AMERICAN JOURNAL OF
Preventive Medicine

CURRENT ISSUES

Proposed Medicare Coverage for Diabetes Prevention: Strengths, Limitations, and Recommendations for Improvement

Natalie D. Ritchie, PhD,[1,2] Edward P. Havranek, MD,[3,4] Susan L. Moore, PhD, MSPH,[4,5] Rocio I. Pereira, MD[3,6]

INTRODUCTION

In July 2016, the Centers for Medicare and Medicaid Services announced new proposed Medicare coverage for the National Diabetes Prevention Program (DPP) that leverages provisions of the Affordable Care Act.[1] The National DPP is a year-long lifestyle change intervention available through structured in-person or online classes. The National DPP has been widely disseminated following efforts led by the Centers for Disease Control and Prevention (CDC) to translate a successful clinical trial of intensive lifestyle support that led to a 58% reduction in diabetes incidence in adults with prediabetes.[2] The Centers for Medicare and Medicaid Services proposal offers an unprecedented opportunity to ensure coverage starting in 2018 for the estimated 51% of seniors who have prediabetes.[3] Notable strengths include allowing lay healthcare professionals to deliver the National DPP and offering extended diabetes prevention coverage beyond an initial 1-year period. However, the proposal also has critical limitations that are important to address, especially given implications of setting precedent for Medicaid and other third-party payers to follow. As researchers and professionals at a large safety net healthcare organization delivering the National DPP, the authors offer a critical analysis of proposed Medicare coverage along with suggested improvements.

Denver Health has offered the National DPP since March 2013 with more than 2,500 enrollees to date. A diverse group of high-risk participants was reached comprising 60% Latino, 20% African American, and 20% non-Hispanic white. One quarter of all enrollees were Medicare beneficiaries, while nearly one half had Medicaid. Additional expertise was gained through extensive research and program evaluation, participation in state and regional meetings to share best practices, and presentations to legislators and insurers to promote coverage. Reimbursement through Medicare and other payers is essential for long-term program sustainability. The current proposed rules have three conditions that would greatly constrain access at Denver Health and other sites.

SITES MUST HAVE PENDING OR FULL RECOGNITION IN THE CDC'S DIABETES PREVENTION RECOGNITION PROGRAM

Standards were established by CDC's Diabetes Prevention Recognition Program to ensure effectiveness and fidelity of the National DPP across sites.[4] There is concern that the standards appear unattainable in many settings. Among more than 1,200 participating sites that were listed, only 72 sites (6%) were listed as having achieved full recognition to date, although the registry does not denote newly enrolled sites that are not yet eligible for full recognition.[5]

Achieving CDC recognition largely hinges on showing that participants obtain at least 5% weight loss on average. However, a meta-analysis of early translations of the National DPP showed average weight loss was 4.0%.[6] More recently, data from large-scale National DPP dissemination across YMCA sites showed that active participants achieved an average of 4.5% weight loss.[7] These results fall below CDC standards, calling into question the suitability of a 5% mean weight loss threshold for reimbursement eligibility. It is also unclear whether achieving at least 5% weight loss is necessary to realize program benefits. In the original clinical trial on which the National DPP is based, each kilogram of weight loss was associated with a 16% reduction in diabetes incidence.[8] Incidence rates appeared to decline

From the [1]Ambulatory Care Services, Denver Health and Hospital Authority, Denver, Colorado; [2]Department of Psychiatry, University of Colorado School of Medicine, Aurora, Colorado; [3]Department of Medicine, Denver Health and Hospital Authority, Denver, Colorado; [4]Department of Medicine, University of Colorado School of Medicine, Aurora, Colorado; [5]Department of Patient Safety and Quality, Denver Health and Hospital Authority, Denver, Colorado; and [6]Department of Endocrinology, University of Colorado School of Medicine, Aurora, Colorado

Address correspondence to: Natalie D. Ritchie, PhD, Denver Health and Hospital Authority, 777 Bannock St., MC 6000, Denver CO 80204. E-mail: natalie.ritchie@dhha.org.

0749-3797/$36.00
http://dx.doi.org/10.1016/j.amepre.2017.02.005

linearly with weight loss.[8] As such, weight loss of 3% or 4% would likely reduce diabetes incidence rates compared with no intervention at all.

Organizations can avoid failing standards by withdrawing from the CDC recognition program and reapplying, which offers a "clean slate" and the opportunity to submit only new data. The proposed Medicare model would allow sites to be re-eligible for payment after 1 year, as opposed to the immediate re-eligibility permitted under current CDC rules. However, a 1-year absence from the recognition program would likely create a coverage gap for many Medicare beneficiaries.

More concerning, there is no provision to ensure that programs adhere to agreed-upon methods for reporting participation and outcomes. Organizations with full recognition have shared in National DPP workgroups that they have used differential methods of reporting to meet requirements. An example is limiting the pool of participants for whom data is reported to only those who have signed agreements to confirm their utmost commitment to the year-long program and weight loss. It is especially concerning that underserved patients who experience systemic barriers to full engagement may be reluctant to sign such agreements and thus dissuaded from participating. Inconsistent reporting standards may also unintentionally penalize organizations using broader eligibility definitions.

A proposed solution is oversight to ensure dissemination sites follow delivery standards and report data appropriately and uniformly, but without imposing requirements to achieve unrealistic outcomes. Following many of the American Diabetes Association's requirements for diabetes self-management programs,[9] which ensure effectiveness and fidelity through robust training, continuing education, quality assurance metrics for program delivery, and record audits, may be helpful.

INDIVIDUAL MEDICARE BENEFICIARIES MUST ACHIEVE 5% OR MORE WEIGHT LOSS TO RECEIVE COVERED SERVICES IN MONTHS 7–12 OF THE NATIONAL DIABETES PREVENTION PROGRAM

The proposed rules for Medicare coverage are more stringent than CDC standards in requiring that individual participants achieve a minimum of 5% weight loss by 6 months to receive covered services in months 7–12. A recent systematic review noted only 20%–64% of participants achieved this goal across programs.[10] For the many participants who may be unlikely to achieve weight loss goals, organizations would be left with the option of continuing to provide the year-long program at the organizations' own cost, charging the participants, or denying services. Requiring individual weight loss also may further health disparities. Specifically, Latinos have been shown to lose less weight in the National DPP than white participants.[11] Thus, Latino seniors may be asked to leave the program at higher rates than white participants.

Requiring quick weight loss to receive covered services in months 7–12 also contradicts evidence that each session is associated with 0.26% weight loss.[6] Greater engagement is expected to yield better outcomes and reimbursement policies should encourage more attendance, not less. Participants in the original lifestyle intervention group also experienced considerable weight regain over time,[12] which is consistent with the poor results of short-term diets expected for the general Medicare population.[13]

Likely consequences of denying coverage are missed opportunities to prevent or delay diabetes onset among the very individuals who want to complete the National DPP. A proposed solution is to support greater duration of engagement, even among participants who lose weight slowly, or who perhaps lose none at all. These participants may experience other health benefits of risk reduction through lifestyle change, although further research is needed to confirm benefits such as improved hemoglobin A1c. Encouraging sustainable weight loss and other risk reduction behaviors in the National DPP that participants are able to maintain over time is recommended. As such, Medicare's proposal to cover extended maintenance sessions beyond the year-long program is encouraging, but this service is important for all participants who want ongoing support. Each year of prevented or delayed incidence matters from a return on investment perspective. Annual healthcare expenditures for prior participants are considerably reduced,[7] and annual healthcare costs can otherwise double after diabetes onset.[14]

THE PROPOSED REIMBURSEMENT AMOUNTS ARE LOW AND LARGELY CONTINGENT ON PROGRAM COMPLETION AND WEIGHT LOSS

The proposed Medicare payment structure for the National DPP does not appear to support a sustainable business model with reimbursement rates tied to individual participant performance. The current payment model offers up to $450 for each participant who completes the year-long program and loses 5% of their body weight at 6 months, and further maintains this loss at 12 months. However, organizations will only be reimbursed up to $175 for each of the many participants (46%–80%[10]) who lose less weight—a difference of $275 per person. A challenge with pay-for-performance models is that organizations must finance the program