Hayes S, Russo G, Muresu D, Giordano A, Foster GD. Using avatars to model weight loss behaviors: participant attitudes and technology development. J Diabetes Sci Technol 2013;7:1057-1065

14. Fukuoka Y, Kamitani E, Bonnet K, Lindgren T. Real-time social support through a mobile virtual community to improve healthy behavior in overweight and sedentary adults: a focus group analysis. J Med Internet Res 2011;13:e49

15. Azar KM, Koliwad S, Poon T, Xiao L, Lv N, Griggs R, Ma J. The Electronic CardioMetabolic Program (eCMP) for Patients With Cardiometabolic Risk: A Randomized Controlled Trial. J Med Internet Res 2016;18:e134

16. Moin T, Ertl K, Schneider J, et al. Women Veteran's experience with a web-based diabetes prevention program: a qualitative study to inform future practice. J Med Internet Res 2015;17: e127

17. Kim H, Faw M, Michaelides A. Mobile But Connected: Harnessing the Power of Self-Efficacy and Group Support for Weight Loss Success through mHealth Intervention. Journal of Health Communication 2017; 22:395-402

18. Su W, Chen F, Dall TM, Iacobucci W, Perreault L. Return on Investment for Digital Behavioral Counseling in Patients With Prediabetes and Cardiovascular Disease. Prev Chronic Dis 2016;13:E13

If CMMI does not exercise its discretion to consider additional relevant data related to improved patient health outcomes, we support, in the alternative, CMMI moving forward with a model demonstration to further confirm that virtual program participants achieve positive health outcomes consistent with those seen in the in-person model and expected from the expanded model. The AMA asks CMMI to use the current available data when determining the model test duration of no more than 12 months as well as the enrollment targets. Any opportunity to expedite the model test would give patients access to this needed service as soon as possible. The AMA also strongly urges that CMMI move quickly forward so that the demonstration will be completed as soon as possible. The AMA urges an accelerated time frame for two reasons:

- A substantial body of evidence already supports that CDC-recognized DPP providers meet the outcomes required of in-person programs from the same data source (the CDC) that CMS relied upon when deciding an expansion of the in-person program.
- Participants currently have no option in markets without an in-person DPP available.

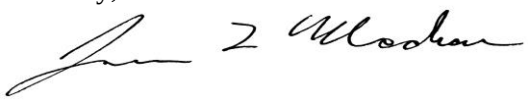
The AMA is also concerned about MDPP providers that lose their vendor license (temporarily or permanently). In prior rule-making the Agency made the assumption that there are multiple in-person programs available to beneficiaries. This assumption is not supported by the current list of programs. There are many areas of the country with only one in-person program in a wide geographic area. If a participant's program loses their MDPP supplier status, the beneficiary can enroll in a different program. But in reality, a virtual program could be the only other option. To put it simply, the DPP was expanded based on projected savings and improved health outcomes that are unlikely to materialize without the addition of a virtual program option.

Conclusion

Substantial, validated data exist to support expansion of coverage to include CDC-recognized virtual DPP providers. Furthermore, there is a tremendous population health need to expeditiously increase access to diabetes prevention programs. Many eligible Medicare patients will not be able to access the program without a virtual option because of a geographic mismatch between where many patients live and the location of in-person programs. The AMA is concerned because the current access and availability of the in-person program with full or preliminary CDC recognition is limited and non-existent in certain markets. The online/virtual option ensures that Medicare patients could take full advantage of the benefit.

If you have any questions, please contact Sandy Marks, Assistant Director, Federal Affairs, at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,



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