



September 2, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS 1654-P
7500 Security Boulevard,
Baltimore, MD 21244-1850

Dear Mr. Slavitt,

Re: Medicare Expansion of Diabetes Prevention Program (MDPP) (CMS 1654-P)

The American College of Preventive Medicine (ACPM) applauds the Centers for Medicare and Medicaid Services (CMS) for expanding the Diabetes Prevention Program as a covered benefit for Medicare Part B beneficiaries. We wholeheartedly support CMS' efforts to increase access to this preventive service which will play a crucial role in addressing the high burden of prediabetes among Medicare beneficiaries.

The American College of Preventive Medicine (ACPM) is the national medical specialty society of physicians dedicated to disease prevention, health promotion and systems-based health care improvement. Established in 1954, ACPM is the leading U.S.-based physician organization focused on practice, research, publication, and teaching of evidence-based preventive medicine. ACPM's 2,500 members are leaders in a variety of health settings, including state and local health departments, federal agencies, hospitals, health plans, community and migrant health centers, industrial sites, occupational health centers, academic centers, private practice, and the military. Our members have the skills needed to understand and reduce the risks of disease, disability and death at the population, community and individual levels.

ACPM strongly recommends the following changes be incorporated into the final rule to ensure the success of the Medicare Diabetes Prevention Program (MDPP):

1. **MDPP Benefit Description - Once per lifetime limit: ACPM strongly recommends that CMS remove the language in 410.79d(2) of the rule that limits enrollment of beneficiaries to only once per lifetime. After reviewing the current body of evidence, we feel that the removal of this language is critical to the success of the program.** The proposed rule limits the coverage of the MDPP to 'only once per lifetime eligible beneficiary' (410.79 d1). The curriculum is structured to address a total of 16 core session topics within the first 26 weeks, some of which include eating healthier, increasing physical



activity, overcoming barriers, managing stress, learning about social cues and staying motivated. The participants are expected to change multiple aspects of their behavior to achieve weight loss, but relapse is common and expected during lifestyle changes.² Stages of change, as it relates to health behavior, is highly complicated and rarely straightforward.³ When participants relapse, it is associated with regression of initial improvements of risk factors toward baseline values.⁴ Social-learning theory suggests that behavioral relapse in patients with risk factors for diabetes is similar to relapse in those with alcoholism, smoking, and obesity and is determined by an interaction of environmental, physiologic, cognitive, and affective variables.⁵ Even when patients complete diabetes treatment programs, relapse rates are high, so lifetime benefit is needed.⁶ Limiting the benefit to once per lifetime per beneficiary is in direct contradiction to the USPSTF recommendation¹ of intensive behavioral counseling with multiple contacts over extended periods of time.

Furthermore, many beneficiaries will also experience additional barriers due to their demographics, socioeconomic status or other social determinants of health which will dictate their ability to successfully modify their behavior. Many social determinants of health, including access to healthy foods, safe neighborhoods, built environment, transportation, level of education, and access to jobs and healthcare play a significant role in the ability of the participants to attend the sessions or understand the effort that goes into making and sustaining behavior change to successfully complete the program. ACPM also recommends that the CMS continue to fund innovation awards to test the cost-effectiveness of offering the MDPP multiple times per lifetime, as needed, to at-risk beneficiaries in markets where there is a high prevalence of people with prediabetes and/or where the community is addressing some of the social determinants of poor health.

2. Enrollment of New Medicare Suppliers- *Requirements for MDPP Coaches*: **ACPM strongly recommends that the proposed rule be modified to allow MDPP lifestyle coaches to obtain a National Provider Identification (NPI) number and not required to enroll in Medicare.** Requiring individual coaches to enroll in Medicare creates a substantial barrier to efficient and effective MDPP program implementation and is unnecessary and unreasonable since this process could take more than six months. The resulting lag time will delay implementation and delivery of MDPP to eligible beneficiaries. Since MDPP suppliers will be filing for reimbursements with CMS, ACPM recommends the inclusion of language in the proposed rule that requires MDPP suppliers to have a program coordinator who will obtain a National Provider Identification (NPI) and enroll in Medicare. CMS should provide clarifying language that enrollment of program coordinators (employed within MDPP supplier organizations) in Medicare is sufficient for all the laws and statutes to apply to the organizations as a whole and to the coaches who will be contracted or employed by the suppliers.

3. Structure of MDPP reimbursement: **ACPM strongly recommends that CMS remove the restriction in the proposed payment which prohibits reimbursement to MDPP suppliers unless participants have achieved a minimum weight loss compared to baseline.** Such a payment structure will inhibit suppliers from optimally implementing the complete curriculum. ACPM is concerned that the proposed payment structure could force suppliers to only enroll healthy participants who can most easily achieve the weight loss requirement. This will disproportionately affect high risk participants from lower socio-economic status who face significant barriers due to various social determinants of health and would be far less likely to achieve the intended outcomes.

ACPM recommends that CMS structure a reimbursement policy that does not adversely affect either the high risk participants who would benefit the most from the MDPP, or the suppliers that serve them. In an effort to receive the proposed payments, organizations and lifestyle coaches could set unhealthy and unrealistic weight loss targets for the participants. ACPM urges consideration of a payment structure that provides reimbursement to a DPP supplier based on a percentage of the organization's clients achieving the intended outcomes, in addition to the proposed reimbursement structure for the core sessions for each participant.

4. MDPP Eligible Beneficiaries: **ACPM strongly recommends that CMS include language in the proposed rule that allow MDPP Suppliers to continue using the paper-based risk assessments as used by the American Diabetes Association (ADA) and YMCA.** The eligibility criteria for the MDPP should focus on enrolling high risk individuals in the program with the goal of preventing future health complications and costs.
5. Quality Monitoring and Reporting: **ACPM strongly recommends that CMS include patient satisfaction as a quality metric for reporting (not payment) to guide beneficiary choice of MDPP suppliers.** Patient satisfaction is a critical additional metric associated with patient activation (and in turn successful behavior modification) and perceived success²⁰, as patients are often among the savviest regarding their needs for lifestyle change and behavior modification.

This metric can also act as a proxy for important predictors of program adherence (including provider-patient relationship, which is recognized by the World Health Organization-), and program outcome.²¹⁻²⁴ Patient satisfaction is usually reported informally via third-party ratings sites and social media platforms. Some industry studies demonstrate that this practice is considered mainstream and is growing in popularity; 77% of the patients used this metric as the first step for seeking healthcare services.²⁵ Public reporting through CMS will benefit potential participants by offering a standardized point of comparison between programs serving widely varied populations.



This metric can also serve to counterbalance the socioeconomic – and thus health outcome – disparities between populations served by varied programs that may be obscured by other metrics such as weight loss and program attendance, which are known to be tightly correlated with socioeconomic status.^{26, 27} As such, reporting patient satisfaction may also encourage programs to serve geographic locations and/or patient demographics associated with limited objective outcomes, which programs may otherwise avoid. **CMS can utilize existing tools such as Medicare Health Outcomes Survey to get feedback from beneficiaries about their experience and satisfaction with MDPP.**

6. Timing of MDPP Expansion: **ACPM strongly recommends that CMS expand the Medicare Diabetes Prevention Program nationwide, as soon as possible, given the high burden of prediabetes.** Since the proposed rule allows MDPP suppliers to enroll up to a year in advance in order to adjust to the various technical requirements, ACPM believes that CMS has sufficient time to resolve any operational issues and make the program available nationwide beginning January 1, 2018.

Phase-in approach: If CMS decides to pursue a ‘phase-in’ approach, ACPM recommends that the initial roll out of the program include underserved populations disproportionately at risk for diabetes. Additionally, CMS should provide a timeline of how quickly it plans to expand the program nationwide.

In addition to the above changes, ACPM has the following recommendations to ensure optimal implementation of MDPP:

7. Recognize MDPP’s alignment with USPSTF recommendation for abnormal glucose screening: **ACPM recommends that CMS formally recognize that MDPP is aligned with USPSTF Grade B recommendation. ACPM further recommends that CMS add MDPP to the personalized prevention plan offered as part of the Medicare Annual Wellness Visit.**^{1b} The Medicare Diabetes Prevention Program (MDPP) does meet the requirement in section 1861(ddd) 1B of the Social Security Act that the program receive a recommendation with a grade of A or B by the USPSTF. In October 2015, the United States Preventive Services Task Force (USPSTF) conducted an evidenced-based review and issued a ‘B’ recommendation for screening for abnormal blood glucose and Type 2 Diabetes Mellitus in adults aged 40-70 years who are overweight or obese.¹ The recommendation also calls for referral of patients with abnormal blood glucose, as measured by fasting plasma glucose (FPG), hemoglobin A1c (A1c), or Oral Glucose Tolerance Testing (OGTT), to intensive behavioral counseling interventions to promote a healthful diet and physical activity. The Center for Disease Control and Prevention’s (CDC) Diabetes Prevention Program (DPP) curriculum proposed as a model for the MDPP is an example of the multi-component behavioral counseling intervention program that is recommended by USPSTF to treat



patients who are overweight / obese or are at risk for diabetes. The proposed rule has already provided an explanation of how the MDPP fulfills the other two requirements described in section 1861 ddd 1A and 1C.

8. MDPP Benefit Description:

A. Curriculum: ACPM recommends that CMS modify the proposed rule to allow MDPP suppliers and coaches to use the DPP curriculum in another language, on a probationary basis for up to 2 years, and with the added requirement that the curriculum has been reviewed by a licensed medical translator and approved by CDC to address all aspects of the CDC DPP curriculum. ACPM supports the requirement that MDPP suppliers and coaches adhere to the CDC- approved DPP curriculum. But the curriculum is not available in all languages, thus inhibiting MDPP suppliers and coaches from providing the program to many non-English speaking beneficiaries.

B. Achieving minimum weight loss: ACPM recommends that the proposed rule allow participants to complete the program by enrolling in the core *or* maintenance sessions during their year-long enrollment; re-enter and engage with any of the core or maintenance sessions without following a particular order and allow coaches to use the entire spectrum of sessions in any combination for maximum benefit of the participants. The proposed rule in 479.10(c) (2)(ii) suggests that participants would be required to achieve and maintain a minimum weight loss before participating in monthly maintenance sessions. The rule also does not allow participants the flexibility to re-engage in core sessions if they relapse and gain weight. Furthermore, coaches are required to address all 16 core sessions within the first 26 weeks without tailoring it to the needs of the beneficiaries. While ACPM agrees that the content of the curriculum is strong and effective, there is too much rigidity in the implementation of the curriculum and the manner in which the participants can access the curriculum. The relapse prevention model suggests that relapse can be avoided by self-management training that includes identification of high-risk situations, training in problem-solving strategies, and development of cognitive coping techniques.⁵ There is a need to develop programs that avoid the common errors including notions that human behavior is rational or that it can be predicted accurately.⁷

9. Including Clinical Entities as New MDPP Suppliers: **ACPM recommends that the proposed rule allow clinical entities (e.g., hospital systems, IPAs, private physician practices, FQHCs & IHS clinics) to offer and bill for providing the MDPP, as long as these clinical entities follow all of the same requirements as other non-clinical MDPP suppliers.** Currently, CDC recognizes more than 800 Diabetes Prevention Recognition Programs (DPRP) that implement the curriculum. But these organizations only reach a total of 40,000 people,⁸ a small percentage of the 86 million individuals who are affected by



prediabetes. Many communities may not have a CDC-recognized program, and many programs continue to face challenges in recruiting participants from their community.⁹ Furthermore it can take between 2-3 years for an organization to be fully recognized by the CDC, and only a small percentage of the programs that apply are granted the certification.¹⁰ The inclusion of our suggested language would also allow clinical entities, that meet the CDC standards, to offer the programs to participants with comorbidities within the context of their medical care.

10. Submission of claims for MDPP services: **ACPM recommends that the proposed rule allow clinical entities to contract with a local MDPP and bill on behalf of that MDPP supplier.** One of the reasons that there may not be a local MDPP supplier available is that many of the non-profit/community-based organizations trying to run these programs do not have the technical capacity for medical billing. The proposed structure also works well for clinical entities that are trying to participate in payment and delivery reform models such as Accountable Care Organizations or that prefer to have the DPP records kept in their own EHR for the purposes of improving quality and outcomes. ACPM suggests that the reimbursement structure for clinical entities be the same as the structure for MDPP suppliers. However, the rule should allow clinical entities to bill separately and simultaneously for coordination of care or chronic disease management if, for example, there is a patient with prediabetes who needs medical management services on the same date of an encounter with an MDPP supplier.
11. IT Infrastructure and Capabilities: **ACPM recommends that the proposed rule allow MDPP suppliers, who lack technical infrastructure, to partner with and use the IT system of a healthcare entity to maintain records and submit claims for Medicare reimbursement.** Many MDPP suppliers may not be able to meet the technical requirements to utilize the free software provided by CMS. It is not reasonable to expect such organizations to have their own record-keeping and billing system without providing an alternative. ACPM's recommendation would also allow such organizations to use the IT systems of healthcare entities to be in compliance with HIPAA and other laws to ensure privacy of the participants' information.
12. Other criteria for MDPP Eligible Beneficiaries: if CMS chooses to restrict the eligibility criteria to what has been proposed in the rule, ACPM suggests the following changes:
 - A. *Fasting Plasma Glucose (FPG)*: **ACPM recommends following the CDC criteria with regard to FPG (100-125 mg/dL) since studies have found that the risk of incident diabetes is continuous as FPG rises, increasing greatly at the higher end of this range.**¹¹ According to current evidence, a slight expansion of the proposed eligibility criteria would aid in better meeting these goals. The CDC eligibility criteria for DPP

patients differ from the proposed MDPP eligibility criteria in regard to BMI and fasting plasma glucose (FPG). In addition, it has been shown that impaired fasting glucose (IFG) does not always accurately predict the probability of developing diabetes or the likelihood of diabetic pathology.¹² Therefore, using the lower cut-off point that is listed in the CDC criteria as well as in the ADA Standards of Care will more effectively identify individuals at risk for developing diabetes.

B. BMI: Given that above-normal weight individuals of certain ethnicities (e.g. Hispanics and Asians) have a high prevalence of prediabetes, **ACPM recommends that the CDC BMI criteria be followed in order to best prevent diabetes in all groups**, using a cut-off value of BMI of ≥ 24 for non-Hispanic, non-Asian patients, and a BMI of ≥ 22 for Asian patients. ACPM also suggests changing the BMI cut-off value for Hispanics to ≥ 23 to better include prediabetes findings in this group.^{13, 14}

C. Hypertension/High Cholesterol/Triglycerides: **ACPM recommends that CMS establish eligibility criteria that incorporate other significant risk factors, such as family history, hypertension, high cholesterol, and high triglycerides, to determine eligibility among patients for whom abnormal blood glucose values are not available.** Evidence suggests that including such risk factors in the eligibility criteria for the MDPP will enhance recruitment of at-risk individuals.¹⁵⁻¹⁷ For instance, studies have estimated that extending MDPP eligibility to patients who are overweight or obese (BMI ≥ 24) and who have hypertension and/or high cholesterol, even if they are not prediabetic as per lab values, would result in additional health benefits for patients and also yield large Medicare cost savings.^{18,19} The proposed rule must clarify whether these additional criteria such as BMI, family history, hypertension, high cholesterol, and/or high triglycerides will be considered separately or in addition to a blood test to determine the eligibility of participants.

13. Program Integrity: **ACPM recommends that the proposed rule clarify that healthcare providers are encouraged but not required to provide feedback about MDPP programs that are not in compliance with CMS or that engage in fraud and abuse.** Healthcare providers, insurers and health systems across the country are reforming their delivery system to provide coordinated care and improve health outcomes. Thus MDPP suppliers, coaches and providers should communicate, as needed, to coordinate the needs of the participant and ensure that the participant is receiving full benefits from the program. Regular communication between suppliers and physicians will also help maintain the integrity of the program and reduce the risk of fraud and abuse. For participants who do not have an established primary care physician, CMS must require the MDPP suppliers and coaches to provide a list of Medicare providers in the participants' community and encourage the participants to establish primary care. But physicians are already overburdened with clinical



and administrative duties and should not be required to take on the additional task of monitoring the quality MDPP suppliers. Thus, we recommend that the language in the proposal encourage, but not require, physicians to provide feedback.

14. **Site of Service:** **ACPM recommends that the proposed rule include language allowing MDPP suppliers who offer their services remotely, to offer all modules of the curriculum live or asynchronously in a manner that make lifestyle coaches accessible to participants.** In addition, lifestyle coaches should be able to offer real-time assistance to those who are participating remotely. ACPM applauds CMS' proposal to allow MDPP suppliers to offer their services through remote technology. In addition, ACPM also supports CMS' proposal to not include these benefits as part of Medicare telehealth services. However, major barriers such as inflexible timing and lack of sufficient transportation may prevent beneficiaries from participating in MDPP services in person. Providing reimbursement for services offered asynchronously would not only increase patients' ability to participate, it could also increase the number of patients a given coach can sustain, with a downstream effect of increased access to a program demonstrated to be effective.

ACPM recommends that CMS also clarify the timeframe in which MDPP suppliers are required to claim reimbursement for offering live and asynchronous sessions. For those participants who are referred to the MDPP suppliers by their physicians, their baseline and subsequent weigh-ins can be completed with their physicians. This would also ensure periodic communication between the physicians and the suppliers and would help mitigate fraud and abuse. Self- and community-referral participants should also be able to complete their periodic weigh-ins with their physicians once they are referred to Medicare physicians by MDPP suppliers. The metrics for evaluation of the online programs should be equivalent to that of the programs delivered in person.

15. **Learning Activities:** **ACPM recommends that CMS offer sufficient technical assistance to all MDPP suppliers on the following issues:**

- A. **Clarify the meaning of preliminary recognition:** Organizations that apply to be recognized by the CDC to offer DPP are classified in two ways: pending and full. However, CMS uses the term 'preliminary' for organizations that are not fully recognized by CDC. Hence, CMS should provide technical assistance that includes the exact definition of preliminary recognition of MDPP suppliers and how this recognition is different from or similar to the 'pending status' offered by the CDC.
- B. **Crosswalk between CMS and CDC:** MDPP suppliers should have clear instructions regarding which beneficiary identifiers they should report to CDC and which ones they should submit to CMS. In addition, CMS should stipulate the additional technical



infrastructure that will be required by the suppliers to maintain the crosswalk between CMS and CDC.

- C. ***NPI and Medicare enrollment:*** Program coordinators within MDPP supplier organizations will need assistance to enroll as Medicare providers. Coordinators, along with lifestyle coaches, should be offered technical assistance to obtain an NPI. Additionally, CMS should offer technical assistance to MDPP suppliers regarding regulation adherence as they claim reimbursements from Medicare.

- D. ***Reporting data:*** In addition to offering technical assistance on data security, claims submission, and medical record keeping, CMS should offer assistance to MDPP suppliers, particularly those who are new to Medicare, on how to accurately and periodically report data collected from the beneficiaries. MDPP suppliers will need additional assistance and clarification to adhere to the different reporting requirements of CDC and CMS, as well as the data they will be asked to share with physicians of beneficiaries.

- E. ***Reimbursement Timeline:*** ACPM recommends that CMS offer financial assistance for MDPP suppliers who are financially limited, so that the suppliers can remain financially sustainable while awaiting reimbursement for DPP programs services. The proposed rule allows for CMS to reimburse MDPP suppliers to enroll and begin offering the DPP beginning January 1, 2017. However, the suppliers can only claim reimbursement for these services, a year later; beginning January 1, 2018. This one year lag time can be cost-prohibitive and could prevent many small, resource-constrained organizations from enrolling as a DPP provider, thus limiting the program's reach in neighborhoods and communities where they may be needed the most.

- F. ***Continuing Education:*** ACPM recommends that CMS partner with the CDC to develop and maintain a clearinghouse of up-to-date, evidence-based resources for the continuing education of DPP suppliers and coaches, to include expanded instruction regarding stress management, its role in diabetes prevention and behavior modification, and practical tips for its effective provision. ACPM offers its support in developing these resources.



We thank CMS for providing an opportunity to comment and help finalize the rules of Medicare Diabetes Prevention Program for its optimal implementation. ACPM members, who have expertise and experience in utilization of the Diabetes Prevention Program, are available to provide additional guidance.

If you have any questions or need any additional information, please contact Paul Bonta, (pbonta@acpm.org) Associate Executive Director of Policy and External Affairs at ACPM.

Sincerely,

A handwritten signature in black ink that reads 'Daniel S. Blumenthal'.

Daniel S. Blumenthal, MD, MPH, FACPM
President, American College of Preventive Medicine

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