J. Expansion of the Diabetes Prevention Program (DPP) Model

1. Summary

This final rule finalizes our proposal to expand the duration and scope of the Diabetes Prevention Program (DPP) model test, which we refer to as the Medicare Diabetes Prevention Program (MDPP) expanded model.[15] The MDPP expanded model aims to prevent the onset of type 2 diabetes among Medicare beneficiaries diagnosed with pre-diabetes. Services available through the MDPP expanded model are MDPP services, which will be furnished in community and health care settings by coaches, such as trained community health workers or health professionals. The MDPP expanded model is a Center for Medicare and Medicaid Innovation (Innovation Center) model that is being expanded in duration and scope under section 1115A(c) of the Act and will be covered as an additional preventive service under Medicare.

We received approximately 700 timely pieces of correspondence containing multiple comments on the MDPP expanded model. We note that some of these public comments were outside of the scope of the proposed rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the corresponding heading.

Commenters ranged from professional organizations, health plans, advocacy groups, individual physicians, and numerous individuals who have direct experience with the National Diabetes Prevention Program (National DPP), and expressed overwhelming support for this model expansion. Commenters raised key considerations as well.

[15] Centers for Medicare & Medicaid Services, Proposed Rules, "Proposed Expansion of the Diabetes Prevention Program (DPP) Model," *Federal Register* 81, no. 136 (July 15, 2016): 46413-46418, https://www.federalregister.gov/documents/2016/07/15/2016-16097/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

Because the MDPP expanded model will be implemented through at least two rounds of rulemaking, we have chosen in this final rule to finalize aspects of this model expansion that will enable organizations to prepare for enrollment. This includes finalizing the framework for expansion and finalizing details of the MDPP benefit, beneficiary eligibility criteria, and MDPP supplier eligibility criteria and enrollment policies.

We are finalizing our proposal to expand the duration and scope of the DPP model test as proposed. We are also finalizing our proposal to designate MDPP services as "additional preventive services" as defined by section 1861(ddd) of the Act. We are finalizing our proposal to use the Secretary's waiver authority under section 1115A(d)(1) of the Act to waive two requirements of the benefit category of additional preventive services: the requirement in section 1861(ddd)(1)(B) of the Act that the services be recommended by a grade of A or B from the United States Preventive Services Task Force (USPSTF) and the requirement of section 1861(ddd)(2) of the Act that the Secretary make the determinations required under section 1861(ddd)(1) of the Act using the National Coverage Determination (NCD) process.

We are finalizing our proposal that the MDPP core benefit is 12 consecutive months and consists of at least 16 weekly core sessions over months 1-6 and at least six monthly core maintenance sessions over months 6-12, furnished regardless of weight loss. Eligible beneficiaries will have access to ongoing maintenance sessions after the MDPP core benefit if they achieve and maintain the required minimum weight loss of five percent. We are adding definitions of "maintenance session bundle" and "maintenance of weight loss" to help provide clarity. We are revising the definition of "CDC-approved core curriculum" to remove specific curriculum topic names. We are also revising the session duration requirement to specify that any session must have a duration of approximately one hour.

We are finalizing the beneficiary eligibility criteria and our referral policy as proposed.

We are finalizing the proposed high screening level for MDPP supplier enrollment, the requirement for coaches to obtain National Provider Identifiers (NPIs), and for DPP organizations to submit a roster of coach NPIs and other coach information upon applying for enrollment. We are modifying our proposal regarding the enrollment of existing Medicare providers or suppliers, and are requiring all DPP organizations, regardless of any existing enrollment in Medicare, to enroll in Medicare as MDPP suppliers in order to furnish and bill for MDPP services.

We are not finalizing our proposal that organizations that deliver DPP virtually or through remote technologies will be eligible to furnish MDPP services to future rulemaking. We intend to address policies related to the delivery of virtual MDPP services in future rulemaking. We are also not finalizing the definition of preliminary recognition. We intend to seek comment on recognition standards in future rulemaking.

We are also deferring certain policies, specifically related to payment, use of coach information during enrollment and monitoring, and other program integrity safeguards to future rulemaking. In particular, specific policies regarding monitoring and enforcement actions for supplier enrollment require future rulemaking. Because we are not implementing such requirements in this rule, we cannot begin any enrollment for organizations seeking to enroll as MDPP suppliers until after the next round of rulemaking is complete in 2017. We intend to begin supplier enrollment before the model expansion becomes effective on January 1, 2018. We intend for organizations to be able to apply to enroll as MDPP suppliers at the conclusion of the next round of rulemaking. We may issue subregulatory guidance to assist in this preparation before subsequent rulemaking is finalized. We will address public comments on sections of the

proposed rule we sought comment on, including payment, quality reporting, and program integrity, in future rulemaking.

The MDPP expanded model will become effective nationwide beginning on January 1, 2018. We will continue to evaluate this expanded model test.

2. Background

In January 2015, the Administration announced the vision of "Better Care, Smarter Spending, Healthier People" with emphases on improving the way providers are paid, improving and innovating in care delivery, and sharing information to support better decisions, and that set goals for payments made through alternative payment models and tied to quality or value. In March 2016, the United States Department of Health and Human Services (HHS) announced that an estimated 30 percent of Medicare payments are tied to alternative payment models that reward the quality of care over quantity of services provided to beneficiaries, nearly a year ahead of schedule.

Diabetes affects more than 25 percent of Americans aged 65 or older[16] and its prevalence is projected to increase approximately 2 fold for all U.S. adults (ages 18-79) by 2050 if current trends continue.[17] Additionally, the risk of progression to type 2 diabetes in an individual with pre-diabetes is 5-10 percent per year, or 5-20 times higher than in individuals with normal blood glucose.[18] Care for Americans aged 65 and older with diabetes accounts for roughly $104 billion annually, and these costs are growing.[19] In total, we estimate that Medicare will spend $42

[16] Centers for Medicare & Medicaid Services, "Chronic Conditions Among Medicare Beneficiaries, Chartbook: 2012 Edition," *Centers for Medicare & Medicaid Services,* 2012, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf.
[17] James Boyle, et al., "Projection of the Year 2050 Burden of Diabetes in the US Adult Population: Dynamic Modeling of Incidence, Mortality, and Pre-Diabetes Prevalence," *Population Health Metrics* 8, no. 29 (2010): 1-12.
[18] X Zhang et al., "A1C Level and Future Risk of Diabetes: A Systematic Review," *Diabetes Care* 33, no. 7 (2010): 1665-1673.
[19] James Boyle, et al., "Projection of the Year 2050 Burden of Diabetes in the US Adult Population: Dynamic Modeling of Incidence, Mortality, and Pre-Diabetes Prevalence," *Population Health Metrics* 8, no. 29 (2010): 1-12.

billion more in the single year of 2016 on fee-for-service, non-dual eligible, over age 65 beneficiaries with diabetes than it would spend if those beneficiaries did not have diabetes -- $20 billion more for Part A, $17 billion more for Part B, and $5 billion more for Part D. On a per-beneficiary basis, this disparity is just as clear. In 2016 alone, Medicare will spend an estimated $1,500 more on Part D prescription drugs, $3,100 more for hospital and facility services, and $2,700 more in physician and other clinical services for those with diabetes than those without diabetes.[20]

Fortunately, type 2 diabetes is typically preventable with appropriate lifestyle changes. The National DPP, administered by the Centers for Disease Control and Prevention (CDC), is an evidence-based intervention targeted to individuals with pre-diabetes, meaning those with blood sugar that is higher than normal but not yet in the diabetes range. The National DPP is a structured health behavior change program delivered in community and health care settings by trained community health workers or health professionals. The National DPP consists of 16 intensive core sessions of a CDC-approved curriculum in a group-based setting that provides practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to sustaining weight loss and a healthy lifestyle. After the 16 core sessions, monthly maintenance sessions help to ensure that the participants maintain healthy behaviors. The primary goal of the intervention is to reduce incidence of type 2 diabetes by achieving at least 5 percent average weight loss among participants. To learn more about the National DPP, please visit http://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html.

[20] Erkan Erdem and Holly Korda, "Medicare Fee-For-Service Spending for Diabetes: Examining Aging and Comorbidities," *Diabetes & Metabolism* 5, no. 3 (2014); The Boards of Trustees: Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, "2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," *Centers for Medicare & Medicaid Services*, 2016, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2016.pdf.; and CMS estimates.

In 2012, the Innovation Center awarded a Health Care Innovation Award (HCIA) to The Young Men's Christian Association (YMCA) of the USA (Y-USA) to test whether DPP services could be successfully furnished by non-physician, community-based organizations to Medicare beneficiaries diagnosed with pre-diabetes and therefore at high risk for development of type 2 diabetes (referred to hereafter as the DPP model test). The DPP model test has been conducted under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative health care payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of patient care.

Between February 2013 and June 2015, the Y-USA, in partnership with 17 local YMCAs, the Diabetes Prevention and Control Alliance, and seven other non-profit organizations, enrolled a total of 7,804 Medicare beneficiaries into the model. Enrolled beneficiaries represented a diverse demographic across the eight states of Arizona, Delaware, Florida, Indiana, Minnesota, New York, Ohio, and Texas. According to the second year independent evaluation report of the DPP model test, Medicare beneficiaries demonstrated high rates of participation and sustained engagement in the Diabetes Prevention Program. Approximately 83 percent of recruited Medicare beneficiaries attended at least four core sessions and approximately 63 percent completed nine or more core sessions. The first and second independent evaluation reports are available on the Innovation Center's website at https://innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/.

3. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary of the U.S. Department of Health and Human Services (the Secretary) with the authority to expand (including implementation on a

nationwide basis) through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the model expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) The Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

● Improved Quality of Care without Increased Spending: The DPP model test was designed to improve care through diabetes-related preventive services in community- and primary-care based settings. Weight loss is a key indicator of success among persons enrolled in a DPP due to the strong association between weight loss and reduction in the risk of diabetes.[21] According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of 9 pounds. Body Mass Index (BMI) was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions. The evaluation also demonstrated a statistically significant reduction in inpatient admissions following the intervention. Based on these findings and results from other DPP evaluations demonstrating the effectiveness of DPP programs in preventing diabetes onset in non-Medicare beneficiaries, some of which were over 65, the Secretary determined that expansion of the DPP model test is expected to improve the quality of patient care for Medicare beneficiaries without increasing spending.

[21] RF Hamman et al., "Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes," *Diabetes Care* 29, no. 9 (2006): 2102-2107.

● Impact on Medicare Spending: The CMS Chief Actuary (referred to hereafter as the Chief Actuary) has certified that expansion of the DPP model test would not result in an increase in Medicare spending. The Chief Actuary has determined that DPP is likely to reduce Medicare expenditures if made available to eligible Medicare beneficiaries based on historical evidence from evaluations of the DPP model test and other DPPs. In addition, to evaluate the longer-term impact of the expanded model, the Chief Actuary developed a model to estimate lifetime per participant savings of a Medicare beneficiary receiving DPP services.

The full Chief Actuary Certification is available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf.

● No Alteration in Coverage or Provision of Benefits: The MDPP model expansion would make MDPP services available to beneficiaries in addition to existing Medicare services, and beneficiaries receiving MDPP services would retain all benefits covered in traditional Medicare. Therefore, the Secretary has determined that expansion of the DPP model test would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

The following is a summary of the comments received and our responses.

Comment: Commenters were overwhelmingly in favor of the proposed expansion and Medicare covering the MDPP services as an additional preventive service. Many commenters offered personal stories of their battles with type 2 diabetes, or caring for those with type 2 diabetes, and expressed gratitude toward the agency for proposing to cover the benefit to prevent future beneficiaries from the challenges posed by type 2 diabetes. Commenters encouraged us to consider ways to increase beneficiary awareness and lower barriers to access. Several commenters expressed their desire to assist us in further development of the model expansion.

Commenters also encouraged us to continue to align with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures (CDC DPRP Standards) on various policies such as supplier requirements, recognition status, and required minimum weight loss percentage. Another commenter recommended that we reimburse for technology such as the continuous glucose monitor. Some commenters encouraged us to continue to take steps toward more preventive models. One commenter disagreed altogether with the proposed MDPP model expansion, stating it allows another high risk supplier type into the Medicare program.

Response: We appreciate the commenters' suggestions to increase beneficiary awareness of the benefit, and look forward to exploring ways we can achieve our shared aims through stakeholder engagement and communications efforts, such as updates to the Medicare & You Handbook. We also hope to engage the public and MDPP stakeholders in further developments and any adjustments we make through future rulemaking, subregulatory guidance, or other guidance, as appropriate. We appreciate the comments to test more preventive models and to pay for technology that could be used in connection with the MDPP expanded model, but those are outside the scope of what we proposed to expand, and we decline to include them in the MDPP model expansion. We disagree with the commenter who believed we should not expand the DPP model test. We describe later in this rule some of the enrollment policies that are intended to protect against the risks introduced by the new supplier class. Additionally, we intend to propose specific program integrity policies in future rulemaking.

Comment: A few commenters expressed concerns that the MDPP model expansion will set a flawed precedent for future model expansions. For example, two commenters expressed concerns that the Secretary's determination that the MDPP model expansion would improve the

quality of care is not substantiated by the evidence, and asked for more discussion of how the MDPP expansion will improve other elements within quality of care, such as patient experience.

Response: We are undertaking the MDPP model expansion in a manner consistent with the statutory requirements of section 1115A(c) of the Act. Therefore we do not agree that expansion of the DPP model test sets a flawed precedent. We also note that the specific data, analyses, and other factors informing the MDPP expansion are unique to this particular model. For example, different approaches to actuarial modeling may be required for a preventive service payment and service delivery model as compared to a payment model focused on treatment. We expect to take into account the specific aspects of each model when evaluating it for expansion. We found that the DPP model test has been shown to reduce risk of type 2 diabetes through weight loss and behavior change. The second year independent evaluation of the DPP model test also found statistically significant reductions in inpatient and emergency room visits and robust engagement by beneficiaries. Expansion of the DPP model test will give eligible beneficiaries access to MDPP services, which are evidence-based, to improve their health. The Secretary has determined that by improving health outcomes, as measured by participation in the DPP and weight loss, the MDPP expanded model will improve beneficiaries' quality of care. Weight loss is a key indicator of success among persons enrolled in the DPP as it predicts the reduced incidence of type 2 diabetes.[22] According to the second year independent evaluation of the DPP model test, which included 6,874 Medicare beneficiaries, those beneficiaries who attended at least one core session lost an average of 7.6 pounds while beneficiaries who attended at least four core sessions lost an average of nine pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries that attended at least four core sessions.

[22] RF Hamman et al., "Effects of Weight Loss with Lifestyle Intervention on Risk of Diabetes," *Diabetes Care* 29, no. 9 (2006): 2102-2107.

Comment: Regarding the Chief Actuary's certification, some commenters expressed appreciation that the determination was made available to the public several months before the proposed rule. One commenter also asked us to clarify if, and how, stakeholders can engage with the certification process in the event that there are outstanding questions of methodology and model assumptions. Two commenters criticized the Chief Actuary's consideration of findings in addition to the DPP model test, such as other DPPs in the National DPP, in making the certification. A commenter stated that the Chief Actuary certified the expansion of a model that is different than the tested model, which the commenter viewed as contrary to the statute. MedPAC expressed concern that the MDPP expanded model would expand far beyond the structure of the initial model test. One commenter expressed concern that this determination was made based on a preliminary, 2-year evaluation.

Response: We appreciate commenters' interest in the certification process. The CMS Office of the Actuary, led by the Chief Actuary, functions in accordance with professional standards of actuarial independence. The statute does not require that in certifying an expansion the Chief Actuary may consider data only from the model evaluation; rather, the statute requires only that the evaluation be taken into consideration.

The Chief Actuary also reviewed data from other sources besides the model evaluations in certifying the Pioneer Accountable Care Organization (ACO) Model, the first Innovation Center model determined eligible for expansion. In April 2015, the Chief Actuary certified that expansion of the Pioneer ACO Model, as it was tested in the model's first 2 years, would reduce net program spending. The Chief Actuary used historical evidence from the formal evaluation of the Pioneer ACO Model as well as the Chief Actuary's independent internal analysis of financial impacts. The Chief Actuary's certification of the Pioneer ACO Model is available at

https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Pioneer-Certification-2015-04-10.pdf. The Secretary also determined that expansion would not limit coverage or benefits, and that expansion would maintain or improve patient care without increasing spending. While the Pioneer ACO Model has not been expanded through section 1115A(c) of the Act, CMS has incorporated successful design elements of the Pioneer ACO Model into the Medicare Shared Savings Program.

The statute does not require that an expanded model test be identical to the initial model test. Indeed, section 1115A(c) of the Act authorizes the Secretary to expand (including implementation on a nationwide basis) the duration and the scope of a model being tested under subsection (b) or a demonstration project under section 1866C of the Act through rulemaking. The rulemaking requirement indicates that the expansion is to be subject to public comment, which, in turn, indicates that the expansion can and should be modified as appropriate to reflect the outcome of the rulemaking process. In addition, we expect that we will need to modify some design features in nearly all cases of expanded model tests, by virtue of the shift in duration or scope. For example, a nationwide expansion may require different policies and operations to manage large-scale provider enrollment or payment than does the initial model test. The Chief Actuary certified expansion of the DPP model test understanding that the expansion would include specific changes driven by policies and operations necessary in bringing the model to a national scale. As the expansion's full design is implemented in future rulemaking, the Chief Actuary will assess whether such expansion will reduce or not increase net program spending, and will update the certification as appropriate.

Comment: Some commenters supported the determination that the DPP model expansion would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries as the MDPP expanded model makes additional services available to eligible beneficiaries. Two commenters asked that in future model expansions we assess the impact of a model on patient access to covered items and services based on a broad evaluation of the direct and indirect barriers to care that may result from a model's expansion.

Response: We appreciate the commenters' support regarding the determination that the expansion of the DPP model test would not deny or limit the coverage or provision of Medicare benefits. We will apply the statutory criteria for expanding a model on an individual basis and will take the particular features of each model into account when making any determinations.

Comment: Several commenters encouraged us to continue to collect data and evaluate the impact of the expanded model test.

Response: We will continue to evaluate this expanded model test as indicated in the proposed rule. Using an evaluation design that could include a before and after assessment and or matched comparison groups, we will examine the impact of the model on utilization of services and cost of care, particularly whether the model has had an impact on the development of diabetes, and other health consequences of diabetes. We will also examine the expanded model's impact on changes in health metrics, such as weight loss.

In general, evaluations of Innovation Center models address the impact of the models on use of services and the quality of care provided, relative to a comparison group, using CMS administrative data and relevant beneficiary experience data when available. Utilization measures can be used to monitor whether beneficiaries are receiving the services that would be expected given beneficiaries' health status. The comparison group generally consists of

beneficiaries who are similar to the beneficiaries receiving services under the model, and are often matched on underlying health status and other important characteristics, including whether the beneficiary is part of another model test. We intend to apply additional information on the evaluation in the future. We will continue to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending, and we will terminate or modify the MDPP expanded model if the expanded model is not expected to meet these criteria.

4. Expansion of the Diabetes Prevention Program Model

We proposed to expand the duration and scope of the DPP model test under section 1115A(c) of the Act, and we proposed to refer to this expanded model as the MDPP. In this section of this final rule, we are finalizing a framework for the MDPP expanded model. We intend to engage in additional rulemaking in 2017, to establish additional requirements of the MDPP expanded model. We solicited comment on all of the proposals below and on other policy or operational issues that need to be considered in implementing this expansion.

a. Designation of MDPP Services as Additional Preventive Services Under Section 1861(ddd) of the Act

We proposed to designate MDPP services as "additional preventive services" available under Medicare Part B. Section 1861(ddd) of the Act defines "additional preventive services" as services (other than screening or other preventive services or personalized prevention plan services described in other sections of the Act) that identify medical conditions or risk factors, and that the Secretary determines, using the National Coverage Determination (NCD) process, are (A) reasonable and necessary for the prevention or early detection of an illness or disability;

(B) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and (C) appropriate for individuals entitled to benefits under Part A or enrolled in Part B.

We believe that MDPP services are consistent with the types of additional preventive services that are appropriate for Medicare beneficiaries. In particular, we believe that MDPP services meet the requirements of section 1861(ddd)(1)(A) of the Act (that is, that they are reasonable and necessary for the prevention or early detection of an illness or disability) because they are specifically designed to prevent pre-diabetes from advancing into type 2 diabetes and their effectiveness is supported by the evaluations of the DPP model test.

We proposed to use the Secretary's waiver authority under section 1115A(d)(1) of the Act to waive two requirements of the benefit category of additional preventive services. MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act in that MDPP services have not been recommended with a grade of A or B by the USPSTF, and thus a waiver of that requirement is necessary. We proposed to use the Secretary's waiver authority to waive this requirement with respect to MDPP services.

We proposed to waive the requirement of section 1861(ddd)(2) of the Act that the Secretary make the determinations required under section 1861(ddd)(1) of the Act using the NCD process. We proposed to waive this requirement because applying the NCD process to the MDPP model expansion is inappropriate, and thus the waiver is necessary. The creation of a new supplier class is necessary for coaches to furnish MDPP services, which the NCD process was not designed to address.

Since Medicare cost-sharing does not apply to additional preventive services, MDPP services would not be subject to Medicare cost-sharing.

We solicited comment on these proposals.

The following is a summary of the comments we received on designating MDPP services as additional preventive services and our responses.

Comment: While some commenters supported the Secretary's use of the waiver authority provided by section 1115A(d)(1) of the Act in expansion of the DPP model test, a few commenters stated that the statute does not permit the Secretary to waive statutory or regulatory requirements when a model is expanded under section 1115A(c) of the Act. These commenters stated that any use of waiver authority in an expanded model is not made "with respect to testing models described in subsection (b)." As a consequence, these commenters stated, the Secretary lacks the authority to waive the provisions of section 1861(ddd) of the Act proposed in the proposed rule.

Response: We disagree with the commenters. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain requirements as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b). We believe that the phrase "described in subsection (b)" is simply a reference that describes the models that are authorized under subsection (b), and that the waiver authority extends to expanded models because they continue to be models described in subsection (b). The language of section 1115A(c) of the Act itself supports this view because it gives the Secretary authority to expand the duration and scope of a model that is being tested under subsection (b).

Therefore, in our view, the Secretary is authorized to waive requirements of Title XI, Title XVIII, and sections 1902(a)(1), 1902(a)(13), 1902(m)(2)(A)(iii), and 1934 of the Act (other than subsections (b)(1)(A) and (c)(5) of such section) in connection with expanded model tests. As the MDPP model expansion is an expansion of the duration and scope of a model described

in and tested under subsection (b), the Secretary may waive Medicare requirements as necessary for the purposes of the expanded model.

Comment: Many commenters believed that the Secretary's waiver of section 1861(ddd)(1)(B) of the Act, which requires that a benefit must be recommended with a grade of A or B by the USPSTF, is unnecessary. These commenters stated that the USPSTF issued guidance in October 2015 entitled Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening, which provided a B rating for intensive behavioral counseling interventions for patients with abnormal blood glucose based on National DPP clinical trial evidence. This recommendation is available at https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/screening-for-abnormal-blood-glucose-and-type-2-diabetes. Because of this recommendation, these commenters suggested, the Secretary does not need to waive the requirement in section 1861(ddd)(1)(B) of the Act.

Response: While the interventions mentioned in the USPSTF's recommendation bears some similarity to the expanded DPP model test, and provides evidence to support DPPs generally, there are differences between the USPSTF's recommendation and the design of the MDPP expanded model, both as initially tested and as we have proposed to expand it. We believe these differences make USPSTF's recommendation inapplicable to MDPP, and therefore the waiver is necessary.

In particular, the specific USPSTF recommendation cited by commenters is for "adults aged 40 to 70 years who are overweight or obese who are seen in primary care settings," which does not include Medicare beneficiaries over 70 who would be eligible for MDPP services or the furnishing of MDPP services by a community service organization.

While the USPSTF recommendation discussed by the commenters does not match with the elements of the MDPP model expansion, we do note that the recommendation supports the principle of the MDPP expanded model. In addition, we have spoken to the USPSTF about its recommendation and shared the findings of the evaluation of the model in case the USPSTF would like to reconsider its recommendation.

Similarly, we note that in 2014, the Community Preventive Services Task Force (CPSTF), a "sister entity" to the USPSTF that is focused on population-based interventions, issued a recommendation for Diabetes: Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes Among People at Increased Risk, specifically recommending "combined diet and physical activity promotion programs for people at increased risk of type 2 diabetes based on strong evidence of effectiveness in reducing new-onset diabetes." The CPSTF recommendation is available at https://www.thecommunityguide.org/findings/diabetes-combined-diet-and-physical-activity-promotion-programs-prevent-type-2-diabetes. We believe that the MDPP expanded model is consistent with the CPSTF recommendation.

Comment: One commenter suggested that the Secretary should not waive the National Coverage Determination (NCD) process required by section 1861(ddd)(2) of the Act. One commenter suggested that it is irrelevant that the NCD process does not address the creation of a new supplier class. This commenter also suggested that the statute does not require CMS to implement an additional preventive service via the NCD process; all it requires is that CMS make the three determinations that are prerequisites for additional preventive service status using the NCD process. This commenter also stated that the timing of the NCD process will not hinder this expansion, suggesting that we have the discretion to expedite the NCD process. Another

commenter suggested that waiving the NCD process is unnecessary because the creation of a supplier class is not hindered by the NCD process.

Response: We disagree that waiving requirements of section 1861(ddd)(2) of the Act is unnecessary. In particular, we disagree with the commenters who believe that using the NCD process would not create timing challenges for the MDPP expanded model. To the contrary, we believe that the use of the NCD process is inappropriate for the MDPP expanded model.

The MDPP expanded model necessitates the creation of a new supplier class that must be able to enroll in Medicare so that it may furnish MDPP services as of the effective date of the expanded model. We are establishing the new supplier class through rulemaking, in conjunction with the model expansion. Contrary to commenters' assertions, using the NCD process to designate MDPP services as additional preventive services would create significant timing challenges, given that we need to expand the model and establish the MDPP supplier class through rulemaking. If we were to use the NCD process to determine that MDPP services are additional preventive services, we would not be able to begin covering MDPP services on the date the NCD was issued, even if it were issued simultaneously with the effective date of a final rule establishing the supplier class. This is because in order to align the effective dates, we would have had to issue a final rule establishing the MDPP supplier class 60 days before we determined that MDPP services were covered by Medicare. Were we to instead issue an NCD simultaneously with the release of a final rule establishing a new supplier class, the benefit would be unavailable for a period of time after the NCD's effective date because of the 60-day delay in effectiveness of the final rule plus time needed thereafter to process MDPP supplier enrollment applications. Because we cannot allow MDPP suppliers to enroll specifically to provide a service that is not yet a Medicare service, we find that it is necessary for purposes of

expanding the MDPP model to waive the requirements of section 1861(ddd)(2) of the Act. This rulemaking establishes MDPP services as additional preventive services that will become available after there is sufficient time to enroll MDPP suppliers to furnish those services, which allows us to avoid timing and logistics problems while also providing the public with the opportunity to comment in a manner similar to the NCD process.

Comment: Commenters overwhelmingly supported the proposal to not hold beneficiaries responsible for cost sharing for MDPP services. A few commenters asked us to clarify that beneficiaries would not have to pay cost-sharing, particularly because they were concerned that cost sharing would restrict beneficiary access.

Response: MDPP services are additional preventive services under section 1861(ddd) of the Act and therefore, consistent with section 1833(a)(1)(W) of the Act, are not subject to the Medicare Part B coinsurance or deductible.

Final Decision: We finalize our proposal to expand the duration and scope of the DPP model test as proposed. We finalize our proposal to designate this benefit as an additional preventive service according to section 1861(ddd) of the Act as proposed, and we also finalize our proposals to waive the requirements of sections 1861(ddd)(1)(B) and (ddd)(2) of the Act as proposed.

b. Timing of the Expansion of the Medicare Diabetes Prevention Program Model

We proposed that the expansion of the duration and scope of the DPP model test would become effective on a nationwide basis beginning on January 1, 2018. Expanding the DPP model test is a complex undertaking, which could be approached in different ways, such as expanding the scope of the DPP model test nationally in its first year of implementation or expanding the duration and scope using a phase-in approach. The phase-in approach could expand MDPP

initially for a period of time in certain geographic markets or regions or among a subpopulation of MDPP suppliers, with the goal of addressing technical issues prior to broader expansion. We solicited comment on whether to expand the scope of the DPP model test nationally or use a phase-in approach, and if phased-in, what factors we should consider in the possible selection of initial phased-in MDPP suppliers.

Comment: We received many comments related to the timing of the MDPP expansion. Commenters overwhelmingly supported nationwide expansion of the DPP model test on January 1, 2018, over a phase-in approach. Several commenters, including MedPAC, supported a phase-in approach, to allow CMS to address program integrity issues before nationwide expansion. Some commenters made suggestions for where and with which providers to phase the benefit in if CMS were to adopt the phase-in approach. Others asked for clarification on what criteria would be used to determine the details of a phased-in approach.

Response: We believe that nationwide expansion of the scope of the model would allow the greatest access to the MDPP services for beneficiaries. We also acknowledge the concerns that the MDPP expanded model introduces a new service and a new supplier type to the Medicare program, and we will prioritize beneficiary safety and the need to consider program integrity concerns in our implementation of this expansion.

MDPP services will be available to eligible beneficiaries beginning on January 1, 2018, subject to additional rulemaking on issues such as payment for the service. However, as a factual matter, eligible beneficiaries' access to MDPP services will increase over time as more organizations seek and receive CDC DPRP recognition, enroll in Medicare as MDPP suppliers, and therefore furnish MDPP services. As of October 2016, more than 1,000 organizations have pending or full recognition from the CDC DPRP to provide DPP services. As described in

section III.J.7.a. of this final rule, these organizations will have to meet certain standards before becoming eligible to enroll as a Medicare supplier. This will provide a de facto phase in that will allow us to gain experience with the MDPP expanded model with fewer organizations initially who meet the supplier eligibility criteria, and more over time as supplier enrollment increases.

c. Other Comments on the Expansion of the Medicare Diabetes Prevention Program Model

Comment: A few commenters expressed concern that MDPP suppliers should be coordinating with primary care providers or other physicians, and a few commenters did not support the MDPP expanded model because they believed it would further fragment the health care system.

Response: We appreciate and respect the concern regarding coordination with the clinical care system, and we encourage MDPP suppliers to promptly communicate with the beneficiary's health care providers as appropriate with the beneficiary's consent to promote care coordination. We also expect that some clinicians will furnish MDPP services on behalf of organizations that have or will obtain CDC DPRP recognition and enroll in Medicare as MDPP suppliers. However, we did not propose specific rules or requirements around coordination with primary care providers or other health care entities for the purposes of this MDPP expanded model because the DPP model test did not require this level of coordination. We also want to provide organizations with the flexibility they need to effectively coordinate care with physicians while decreasing the administrative burden of offering the services. We will take these comments into consideration as we finalize various aspects of MDPP in future rulemaking.

Comment: One commenter suggested the use of mobile application-based technology with built in incentives for beneficiaries.

Response: We appreciate the suggestion and we will consider it as we engage in future rulemaking.

Comment: A few commenters recommended they be allowed to apply Diabetes Self-Management Training (DSMT) to beneficiaries with pre-diabetes. One commenter suggested that CMS merge DSMT and MDPP because core training elements are identical.

Response: While we acknowledge that there may be similarities between the two benefits, DSMT and MDPP have different eligibility criteria and goals. Beneficiaries with a type 2 diabetes diagnosis have different needs than those with pre-diabetes. We therefore do not believe we should merge these benefits.

Comment: Several commenters recommended that we add MDPP services to the personalized prevention plan offered as part of the Medicare Annual Wellness Visit (AWV). A few commenters expressed disagreement with the focus on weight loss, citing fitness and physical activity, metabolic and behavioral markers, and other alternatives that CMS should consider as outcomes for value-based payments.

Response: We did not test the other indicators that commenters recommended such as fitness, metabolic activity and behavioral markers. We will make adjustments through rulemaking, as necessary, if through our continuing evaluation we find that such adjustments are warranted. One of the elements of the AWV is for the health professional to furnish personalized health advice to the beneficiary, and a referral, as appropriate, to health education or preventive counseling services or programs. An eligible beneficiary can be referred for MDPP services as part of a personalized prevention plan. We reiterate, however, that we did not propose to require that beneficiaries obtain a referral for MDPP services, though as discussed in section III.J.7.c. of this final rule, referrals are permitted.

Comment: Some commenters suggested using the term "delay" rather than "prevent" diabetes, and others suggested using the name National Diabetes Prevention Program (National DPP), rather than MDPP, citing confusion in the market of payers that currently cover DPP for their members.

Response: We believe prevention of type 2 diabetes is the goal of the MDPP expanded model even though some beneficiaries may still be diagnosed with type 2 diabetes, so we decline to change the name to reference a "delay" in diabetes onset. We also believe MDPP is the appropriate name for this expanded model because there are differences between MDPP and the National DPP, such as the age of the beneficiaries served, beneficiary eligibility criteria, and the DPP organization or MDPP supplier eligibility criteria.

5. MDPP Benefit Description

We proposed the MDPP core benefit to be 12-months of sessions using a CDC-approved DPP curriculum, consisting of at least 16 core sessions furnished over a range of 16 to 26 weeks (that is, the first 6 months) and at least 6 monthly core maintenance sessions over weeks 27-52 (second 6 months). We proposed that beneficiaries who complete the 12-month core benefit, and achieve and maintain a required minimum weight loss of 5 percent from the first core session, in accordance with the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures (CDC DPRP Standards), would be eligible for monthly ongoing maintenance sessions for as long as the weight loss is maintained. The CDC DPRP Standards are available at http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf. We proposed to require each MDPP core and maintenance session (both core and ongoing) be at least one hour in duration. We proposed that the MDPP expanded model will use the CDC-approved curriculum. Details

pertaining to the content of both the core sessions and maintenance sessions, as set by the CDC, are available at http://www.cdc.gov/diabetes/prevention/pdf/curriculum_toc.pdf.

We proposed that during the first 6 months (weeks 1-26) of the MDPP core benefit, each of the 16 core sessions must address a different curriculum topic included on the list of 16 curriculum topics, ensuring all topics are addressed by the end of the 16 sessions. We proposed that the second 6 months (weeks 27-52) of the MDPP core benefit must include at least one core maintenance session furnished in each of the 6 months (for a minimum of six sessions), and all core maintenance sessions must address different topics. We proposed that ongoing maintenance sessions adhere to the same curriculum requirements as the core maintenance sessions.

We solicited comment on these proposals.

The following is a summary of the comments received and our responses.

Comment: Several commenters suggested that we clarify whether MDPP suppliers must furnish MDPP services in the second 6 months of the core benefit (the core maintenance sessions) or Medicare payment for services furnished in the second 6 months of the core benefit without achievement of the required 5 percent weight loss. The commenters recommended that we allow MDPP suppliers to document and bill for achievement of beneficiary weight loss at any time during the first year, rather than during only the first 6 months. One commenter suggested that CMS clarify if there is a minimum or maximum number of beneficiaries that an MDPP supplier must/may serve.

Response: We clarify that core maintenance sessions in the second 6 months are furnished as part of the 12-month core benefit, regardless of weight loss. We refer readers to section III.J.7.b. of this final rule for discussion of the requirement that organizations maintain CDC DPRP recognition to enroll in Medicare to bill for furnishing MDPP services. The CDC

DPRP Standards require that DPP-eligible individuals be able to access the core maintenance sessions, regardless of weight loss, in order for an organization to maintain CDC DPRP recognition. Therefore, we are finalizing our proposal that the MDPP core benefit is a 12-month program that consists of at least 16 weekly core sessions, over months 1-6, and at least 6 monthly core maintenance sessions over months 6-12, furnished regardless of weight loss. We are making corresponding changes to the regulations text to address when the MDPP core benefit will be available. We intend to address payment for MDPP services in future rulemaking. We will not require a minimum or maximum number of beneficiaries at this time, recognizing that MDPP suppliers will vary in capacity and mode of delivery. However, we will monitor for signs of adverse selection of beneficiaries and propose specific program integrity requirements in future rulemaking, as appropriate.

Comment: Numerous commenters expressed general support for ongoing maintenance sessions after the 12-month core benefit and recommended that CMS allow beneficiaries access to ongoing maintenance sessions if they achieve the required 5 percent weight loss any time during the 12-month core benefit. A few commenters recommended that CMS clarify the definition of maintenance of weight loss, noting that it is common for individuals to lose, regain, and lose weight again. One commenter recommended that beneficiaries whose weight increases during the maintenance period should have up to 3 months to bring their weight back to the maintenance level. Another commenter requested clarification on when and how MDPP suppliers should track weight on an ongoing basis to ensure a beneficiary qualifies for maintenance sessions, and whether beneficiaries should be weighed every month to qualify.

Several commenters recommended allowing beneficiaries who did not achieve and maintain the required 5 percent weight loss to still be able to access the ongoing maintenance

sessions. The commenters stated various reasons, including that weight loss of less than 5 percent is clinically relevant and also reduces type 2 diabetes risk; the evidence base suggests greater impact on onset of diabetes through re-enrolling beneficiaries who are regaining weight than through continuing the service for those who can maintain weight loss; weight regain is common due to metabolic adaptation or receding behavior changes; discontinuing the service for beneficiaries who do not lose weight will discourage them and increase their risk for diabetes; the opportunity to provide a safe environment of recovery for individuals who have a binge-eating disorder; and that the intervention will still reduce diabetes among beneficiaries who are unable to achieve or maintain weight loss. Additionally, commenters stated that exclusion from maintenance sessions for beneficiaries who do not achieve the required weight loss would be punitive, particularly for beneficiaries who need the additional support to achieve the desired weight loss goal. Some commenters suggested that MDPP expanded model risks perpetuating health inequities because low-income beneficiaries who need MDPP services the most struggle disproportionately to achieve the required weight loss and will not be able to access ongoing maintenance sessions.

One commenter suggested that CMS use an aggregate, not individual, 5 percent weight loss across a supplier's beneficiaries to align with the CDC DPRP Standards and promote ongoing maintenance session eligibility for populations that experience difficulty achieving the 5 percent weight loss due to socioeconomic or demographic factors. Another recommendation was to allow participants within 2 percentage points of the minimum weight loss to have their maintenance sessions covered to account for weight gain during extenuating circumstances (for example, falling ill or other circumstances that interfere with weight loss).

Several commenters recommended that access to ongoing maintenance sessions, and payments for maintenance session attendance, depend not on the 5 percent weight loss, but instead on attendance of monthly maintenance sessions. Other commenters suggested that payment should be linked to alternative measures rather than weight loss, such as A1C, waist measurement, and knowledge tests.

Response: As noted previously, MDPP eligible beneficiaries are eligible to access core maintenance sessions in the second 6 months of the 12-month core benefit regardless of weight loss. MDPP eligible beneficiaries are eligible to access ongoing maintenance sessions after the 12 month core benefit if the beneficiary achieves and maintains the required minimum weight loss percentage. We understand that beneficiaries' weight may fluctuate after meeting the 5 percent required weight loss. We are defining maintenance of weight loss, which allows a beneficiary to access ongoing maintenance sessions, as achieving the required minimum weight loss from baseline weight at any point during each 3 months of core maintenance or ongoing maintenance sessions. In other words, a beneficiary can access the next three months of ongoing maintenance sessions if the beneficiary achieved maintenance of weight loss at any point during the previous three months of maintenance sessions. As mentioned in comments, 3 months is the appropriate interval because it aligns with the proposed payment structure that pays for each three maintenance sessions attended with maintenance of weight loss. A beneficiary's weight must be measured and recorded during every core session and maintenance session the beneficiary attends. In response to comments, we are also adding a definition for maintenance session bundle to refer to each 3-month interval of core maintenance or ongoing maintenance sessions. Each bundle must include at least one maintenance session per month, for a minimum of three sessions in each bundle.

We acknowledge some commenters' desire for CMS to cover ongoing maintenance sessions for beneficiaries who do not achieve and maintain the required 5 percent weight loss. The requirement that eligible beneficiaries must maintain 5 percent weight loss is consistent with the weight loss goal tested in the DPP model test, and was factored into the Secretary's determination to expand the model and the Chief Actuary's certification that MDPP expansion would not result in an increase of Medicare spending. We are not changing the requirement that beneficiaries must maintain the 5 percent minimum weight loss in order to receive ongoing maintenance sessions. We acknowledge commenters' concerns regarding potential unintended consequences if the MDPP expanded model results in low-income or other disadvantaged populations having less access to ongoing maintenance sessions. We may consider making adjustments as appropriate if, through our monitoring and evaluation and through tribal consultation, we find that such adjustments are warranted to address disparities in access.

We disagree with a commenter's suggestion that we use an aggregate, not individual, 5 percent weight loss for ongoing maintenance session eligibility. We do not believe aggregate weight loss is an appropriate application for individuals' eligibility for ongoing maintenance sessions. We believe it is unfair to deny a beneficiary access to ongoing maintenance sessions if the beneficiary achieves 5 percent or more weight loss but happens to attend MDPP sessions with other beneficiaries who gain or do not lose the minimum weight. Aggregate weight loss can be arbitrary because there is no minimum or maximum number of beneficiaries per MDPP supplier, and there is no way to ensure equal access to the benefit. It decreases a beneficiary's incentive to meet the weight loss goal in order to access ongoing maintenance sessions and a suppliers' incentive to actively help each beneficiary to meet that weight loss goal, particularly if a few people lost a large percent of their weight. The goal of the DPP model test is at least 5

percent weight loss for each individual, which is expected to lead to a reduction in the incidence of diabetes. We do not have data to support an expanded model that does not require the achievement and maintenance of the minimum weight loss. We clarify that beneficiaries have access to the MDPP core benefit regardless of weight loss. This provides all eligible beneficiaries with access to 12 months of MDPP services, without cost-sharing, to achieve the target weight loss. We believe the incentive to achieve the target weight loss would be diluted for beneficiaries if they could access the ongoing maintenance sessions regardless of weight loss.

Comment: Commenters recommended limiting the number of years of payment for ongoing maintenance sessions due to the limited administrative and operational capability of many MDPP suppliers to provide ongoing maintenance sessions in perpetuity. A few commenters opposed payment for ongoing maintenance sessions at all, stating that indefinite monthly maintenance sessions extend beyond what is supported by scientific research. The commenters recommended additional review of clinical effectiveness and cost implications of payment for ongoing maintenance sessions, suggesting that we study the optimal number of maintenance sessions for beneficiaries who achieve and maintain the required weight loss. One commenter recommended that we eliminate ongoing maintenance sessions or make them voluntary for MDPP suppliers to furnish. The commenter noted the potential difficulty of assembling enough ongoing maintenance session attendees to cover a supplier's costs due to factors such as beneficiary attrition or schedule variation and administrative burdens associated with documenting beneficiary eligibility. The commenter also suggested that we clarify whether MDPP suppliers can offer and charge beneficiaries directly for additional services, such as health coaching beyond MDPP services or counseling to beneficiaries who regain weight and are no longer receiving MDPP services.

One commenter recommended that we clarify whether beneficiaries must participate with the same coach or group of beneficiaries upon the transition from the core benefit to ongoing maintenance sessions. Another commenter recommended that CMS use different terminology for the ongoing maintenance sessions after the 12-month core benefit because it is confusing that the core maintenance sessions in the second 6 months are also called maintenance sessions.

Response: We believe it is important for CMS to cover ongoing maintenance sessions after the 12-month core benefit to better equip beneficiaries to maintain healthy lifestyle changes and prevent type 2 diabetes. As part of the expanded model, MDPP suppliers are required to provide eligible beneficiaries access to ongoing maintenance sessions. We acknowledge commenters' concern regarding the sustainability of ongoing maintenance sessions in perpetuity, and we intend to propose a limit to the duration of ongoing maintenance sessions in future rulemaking. As acknowledged by several commenters, continued participation by an individual in a DPP after year 3 has been generally untested, and we intend to take this into consideration when we address a limit in future rulemaking.

In response to comments on the provision of services outside of MDPP, the MDPP model expansion only includes MDPP services. We note the distinction between core maintenance sessions and ongoing maintenance sessions is important in that core maintenance sessions are a part of the core benefit and are accessible to all eligible beneficiaries, while ongoing maintenance sessions require beneficiaries to maintain weight loss after the 12 month core benefit. As mentioned in section III.J.6. of this final rule, we defer questions of beneficiary attribution, such as how to address beneficiaries who switch suppliers upon the transition from the core benefit to ongoing maintenance sessions, to future rulemaking.

Comment: Numerous commenters supported the use of CDC's DPRP Standards for the

MDPP curriculum. Several commenters suggested that we permit MDPP suppliers to furnish any CDC-approved curriculum, rather than requiring the use of a particular curriculum. Commenters stated that CDC regularly updates its suggested curriculum, as well as reviews and approves alternative curricula that are submitted with an organization's application for CDC DPRP recognition. Commenters requested clarification on whether suppliers may use the 2016 CDC Prevent T2 Curriculum or the 2012 CDC-developed curriculum, both of which are permitted by the CDC DPRP Standards. Commenters recommended that CMS clarify whether CMS would need to undergo a rule change if CDC makes changes to the curriculum.

Commenters also suggested clarification on the curriculum topics that MDPP suppliers should follow for ongoing maintenance sessions, as the National DPP curriculum only specifies content for what is analogous to the MDPP core benefit. Other commenters recommended allowing MDPP suppliers to use the CDC-approved DPP curriculum in another language or making the curriculum more culturally sensitive. Commenters suggested changes to the curriculum, such as shifting the focus away from calorie counting, emphasizing physical activity and exercise goals, training coaches to handle emotional issues and offering oral hygiene sessions.

One commenter suggested we consider ways to embed the curriculum into the Diabetes Self-Management Training (DSMT) benefit.

Response: We agree with commenters that MDPP suppliers should be permitted to, consistent with their CDC DPRP recognition, use any curriculum approved by the CDC. The CDC-preferred curriculum is available at http://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html. We note that if a DPP organization chooses to use a different curriculum, it must send the curriculum to the CDC DPRP so it can be evaluated to ensure that it

covers similar content and is consistent with the current evidence base. To mitigate confusion surrounding the use of specific topic names, we will remove specific curriculum topics from the regulations text and instead specify that the sessions must be furnished consistent with any CDC-approved curriculum. We believe this change also will make it unnecessary for us to undertake rulemaking to address regular CDC curriculum updates. This will reduce the risk that MDPP suppliers would need to have two separate curricula, one for their Medicare beneficiaries and one for the rest of their enrollees, which could be unnecessarily burdensome.

For the ongoing maintenance session curriculum, we are requiring that MDPP suppliers use a CDC-approved curriculum. The purpose of ongoing maintenance sessions is to reinforce and revisit what was learned and practiced in the core benefit, so beneficiaries can maintain healthy behavioral changes and weight loss. Coaches can offer any of the curriculum topics except for the introductory sessions. We support the use of culturally sensitive curricula based on the MDPP supplier's population and furnishing MDPP services in languages other than English. If the CDC approves a curriculum that has adjustments to address language barriers or cultural differences, the MDPP supplier can use the curriculum. We remind organizations that the policies and procedures of approved curricula must ensure accessibility to persons with disabilities, persons with limited English proficiency, and other populations in compliance with HHS civil rights non-discrimination regulations, including those implementing section 504 of the Rehabilitation Act of 1973, Title VI of the Civil Rights Act, section 1557 of the Patient Protection and Affordable Care Act, and Title IX of the Education Amendments of 1972, as amended. More information is available at http://www.hhs.gov/civil-rights. With respect to embedding the DPP curriculum into DSMT, we decline to adopt this recommendation. As noted previously, DSMT and MDPP services, though similar, serve different purposes and are for

individuals with different needs.

Comment: Some commenters recommended that CMS modify the session duration requirement from "at least one hour" to align with the CDC DPRP Standards of "each session must be of sufficient duration to convey the session content – or approximately one hour in length." Commenters stated that the time it takes to complete a curriculum topic depends on the number of attendees, how the services are furnished, beneficiaries' assessed need, the curriculum topic, and the approach to the curriculum, and the one-hour requirement would be too rigid and too long for many CDC-recognized organizations. Other commenters recommended we focus on completion of modules in the required curriculum, not session-based time standards, since module completion requires active participation and the ability to turn learning into action, while a time-based standard does not correlate with impact on outcomes. Some commenters stated that value-based care de-emphasizes the amount of time involved with furnishing a given service and focuses on the results achieved.

Response: We agree with commenters that the one-hour requirement may be too rigid when compared against CDC-approved DPP curricula that vary in approach and mode of delivery. We agree that "approximately one-hour in duration" is an appropriate requirement for in-person sessions because completion of a curriculum topic may vary depending on factors such as number of attendees, how the program is delivered, beneficiaries' assessed need, the curriculum topic, and the approach to the curriculum. We do not believe the CDC DPRP Standard that "each session must be of sufficient duration to convey the session content" is an auditable requirement, and therefore, we decline to adopt it for MDPP because, as noted in the proposed rule, having auditable requirements is a critical component of our program integrity

efforts. For these reasons, we are amending our regulations to specify that sessions must be "approximately one-hour in duration."

Final Decision: After consideration of the public comments received, we are finalizing the proposal that the MDPP core benefit is a 12 consecutive month program that consists of at least 16 weekly core sessions over months 1-6 and at least six monthly core maintenance sessions over months 6-12, furnished regardless of weight loss. We are also finalizing the proposal that beneficiaries have access to ongoing maintenance sessions after the 12-month core benefit if they achieve and maintain the required minimum weight loss of 5 percent. We are modifying the regulations in §410.79 to add the definition of "maintenance session bundle" to refer to each 3-month interval of core maintenance or ongoing maintenance sessions, with at least one maintenance session delivered in each of the 3 months. We are also adding the definition of "maintenance of weight loss" to clarify that maintenance of weight loss is achieving the required minimum weight loss from baseline weight at any point during each 3-month core maintenance or ongoing maintenance session bundle. We are revising the definitions of the CDC-approved core curriculum to remove specific curriculum topic names and to indicate MDPP suppliers must use any CDC-approved curriculum. We are revising the session duration to specify that sessions must have a duration of approximately one hour. We are also making minor technical changes to the proposed definitions to improve clarity.

6. Beneficiary Eligibility

a. MDPP Eligible Beneficiaries

We proposed that coverage of MDPP services would be available for beneficiaries who meet all of the following criteria: (1) are enrolled in Medicare Part B; (2) have, as of the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified

as Asian or a BMI of at least 23 if self-identified as Asian. The CDC DPRP Standards have defined a lower BMI for self-identified Asian individuals based on data that show Asians develop abnormal glucose levels at a lower BMI; (3) have, within the 12 months prior to attending the first core session, a hemoglobin A1c (HgA1c) test with a value between 5.7 and 6.4 percent, or a fasting plasma glucose of 110-125 mg/dL, or a 2-hour post-glucose challenge of 140-199 mg/dL (oral glucose tolerance test); (4) have no previous diagnosis of type 1 or type 2 diabetes with the exception of a previous diagnosis of gestational diabetes; and (5) does not have end-stage renal disease (ESRD).

Comment: MedPAC commented that the proposed eligibility requirements may be too broad and could result in the inclusion of beneficiaries who meet the stated eligibility criteria but have other conditions such as dementia or frailty that could render a weight loss program inappropriate.

Response: We appreciate the views of commenters, including MedPAC. We are considering ways to monitor for MDPP suppliers who consistently bill for session attendance and not weight loss, and intend to address this in our program integrity and payment proposals in future rulemaking. We recognize that performing mental capacity assessment prior to enrollment would be difficult and create an additional burden for MDPP suppliers. We will consider how to address the issue of beneficiaries who are eligible to receive MDPP services, but for whom MDPP may not be clinically appropriate, in future rulemaking, as necessary.

Comment: Many commenters stated that differences between the MDPP expanded model's proposed eligibility criteria and the National DPP eligibility criteria will cause confusion for providers and beneficiaries. Commenters specifically noted that the BMI cut off for National DPP eligibility is 24 kg/m^2 and 22 kg/m^2 for those self-identified as Asian, whereas the proposed

BMI cut offs for the MDPP expanded model are 25 kg/m^2 and 23 kgm^2 for those self-identified as Asian. Commenters also noted the differences in the blood test criteria for the fasting plasma glucose test between the National DPP (range is 100-125 mg/dL) and MDPP expanded model (range is 110-125 mg/dL). Commenters who pointed out these differences recommended that CMS align its eligibility criteria with CDC's eligibility criteria.

Several commenters also supported the lower BMI threshold for self-identified Asians.

Response: We agree with commenters that there are differences between the MDPP beneficiary eligibility criteria and National DPP eligibility criteria, which may be a source of confusion for suppliers, providers and beneficiaries. However, we proposed a BMI cut off for non-Asians of 25 kg/m^2 because this was the cut off used in the DPP model test. In addition, the generally accepted clinical definition of overweight is a BMI of 25.0 - 29.9 in adults over age 20.[23] We proposed a lower BMI cut off for self-identified Asians of 23 kg/m^2 which is endorsed by the American Diabetes Association and aligns with the CDC DPRP Standards which allow for a lower BMI in self-identified Asians consistent with the latest research.[24] In summary, the evidence used to make the certification determination indicated that individuals who fall into the 100-110mg/dL range for fasting plasma glucose and those with BMIs of 24 kg/m^2 (22 kg/m^2 for Asians) or less have lower risk for developing type 2 diabetes. We have chosen to focus on the highest risk population, and therefore the Chief Actuary's analysis for certification focused on this population.[25, 26]

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[23] Centers for Disease Control and Prevention, "Healthy Weight," *Centers for Disease Control and Prevention*, 2015, https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html.
[24] William Hsu et al., "BMI Cut Points to Identify At-Risk Asian Americans for Type 2 Diabetes Screening," *Diabetes Care* 38, no. 1 (2015): 150-158.
[25] Gregory Nichols et al., "Trends in Diabetes Incidence Among 7 Million Insured Adults, 2006-2011: the SUPREME-DM Project," *American Journal of Epidemiology* 181, no. 1 (2015): 32-39.
[26] DH Morris et al., "Progression Rates from HbA1c 6.0-6.4% and Other Prediabetes Definitions to Type 2 Diabetes: a Meta-Analysis," *Diabetologia* 56, no. 7 (2013): 1489-1493.

Comment: Several commenters stated that Medicare currently does not cover the HgA1c test for people without diabetes. These commenters recommended that the HgA1c test be covered with no cost-sharing under Medicare for those seeking to receive MDPP services. Commenters suggested the precedent of Diabetes Self-Management Training (DSMT) requiring HgA1c as a diagnostic test for DSMT eligibility, and that the test is covered for this purpose. Commenters recommended a parallel coverage determination should be made for the MDPP expanded model. One commenter stated that the oral glucose tolerance test should be covered if it is being considered as one of the eligibility tests.

Response: CDC standards for eligibility, which align with the American Diabetes Association definition for pre-diabetes, include an option for demonstrating eligibility using an HgA1c test and we proposed to adopt these eligibility standards for the MDPP expanded model. However, the blood tests that are permitted to be used to demonstrate MDPP eligibility are not covered as part of the MDPP services and occur before the start of the beneficiary's participation in MDPP. We did not propose to cover HgA1C tests for purposes of screening for pre-diabetes, but we note that the other blood tests that can be used to demonstrate eligibility for MDPP services, the oral glucose tolerance test and fasting plasma glucose test, are covered for pre-diabetes screening under Medicare. To cover HgA1C tests for purposes of screening for pre-diabetes, we would first need to make a separate coverage determination.

Comment: Commenters requested clarity on how suppliers would verify that beneficiaries meet certain eligibility criteria. Specifically, commenters asked how suppliers would determine whether a Medicare beneficiary has had a prior diagnosis of type 1 or type 2 diabetes, or whether they have already used the benefit. Commenters requested clarity that beneficiaries would be able to self-report their history of gestational diabetes to become eligible

for MDPP. Commenters also encouraged us to explain what documentation MDPP suppliers will be required to collect from participants who are presenting MDPP-qualifying blood test results to confirm eligibility. Commenters also suggested allowing beneficiaries to complete an eligible risk questionnaire in lieu of the qualifying lab tests for up to 50 percent of their participants as this would align with the current CDC DPRP Standards for eligibility. Commenters suggested using other types of criteria such as family history, hypertension, high cholesterol, and high triglycerides, to determine eligibility among patients for whom abnormal blood glucose values are not available. One commenter requested that we clarify the timeframe in which the BMI and blood tests must occur to qualify for participation, such as whether the beneficiary has to have a qualifying BMI either when the blood tests were completed or upon enrollment. Other commenters requested guidance on whether the blood tests have to come from a lab or primary care physician or if the supplier can provide HgA1c finger pricks to determine eligibility. Commenters also asked if proof of lab work is required or if documentation of the values is sufficient. MedPAC commented that beneficiaries should receive blood tests by a provider other than the MDPP supplier as a safeguard to prevent fraud.

Response: The following eligibility criteria can be self-reported: Asian ethnicity; no history of type 1 or type 2 diabetes; and no previous receipt of MDPP services. We cannot verify self-reported eligibility criteria when beneficiaries begin receiving MDPP services. We will know which beneficiaries are participating in MDPP when the MDPP supplier submits claims with beneficiary identifiers. In our next round of rulemaking we intend to propose specific policies and requirements to protect MDPP suppliers from furnishing services that may not be covered by Medicare in cases where the beneficiary's eligibility for MDPP services is assessed based on self-reported eligibility criteria that cannot be verified prospectively. We

clarify that beneficiaries can participate in MDPP regardless of a history of gestational diabetes (so long as they do not have a history of type 1 or type 2 diabetes), but must also meet the other criteria such as qualifying BMI and blood test results.

We believe the requirement to obtain blood test results is important for maintaining program integrity, and use of risk questionnaires presents opportunities for invalid and unreliable data reporting. The DPP model test required blood test results as part of its eligibility criteria to show a beneficiary has pre-diabetes, and therefore we are requiring blood tests for MDPP eligibility. In considering how to expand the DPP model test, we relied on eligibility criteria that was either tested in the initial DPP model test and/or set forth by the American Diabetes Association or World Health Organization, and we do not intend to include additional eligibility criteria at this time.

Regarding comments about the timeframe of eligibility tests and required documentation: We did not propose specific requirements for how or where blood test results may be obtained as we do not want to create unnecessary obstacles for beneficiaries and MDPP suppliers. An MDPP supplier may administer an HgA1c finger prick to determine eligibility. We note that Medicare only covers the fasting plasma glucose test and the oral glucose tolerance test when the beneficiary has a referral from his or her primary care physician or qualifying provider. Similarly, we did not propose specific documentation methods beyond our proposal that MDPP suppliers maintain records that document each beneficiary's eligibility status. We will consider whether it is necessary or appropriate to establish specific documentation standards in future rulemaking.

Comment: Commenters requested guidance on how to handle beneficiaries who are diagnosed with diabetes during the screening process or while receiving MDPP services.

Commenters recommended we work with CDC to develop a protocol of how to address beneficiaries who receive a diagnosis of diabetes while being screened for or while receiving MDPP services. Several commenters stated that this protocol should ensure participants receive proper care and a referral into a DSMT program.

Response: We reiterate that beneficiaries who are diagnosed with diabetes before they begin receiving MDPP services, such as during the enrollment process, based on their lab results or history of type 1 or type 2 diabetes are not eligible beneficiaries. These beneficiaries may be eligible for other types of diabetes-related care under Medicare, such as DSMT.

We did not propose an eligibility policy for beneficiaries who receive a diagnosis of diabetes while receiving MDPP services. However, we agree with commenters that a protocol needs to be developed to ensure beneficiaries who are diagnosed with diabetes while receiving MDPP services are receiving the proper care for their condition. We intend to address this issue in future rulemaking.

Comment: A number of commenters requested that we include populations beyond those that meet the eligibility criteria, such as all Medicare beneficiaries, Medicaid beneficiaries, those with ESRD and those who have been diagnosed with type 1 or type 2 diabetes. Additionally, one commenter suggested that beneficiaries who do not meet the BMI criteria, but have a family history of diabetes and motivation to receive MDPP services, should be able to do so.

Response: We believe that beneficiaries who meet the eligibility criteria that we proposed are the most appropriate population to access MDPP services because these beneficiaries are among the highest risk within the pre-diabetic population for developing diabetes. Targeting lower risk beneficiaries is not consistent with the model that we are expanding. Beneficiaries with type 1 or type 2 diabetes do not meet the eligibility criteria for

MDPP but may be eligible for services such as Medicare's obesity counseling benefit and DSMT. We do not believe MDPP is appropriate for those with ESRD because beneficiaries with ESRD have more complex dietary requirements that are better addressed by dieticians and other health care professionals.

We appreciate the commenters' interest in Medicaid coverage. However, this model expansion pertains only to Medicare beneficiaries, though we note that Medicaid beneficiaries who are also Medicare beneficiaries are eligible if they meet the MDPP beneficiary eligibility requirements. We encourage states to work with the Center for Medicaid & CHIP Services (CMCS) to discuss options to cover diabetes preventive services within the Medicaid program.

Final Decisions: We are finalizing the beneficiary eligibility criteria as proposed. These criteria are set forth in §410.79.

b. Limitations on Coverage

We proposed that beneficiaries who meet the beneficiary eligibility criteria would be able to receive MDPP services only once in their lifetime.

Comment: Many commenters asked CMS to allow exceptions to the once per lifetime restriction based on significant life events. Commenters recommended that CMS allow beneficiaries to access the benefit again after a certain period of time (for example, 6 months or 1 year) and to allow beneficiaries to access MDPP services at least two times in their lifetime. Several commenters suggested the lifetime benefit policy may be unfair due to extenuating circumstances that may arise throughout the core benefit, such as hospitalization or death of a loved one.

Commenters also requested clarity on how we may handle attribution if beneficiaries switch suppliers. One commenter believed there may be operational implications of managing

this benefit across hundreds of suppliers should participants change suppliers or elect to withdraw from MDPP while it is underway and re-enroll at a later date. The commenter recommended that we issue guidelines on how MDPP suppliers should address changes, particularly with respect to beneficiary eligibility and billing and reimbursement.

Response: We understand concerns regarding the potential for life events to disrupt the beneficiary's receipt of MDPP services. However, the MDPP expansion is designed to generate savings for the Medicare program by preventing individuals with pre-diabetes from developing type 2 diabetes. We believe the once per lifetime restriction is necessary in order to generate enough savings to offset the cost of delivering MDPP services.

We are finalizing the policy that eligible beneficiaries can participate in MDPP only once in their lifetimes. However, we acknowledge the commenters' concerns, and plan to address any exceptions to the once per lifetime restriction in future rulemaking as appropriate. As we did not propose to restrict eligible beneficiaries' choice of MDPP suppliers, we are confirming that they will be able to change suppliers at any time; however, because beneficiary attribution directly relates to payment, we will consider the comments on how to address attribution and its attendant effect on payment in developing proposals for future rulemaking.

Final Decision: We will finalize limitations on coverage of MDPP as proposed. The MDPP core benefit is available only once per lifetime per MDPP eligible beneficiary, and ongoing maintenance sessions are available only if the MDPP eligible beneficiary has achieved maintenance of weight loss. These limitations are specified in §410.79.

c. Referrals

The DPP currently allows community-referral such as by Y-USA and self-referral of patients, in addition to referral by physicians and other health care practitioners, if the patient

presents DPP-qualifying blood test results that the DPP organization keeps on record. We proposed to similarly permit beneficiaries who meet our eligibility criteria to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral.

The following is a summary of the comments received and our responses.

Comment: Commenters generally supported our proposal allowing for self-referral, community-referral, or health care practitioner referral to obtain MDPP services, although MedPAC expressed concern that MDPP services could be inappropriately used and suppliers could initiate services without a referral. Commenters suggested that we broaden the types of providers eligible to make referrals to MDPP suppliers. For example, a commenter recommended clarification of what types of provider referrals would be permitted for MDPP and recommended that such providers include nurse practitioners to broaden program access; another commenter suggested that we will be able to increase access to and streamline beneficiary access to MDPP services by allowing community-based organizations to refer beneficiaries. Many commenters recommended that we promote referrals from MDPP suppliers to psychologists to help address psychosocial components of their care. Other commenters opposed a physician referral requirement. One commenter opposed the requirement of blood tests as part of referral pathway. Some commenters recommended that we explicitly state that MDPP services will be paid for when ordered/referred by non-physician practitioners. A commenter recommended that we require non-clinician health care MDPP suppliers to ask beneficiaries about their usual source of care and mandate that MDPP suppliers share results with the beneficiary's self-identified primary care physician.

Response: We agree with commenters that there should be broad program access, which is why we are not requiring any specific type of referral for this expanded model test. With

respect to the comments on program integrity, we will take these comments into consideration in future rulemaking, as discussed in section III.J.8.b. of this final rule. We agree with commenters and clarify that non-physician practitioners can order or refer eligible beneficiaries for MDPP services. We understand the value of coordinating results from the MDPP with a beneficiary's primary care provider, however, we will not require this type of coordination because we believe it creates an additional burden for this new supplier type that will discourage DPP organizations from enrolling in Medicare as MDPP suppliers. Additionally, the MDPP suppliers have no reimbursement mechanism for coordinating services with primary care physicians, specialists or other providers. The value-based payment proposed for the MDPP expanded model affords no compensation for coordination among providers. We are concerned that holding MDPP suppliers to a higher service coordination standard than other Medicare suppliers and providers may negatively impact MDPP supplier capacity. We do not believe it is appropriate to address referrals from MDPP suppliers to other providers in this expansion because suppliers may or may not employ providers with the credentials to make referrals to other providers, and we believe this is beyond the parameters of the MDPP expanded model.

Final Decision: We are finalizing the procedure for referrals to MDPP as proposed.

7. Enrollment of MDPP Suppliers

a. MDPP Supplier Enrollment Requirements

We proposed that any organization with preliminary or full CDC DPRP recognition would be eligible to apply for enrollment in Medicare as an MDPP supplier beginning on or after January 1, 2017. This proposal would promote timely enrollment of CDC-recognized organizations before the MDPP expanded model becomes effective on January 1, 2018. We

proposed that MDPP suppliers would be subject to the enrollment regulations set forth in 42 CFR part 424, subpart P.

Organizations seeking to enroll in Medicare to become MDPP suppliers would be subject to screening under §424.518. We proposed that potential MDPP suppliers be screened according to the high categorical risk category defined in §424.518(c) because the MDPP expanded model allows organization types that are new to Medicare to enroll. We also believe that MDPP suppliers have some similarities to home health agencies, a provider screened according to the high categorical risk category, because non-licensed personnel may furnish MDPP services in a non-clinical setting, such as at Y-USA.

We proposed that existing Medicare providers and suppliers that wish to bill for MDPP services would have to inform us of that intention and satisfy all other requirements, such as preliminary or full CDC DPRP recognition, but would not need to enroll a second time. These existing Medicare providers and suppliers would be eligible to bill for MDPP services furnished on or after January 1, 2018. We also considered an alternative approach where existing Medicare providers and suppliers would have to submit a separate enrollment application (including any applicable enrollment application fee) and be separately screened to be eligible to bill for MDPP services. This alternative would enable all organizations furnishing MDPP services to have the same classification as MDPP suppliers and undergo the same application requirements. Under this option, should an entity have an issue related to their MDPP enrollment, for example, falsely attesting to beneficiary weight loss, CMS would have discretion to apply revocation to its MDPP enrollment, rather than affecting their broader enrollment in Medicare.

We proposed to require that all MDPP suppliers comply with applicable Medicare supplier enrollment, program integrity, and payment rules. These regulations include, but are not

limited to, time limits for filing claims (§424.44), requirements to report and return overpayments (§401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§405.371).

The following is a summary of the comments we received regarding supplier enrollment.

Comment: Several commenters supported the proposal to allow organizations that previously would not be eligible to enroll in Medicare to enroll as MDPP suppliers. One commenter stated that enabling organizations with either preliminary or full CDC DPRP recognition to furnish MDPP services as officially enrolled suppliers is an important step in validating community health workers' place in the health care system. Other commenters stated that these organizations should be able to enroll and furnish MDPP services, but that they should do so with a clinical affiliate to serve as a resource to provide medical insight or oversight as necessary.

Many commenters who supported allowing these organizations to enroll in Medicare as MDPP suppliers recommended that the enrollment policies should be aligned as closely to CDC DPRP Standards as possible to avoid additional burden to organizations that are less familiar with Medicare rules and regulations.

Response: We appreciate the commenters' support for allowing organizations that meet the MDPP supplier eligibility criteria to enroll in Medicare, even for those that in other circumstances would be ineligible to enroll in Medicare. As described in detail in section III.J.7.c. of this final rule, the literature does not support the need for coaches to have clinical credentials to successfully achieve the behavior change MDPP seeks to encourage. Therefore, we disagree with commenters who suggested requiring that these new suppliers enroll with a clinical affiliate, that is, a provider or supplier that is currently enrolled in Medicare and currently

furnishes services.

For those who requested that we closely align MDPP supplier eligibility requirements to the DPP organization recognition requirements in the CDC DPRP Standards, an organization that obtains CDC DPRP recognition can become an MDPP supplier if they meet a few additional Medicare requirements.

Comment: Some commenters disagreed with requiring community-based organizations to enroll as an MDPP supplier in order to furnish MDPP services, stating that the enrollment process would be too burdensome. Others recommended that due to the burden that enrolling as a Medicare supplier could place on smaller, community-based organizations that wish to furnish MDPP services, we should offer them an easier, expedited enrollment process that is less complex and burdensome. Other commenters noted that given the burden that enrolling, recordkeeping, and billing could impose on these organizations, particularly smaller community-based organizations, many such organizations utilize third party administrators to assume these roles on their behalf. Commenters recommended that we consider the role that third party administrators, which are not CDC-recognized to deliver DPP, could play in MDPP, particularly providing administrative services to new Medicare suppliers to lighten their burden.

Response: We acknowledge that smaller, community-based organizations without experience in the traditional health care system may not be familiar with Medicare's enrollment requirements, and may find Medicare enrollment burdensome. Medicare enrollment is the process through which suppliers acquire eligibility to submit claims to Medicare to bill for services furnished. (In other contexts enrollment can also be the process used to establish eligibility to order or certify Medicare covered items and services.) Furthermore, enrolling into Medicare also enables us to maintain program integrity through screening, monitoring and

revocation. Thus, we believe the benefits of enrollment, even for smaller community-based organizations, outweigh the costs of the associated administrative burden. We note that organizations that face financial difficulty related to the enrollment application fee may apply for a hardship exception. For more information on the hardship exemption, please visit: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7350.pdf.

We recognize the role that third party administrators may play in facilitating the enrollment process for DPP organizations. We intend to allow MDPP suppliers to utilize third-party administrators for the purposes of enrollment but will further consider how these entities may fit into the MDPP enrollment and policy framework in future rulemaking, as appropriate.

Comment: A few commenters questioned whether new suppliers could obtain a National Provider Identifier (NPI) to become eligible to enroll in Medicare. Some commenters believed that many DPP organizations with CDC DPRP recognition do not meet the requirements to obtain an NPI given the definition of health care provider under 45 CFR 160.103, and requested that we explain how unlicensed organizations and individuals with no health care experience qualify for an NPI.

Commenters requested clarity regarding what supplier type an MDPP supplier would indicate on the Medicare enrollment application. Other commenters requested clarity on what taxonomy code suppliers would use when applying for their NPI.

Response: We disagree with commenters who stated that some organizations that meet the MDPP supplier requirements would be unable to obtain an NPI. Under 45 CFR part 162, subpart D, health care providers, as defined in 45 CFR 160.103, may obtain NPIs. The definition of health care provider at 45 CFR 160.103 specifies, in part, that any person or organization who

furnishes health care in the normal course of business is a health care provider. Section 45 CFR 160.103 defines "health care" to include, among other things, preventive services. Because MDPP services are considered additional preventive services, we believe MDPP suppliers and coaches who furnish MDPP in the normal course of business are furnishing health care and therefore qualify as health care providers that are eligible for NPIs under 45 CFR part 162, subpart D.

We acknowledge commenters' questions regarding which provider taxonomy to include when applying for an NPI, as well as which supplier type MDPP organizations would denote when enrolling. We plan to issue additional details through guidance or future rulemaking as appropriate to help guide organizations in applying for an NPI. For the purposes of providing guidance in this final rule, we would like to note for DPP organizations that we believe the taxonomy code of Health Educator (174H00000X) could be appropriate for MDPP suppliers when applying for an NPI. As for supplier type to denote upon applying to enroll in Medicare, we intend to create a new supplier type, specific to MDPP suppliers, and may release an appropriate application form accordingly.

Comment: Many commenters sought clarity regarding enrolling suppliers new to Medicare. One commenter asked whether these suppliers could furnish MDPP services at community locations such as faith-based organizations and community centers, as was permitted in the DPP model test. One commenter stated that DSMT and MDPP should be subject to consistent rules, but noted that current rules for DSMT do not permit hospital-based programs to be offered at community locations. Another commenter noted that while we do not define "qualified physical practice location," the Medicare Program Integrity Manual suggests that in order to enroll in Medicare, organizations must have a physical location where a Medicare

beneficiary could visit in person. This commenter recommended that CMS clarify how suppliers furnishing virtual DPP services would meet this physical location requirement, whether it would be waived, or whether their company headquarters would serve as the "qualified physical practice location."

Response: Consistent with the DPP model test, MDPP suppliers will be able to provide the service at community-locations such as faith-based organizations and community centers. Given that MDPP services can be furnished in community-based settings, the physical location associated with the MDPP supplier's base of operations in each state, as indicated on their enrollment application, would meet the requirements for the qualified physical practice location, provided that the location was open and operational as described in Chapter 15 of Medicare's Program Integrity Manual, Section 19.2.2. As described in III.J.7.e. of this final rule, we will address policies related to virtual DPP organizations in future rulemaking.

Comment: Several commenters agreed with our proposal that we would screen MDPP suppliers as high categorical risk. Many other commenters disagreed and stated that MDPP, like Diabetes Self-Management Training (DSMT), is educational by teaching beneficiaries about eating healthy and being active, which makes MDPP suppliers more analogous to DSMT organizations than Home Health Agencies (HHAs). Both the MDPP expanded model and DSMT are educational in nature, and both MDPP and DSMT organizations require recognition or accreditation by a third party organization or agency to be eligible to furnish services. Given these similarities, commenters noted that organizations that enroll as DSMT providers are screened according to the limited categorical risk, and therefore MDPP suppliers should similarly be screened at the limited categorical risk. Some commenters stated that MDPP suppliers should face less scrutiny and screening than that of medical professionals because of

the fundamental difference between the educational MDPP and the medical services furnished by traditional Medicare providers.

Other commenters disagreed with CMS' parallel between HHAs and MDPP, noting that the requirement to obtain CDC DPRP recognition establishes a higher level of program integrity than that faced by HHAs. One commenter noted that Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) suppliers and HHAs became classified as high categorical risk in response to reports issued by the HHS Office of Inspector General (HHS-OIG) and the Government Accountability Office (GAO).

Response: We understand that MDPP bears similarities to an educational service like DSMT, but do not agree with commenters who stated MDPP suppliers should face less scrutiny or screening than that of medical professionals. CMS assigns risk level based not on the nature of the benefit that the supplier furnishes, but on the level of risk that the supplier type may pose to the Medicare program. Therefore, we disagree with commenters who sought a limited screening level for MDPP suppliers on the basis that DSMT suppliers face limited screening. Fewer organizations are eligible to furnish DSMT than MDPP because DSMT organizations must already be enrolled in Medicare to furnish services other than DSMT. Due to their existing enrollments, all DSMT providers are affiliated with medical professionals enrolled in Medicare. Medical professionals face many additional regulations outside of those set by Medicare, including state licensure requirements that help to protect against fraud or abuse by these individuals. This is not comparable to MDPP suppliers that are not required to have an existing enrollment in Medicare. Given the requirements that credentialing and licensure place on these providers, the DSMT supplier type poses less risk to Medicare than suppliers like HHAs and DMEPOS suppliers that do not have the same credentialing and licensure requirements to serve

as an additional check on fraud or abuse in addition to Medicare efforts. Similar to home health aides, individuals who furnish MDPP services are not required to have medical credentials or state licensure. Given the similarities between MDPP suppliers and HHAs, we believe the concerns HHS-OIG and GAO have regarding HHAs' vulnerability for fraud and abuse could also apply to MDPP. We believe our policy to require high-risk screening during enrollment will safeguard against potential fraud and abuse associated with this new supplier type.

Comment: Some commenters stated that the high categorical risk screening requirement would carry a substantial financial burden that may discourage MDPP supplier enrollment. One commenter noted that the on-site visits required in moderate and high categorical risk screenings would be redundant to the CDC DPRP Standards that already subject recognized organizations to random audits and site visits. These commenters noted that financial burdens may disproportionally affect community-based organizations that are well-suited to furnish a behavioral change program like the DPP. Commenters highlighted that the burden of collecting fingerprints would disproportionately affect independently run community-based organizations more so than corporate entities that typically only have one central board.

Commenters also requested additional information on the requirements for high categorical risk screening. One commenter stated that for entities that are corporately owned or traded, requirements for regional, privately owned suppliers may not be appropriate given the different ownership structures that are not well captured by CMS's enrollment applications. A few commenters also noted that suppliers newly enrolled into Medicare for MDPP, and providers or suppliers with existing enrollment in Medicare who wish to furnish MDPP, should be screened at the same level.

Response: While we agree that CDC ensures the quality of DPP programs using

performance data, which will help ensure the quality of MDPP suppliers, CDC is not a regulatory body responsible for the integrity of Medicare payments. We therefore disagree that program integrity policies in Medicare would duplicate CDC's random site visits and audits of DPP organizations because the agencies play different roles. CMS's program integrity and audits focus on payments, whereas CDC focuses on monitoring whether organizations are meeting the CDC DPRP standards.

We agree with commenters who noted that suppliers newly enrolling into Medicare for MDPP should be screened at the same level as those with existing enrollment in Medicare who wish to furnish MDPP services. We acknowledge the financial burden that enrolling may place on some community-based DPP organizations. It is not our intent to hinder smaller organizations' ability to enroll in Medicare. We do not, however, believe that a high screening level as opposed to limited or moderate would greatly affect participation given the minimal additional requirements the higher screening levels entail. The difference between limited and high categorical risk screening includes a site visit for each base of operations and fingerprinting of certain individuals within the organization. This site visit poses no cost to the supplier, and should not delay the enrollment process beyond the 45 to 60 day window. Fingerprints are required of all individuals with 5 percent or more ownership interest in the entity. Organizations would not be required to submit fingerprints from managing members, coaches, or other employees. The enrollment application fee a supplier pays to Medicare is the same regardless of screening level, therefore the only difference in cost to the supplier amounts to the cost of obtaining fingerprints of those with 5 percent or more direct or indirect ownership interest in the entity. We do not believe this additional cost of high screening is cost prohibitive for enrollment, even for smaller community-based organizations. We understand the commenter's concern that

for entities that are corporately owned or traded, screening requirements and CMS's enrollment applications may be difficult or may not be applicable given the different ownership structures. We will not change our requirement to collect fingerprints from all individuals with a direct or indirect ownership interest, though we recognize that not all suppliers under this requirement will have individual owners who meet this criterion. However, when an individual has 5 percent or more direct or indirect ownership in a prospective MDPP supplier, whether private or publically traded, submitting a set of fingerprints would be required for enrollment into Medicare.

We refer those interested in learning more about the requirements associated with a high screening level to §424.518. Given the nominal financial difference of obtaining fingerprints from 5 percent or more owners, we do not believe that application of the high screening level will be a barrier to organizations to enroll in Medicare as an MDPP supplier. Additionally, we expect that MDPP suppliers will revalidate at a moderate risk level, consistent with the revalidation policy of other high risk suppliers. We will address the screening level of MDPP suppliers seeking to revalidate in future rulemaking.

Comment: Various commenters recommended that we clarify whether the MDPP supplier eligibility criteria would apply to existing providers and suppliers in Medicare. Specifically, commenters asked whether certified diabetes educators, pharmacies, pharmacists, physical therapists, registered dietitians, licensed clinical social workers, and licensed naturopathic physicians who graduated from accredited medical schools would have the ability to bill Medicare for MDPP services. Other commenters highlighted that certain types of medical professionals that are not currently eligible to enroll in Medicare, like RNs, have the capabilities to furnish MDPP services as a coach, and requested the ability to enroll in Medicare to furnish and bill for MDPP services.

Some commenters noted that many existing health care providers are well suited to furnish MDPP services, but may lack familiarity with the CDC National DPP and the process to obtain CDC DPRP recognition. These commenters recommended that CMS provide education and outreach to these providers to ensure that they have the opportunity to obtain CDC DPRP recognition in a timely manner and eligible to furnish MDPP services.

Response: We appreciate interest from existing Medicare providers and suppliers in furnishing MDPP services. Any organization that obtains CDC DPRP recognition would be eligible to enroll in Medicare as an MDPP supplier. The CDC recognizes organizations, not individuals. As such, only organizations, not individuals, would be able to enroll as an MDPP supplier. Any claims submitted for MDPP services would therefore be billed by the MDPP supplier, and not by an individual or any other enrollment type a supplier may have.

Although many individual clinicians could serve as MDPP coaches, we note that entities, not individuals, receive CDC DPRP recognition. Furthermore, we would like to reiterate that entities enrolled in Medicare for the sole purpose of furnishing MDPP services would be eligible to submit claims only for MDPP services.

We agree that many health care entities may be well suited to furnish MDPP services but may lack familiarity with the CDC DPRP recognition process. We will further consider the recommendations to undertake targeted education and outreach efforts to build supplier capacity.

Comment: Some commenters noted that rural health clinics (RHCs) and federally qualified health centers (FQHCs) serve beneficiaries who could benefit from MDPP services, and sought clarification and/or recommended that RHCs and FQHCs be eligible to furnish MDPP services. One of these commenters also recommended that we allow RHCs to bill for MDPP services using the UB-04 form so that RHCs would not have to remove the cost of

furnishing MDPP services from their cost report, which they said would make the benefit too administratively difficult to implement.

Response: RHC and FQHC services are defined in section 1861(aa) of the Act as services furnished by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker. Under certain conditions, an FQHC visit may be furnished by a qualified practitioner of outpatient DSMT and medical nutrition therapy (MNT) when the FQHC meets the relevant program requirements for provision of these services. RHC and FQHC visits are medically-necessary primary health services, and qualified preventive health services, that are furnished face-to-face to a patient by a RHC or FQHC practitioner.

RHCs and FQHCs can enroll as MDPP suppliers if they otherwise meet the enrollment eligibility criteria, but we clarify that MDPP is not a RHC/FQHC service. However, a clinic that chooses to furnish MDPP services could exclude all costs related to furnishing MDPP services from its cost report and instead submit claims for MDPP services under its separate MDPP supplier enrollment. RHCs and FQHCs must ensure that there is no commingling of RHC or FQHC resources in the cost report used to furnish MDPP services. We understand that some clinics believe this will be burdensome, but only RHC or FQHC services can be billed on a UB-04 form.

Comment: Commenters generally supported the proposal that providers and suppliers with existing enrollment in Medicare only be required to inform us of their intent to furnish MDPP services. A few commenters explicitly stated that providers and suppliers with existing enrollment should not have to create a separate enrollment as an MDPP supplier to bill for MDPP services because the burden of doing so would unnecessarily discourage enrollment. In support of this assertion, commenters stated that providers and suppliers with existing enrollment

face stringent regulations both from and outside of Medicare requirements, and therefore requiring an additional enrollment process for MDPP would only add redundancy, rather than support program integrity concerns. One commenter highlighted that under current CMS requirements, retail pharmacies must already undergo two enrollment processes and pay two application fees to serve dual roles as durable medical equipment suppliers and mass immunizers. The commenter stated that an additional enrollment process and fee would not further protect against fraud and abuse, but would simply add redundancy and inefficiency that could deter supplier uptake and limit beneficiary access.

For providers and suppliers with existing enrollment in Medicare, some commenters noted that they should not have to be held to the CDC DPRP Standards, but instead meet other requirements, as noted above. Other commenters expressed support for specific health care provider types that are well suited to furnish MDPP services.

A few commenters supported our alternative proposal that existing Medicare providers and suppliers separately enroll as MDPP suppliers and be separately screened to be eligible to bill for MDPP services. One commenter noted that consistency of procedures and guidelines among organizations furnishing MDPP services, regardless of whether they were new entrants to Medicare, would benefit the program to ensure the same requirements applied across all entities furnishing MDPP services.

Response: We agree with commenters who support the alternative approach we proposed that suppliers and providers with existing Medicare enrollment enroll separately as an MDPP supplier. We believe existing providers and suppliers will benefit from a standardized procedure that all MDPP suppliers follow.

Though requiring existing Medicare providers and suppliers to separately enroll as MDPP suppliers initially imposes an additional requirement, this is a standard procedure for current suppliers. Other types of Medicare providers, such as hospitals or clinics who wish to provide home health services, would similarly need to enroll as HHA suppliers and undergo screening requirements associated with HHAs. We also believe this requirement would ultimately protect existing Medicare providers from revocation action against their enrollment and ability to furnish services outside of MDPP. For example, should an existing provider furnishing MDPP services lose CDC DPRP recognition, the provider would be subject to revocation. If the provider were not enrolled separately as a MDPP supplier, the provider's Medicare enrollment would be subject to revocation action, not just the billing privileges associated with MDPP services. As discussed in section III.J.7.d. of this final rule, many commenters agreed with the proposal that loss of CDC DPRP recognition should result in revocation only of MDPP billing authorities, and not necessarily affect the existing provider or supplier's eligibility to furnish and bill for non-MDPP services. By requiring all prospective MDPP suppliers – regardless of whether they have existing enrollment in Medicare – to enroll as an MDPP supplier, CMS has the discretion to target any revocation action against the MDPP supplier enrollment alone, rather than affect the existing provider or supplier's other enrollment. It is important to note that revocation removes a provider or supplier's enrollment in Medicare, not just its billing privileges for a particular Medicare service. For example, if a hospital had an additional enrollment as an MDPP supplier and one of their coaches was fraudulently reporting weight loss that beneficiaries did not achieve, CMS would have the discretion to revoke the hospital's MDPP supplier enrollment, but could withhold revocation of the hospital's Part A Medicare enrollment. Alternatively, if CMS pursued the original proposal and the hospital did

not reenroll as an MDPP supplier, under the same scenario, the hospital's entire enrollment could be revoked for up to three years, which could have deleterious effects on the provision of care well beyond MDPP. For this reason, we are adopting our alternative proposal.

We acknowledge the concerns that requiring enrolled providers and suppliers to separately enroll as an MDPP suppler imposes a burden. However, we disagree that enrollment screening for the purposes of one supplier type would satisfy program integrity concerns for a different supplier type. Many program integrity checks specifically target the licensure and credentials of a particular supplier type that would not necessarily transfer to other suppliers. Similarly, we disagree with commenters who stated that the program integrity efforts and regulations on providers or suppliers with an existing, non-MDPP enrollment in Medicare would sufficiently address any program integrity related concerns with regards to MDPP services. MDPP services and the manner in which those services will be provided differ from other Medicare benefits and therefore require separate monitoring and regulation to ensure the program integrity.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to permit organizations that meet the supplier enrollment eligibility criteria to enroll in Medicare as MDPP suppliers. We are modifying our proposal with respect to existing Medicare providers or suppliers and requiring them to adhere to the same enrollment requirements as MDPP suppliers if they wish to furnish and bill for MDPP services and otherwise meet the MDPP supplier enrollment eligibility criteria.

We are finalizing the high screening level as proposed. We will continue to monitor enrollment efforts and program integrity, and should our policy merit adjustment, we may amend this decision in future rulemaking as necessary.

We are finalizing that MDPP suppliers are obligated to comply with all statutes and regulations that establish generally applicable requirements for Medicare suppliers. These regulations include, but are not limited to, time limits for filing claims (§424.44), requirements to report and return overpayments (§401.305), and procedures for suspending, offsetting or recouping Medicare payments in certain situations (§405.371). As explained in more detail in section III.J.7.c. of this final rule, we will not be able to begin supplier enrollment until enforcement activities are finalized during subsequent rulemaking in 2017, but we encourage DPP organizations to use this final rule to prepare for enrollment. This may include working towards CDC recognition, as detailed in III.J.7.b. of this final rule, obtaining NPIs, or obtaining claims processing software.

The final policies for MDPP supplier enrollment are set forth in §424.59.

b. CDC DPRP Recognition

CDC grants pending recognition to an organization upon its approval of the organization's application and the organization's agreement to comply with requirements for use of a CDC-approved curriculum and for duration and frequency of sessions. CDC also establishes an effective date for each approved organization which is the first day of the month following their approval date. Organization must submit data every 12 months from their effective date. CDC grants full recognition after an organization with pending recognition has consistently furnished sessions with a CDC-approved curriculum, met CDC performance standards, and met CDC reporting requirements. CDC makes the first determination for full recognition 24 months after their effective date. Organizations not meeting full recognition at that time are reassessed at 36 months. Organizations that do not achieve full recognition within 36 months after their effective date will lose any recognition and must wait 12 months before reapplying.

In our proposal regarding eligibility of DPP organizations to enroll in Medicare, we proposed the use of an additional CDC recognition status: preliminary recognition.

We proposed that DPP organizations must have either preliminary or full CDC DPRP recognition in order to be eligible to enroll in Medicare as MDPP suppliers. We proposed that DPP organizations can attain preliminary CDC DPRP recognition upon meeting CDC DPRP performance standards and reporting requirements for 12 months after applying for recognition, and full recognition upon demonstrating program effectiveness for 24-36 months after applying for CDC DPRP recognition. We proposed that if an organization loses its CDC DPRP recognition status at any point, for example for not meeting CDC standards or failing to move from preliminary to full recognition within 36 months of their effective date, or withdraws from the CDC DPRP at any point, the organization would be subject to revocation of its Medicare billing privileges for MDPP services as provided by 42 CFR part 424, subpart P. Under the CDC DPRP Standards, an organization that loses its CDC DPRP recognition (and thus, under our proposal, would no longer be able to bill Medicare for MDPP services) must wait 12 months before reapplying for recognition. We proposed that DPP organizations would be eligible to re-enroll in Medicare as an MDPP supplier if, after reapplying for CDC DPRP recognition, the organization again achieves preliminary recognition.

The following is a summary of the comments we received and our responses.

Comment: The majority of commenters supported requiring DPP organizations to obtain CDC DPRP recognition in order to be eligible for enrollment in Medicare as an MDPP supplier. Some commenters recommended we take into account the socioeconomic status of participants when considering CDC's recognition, and work with CDC to account for the risk of inadvertently precluding suppliers serving vulnerable populations who have fewer resources to

achieve healthy eating and fitness goals. Some commenters requested that CMS allow MDPP supplier eligibility to be based on alternative accreditations and standards focused on diabetes education.

A few commenters noted that CDC DPRP recognition is difficult to attain because it relies on average weight loss of 5 percent across the population of participants an organization serves, and if organizations fall a few decimal points short of that threshold, they can lose their recognition. Some commenters expressed the concern that beneficiary access may be disrupted if a supplier falls short of CDC DPRP Standards, therefore losing recognition and Medicare eligibility. Furthermore, commenters were concerned with the timelines the CDC DPRP Standards require for reapplication. Tribal organizations collectively requested CDC DPRP recognition be automatically granted to providers of the Special Diabetes Program for Indians.

Response: In response to comments regarding CDC recognition (socioeconomic status of participants, average weight loss requirement, timelines with reapplication) we note that CDC is responsible for developing standards related to CDC recognition, and we are not. We are coordinating with CDC to promote alignment between the CDC DPRP and MDPP expanded model requirements, to the extent possible. We are not considering other accrediting bodies or at this time. We expect that the updated CDC DPRP Standards will be published for public comment in 2017 and go into effect in 2018.

We welcome consultation with tribes and tribal organizations as required by the CMS Tribal Consultation Policy,[27] and will address this and other concerns that have tribal implications, as appropriate, in future rulemaking.

Comment: Several commenters expressed support for the proposal that organizations

[27] Centers for Medicare & Medicaid Services, "CMS Tribal Consultation Policy," *Centers for Medicare & Medicaid Services*, 2015, https://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTribalConsultationPolicy2015.pdf.

must obtain preliminary or full CDC DPRP recognition in order to become eligible to enroll in Medicare as an MDPP supplier. Other commenters recommended that we clarify the requirements for preliminary recognition and how preliminary recognition differs from the CDC DPRP Standards' definition of pending recognition. The commenters noted that the CDC DPRP Standards currently do not have a preliminary recognition definition. A commenter recommended that CDC be the entity responsible for recognizing organizations with preliminary recognition, just as CDC is responsible for recognizing organizations with pending recognition and full recognition.

Several commenters recommended that CMS clarify which performance standards and reporting requirements need to be met for 12 consecutive months to qualify for preliminary recognition. The commenters noted that they assume that an MDPP supplier would comply with the first year of CDC DPRP Standards for pending recognition status, starting at the effective date of the DPP organization's pending recognition. The commenters also noted that this means submitting data at 12 months from the effective date, but not achieving any particular outcomes at 12 months because current CDC DPRP Standards do not consider outcomes for achieving recognition until 24 months from the effective date. Several commenters recommended that we clarify whether an organization must submit 6 months or one year of data to obtain preliminary recognition. The commenters expressed their support that an organization offer DPP services for at least a year before qualifying for recognition as an MDPP supplier. A separate commenter suggested that CMS clarify that to obtain preliminary recognition, an organization must offer the CDC-approved curriculum within 6 months of the effective date of the organization's CDC DPRP application and submit at least 6 months of participant data at 12 months post-effective date of the application. Several commenters recommended removing the requirement to submit

one year's worth of data before obtaining preliminary recognition.

One commenter noted that given the work and time required for DPP organizations to start providing DPP services, it may be difficult to obtain 12 months of reporting data immediately after the effective date of the DPP organization's pending recognition status. The commenter expressed concern that an organization that has met the standards and reporting requirements for 11 of the 12 months immediately following its application to participate in the DPRP should not have to reapply for preliminary recognition and start the 12-month process over again. Another commenter recommended that preliminary recognition performance standards focus on percent of weight loss achieved, as opposed to average weight loss, and maintenance of weight loss among participants.

Some commenters recommended that we allow organizations that have either pending recognition or full recognition from CDC to enroll as MDPP suppliers. The commenters noted that organizations obtain pending recognition from CDC after they agree to curriculum, duration, and intensity requirements. One commenter noted that the additional status of preliminary recognition adds a complicated layer of bureaucracy to the existing CDC DPRP, adds little value, and will likely delay enrollment of organizations in Medicare as MDPP suppliers due to lack of defined requirements for preliminary recognition. Several commenters suggested that we allow participation of DPP organizations with pending recognition until CDC standards for preliminary recognition status are established. One commenter requested that we explain why we proposed an additional recognition status, whether we can create new CDC DPRP recognition standards, and if so, how the new recognition standards will be incorporated into the CDC DPRP Standards.

One commenter recommended that only organizations with full CDC DPRP recognition may serve as MDPP suppliers in order to eliminate potential confusion caused by the preliminary

recognition standard and preserve program integrity. The commenter suggested that we should only pay suppliers that have demonstrated their effectiveness as MDPP suppliers or their ability to establish and maintain the necessary infrastructure. Another commenter suggested that organizations with full recognition be paid at a higher rate than organizations with preliminary recognition.

Several commenters recommended that CMS adopt a grandfathering policy where organizations with 12 months of data may obtain preliminary recognition. A few commenters noted that the creation of the preliminary recognition definition risks having few or no MDPP suppliers with preliminary recognition by MDPP's scheduled effective date of January 1, 2018, thus delaying the implementation of MDPP. One commenter noted that the preliminary recognition status does not exist in CDC DPRP Standards, and that the preliminary recognition definition would be published in CDC DPRP Standards too late for MDPP suppliers to begin enrolling into Medicare in time to begin furnishing MDPP services on January 1, 2018. The commenter recommended that we require CDC to identify organizations with pending recognition that qualify for preliminary recognition no later than December 31, 2016 and require that CDC release interim guidance on standards or requirements for preliminary recognition no later than March or April 2017. The commenter notes that additional, minor clarifications may also be needed when the CDC issues updated CDC DPRP Standards in January 2018 to reflect early experience with the new preliminary recognition definition. One commenter believed it should be permitted to enroll as an MDPP supplier because it has one year of data, even though it lacks CDC DPRP recognition. Another commenter urged that we review its organization's data before 2018, and if it meets the standards for MDPP suppliers in 2017, that CMS reimburse the organization in 2017.

Response: We appreciate the support for our proposal to allow DPP organizations with full CDC recognition, as well as certain DPP organizations that do not yet have full CDC recognition, to enroll as MDPP suppliers. We received many comments that raised questions and concerns about preliminary CDC recognition status or offer suggestions about how preliminary CDC recognition status should be determined. Because the CDC has not adopted standards for preliminary recognition, however, we are not finalizing any of our proposals with respect to preliminary recognition status at this time. Although we anticipate that CDC will address standards for preliminary recognition when it publishes updated DPRP Standards for public comment next year, because any such standards for CDC preliminary recognition would not take effect until 2018, it will not be possible to permit DPP organizations to enroll in Medicare based on achievement of CDC preliminary recognition before then.

For this reason, we intend to use future rulemaking to propose interim standards for preliminary recognition, under CMS authority, that would bridge the gap until CDC preliminary recognition standards are established. We anticipate that our proposed interim preliminary recognition standards would be consistent with the principles described in the proposed rule. We intend to align our MDPP supplier enrollment policies with CDC recognition standards, as appropriate, as they are established. We will take the commenters' comments on preliminary recognition into account as we develop our proposal for interim CMS recognition standards. We do not intend to delay implementation of the MDPP expansion.

We proposed that certain DPP organizations that had not yet achieved full recognition could enroll in Medicare in acknowledgement that full recognition might take 36 months and require achievement of certain performance standards. We proposed this eligibility requirement for Medicare enrollment to allow an increased number of organizations that have demonstrated a

capacity to provide DPP services to enroll in Medicare, thereby allowing access to MDPP services in a timely manner as of January 1, 2018. We continue to believe that it is appropriate to permit enrollment in Medicare prior to achievement of full CDC recognition in cases where there is demonstrated capacity to furnish DPP services, and as noted above, we intend to address this issue in future rulemaking. Therefore, we decline to permit DPP organizations that have only pending recognition to enroll in Medicare because such organizations may not have any demonstrated capacity to furnish DPP services. We are aware that most DPP organizations are currently in pending recognition status, and that CDC's definition for pending recognition currently includes a 6-month grace period before organizations are required to start offering DPP sessions. We are also aware that the current definition of full recognition requires organizations to meet certain standards for average weight loss and participation, and relative to those in pending status, few organizations have obtained full recognition. However, we believe it is important to ensure that prospective MDPP suppliers have demonstrated experience in actually furnishing DPP services, and therefore we do not believe it is appropriate to permit organizations to enroll in Medicare before they have submitted any performance data to CDC that allows CDC to assess their capacity to deliver DPP services.

We recognize the timing and nature of our proposal has caused some confusion, particularly because we intend to use CDC recognition status as a Medicare enrollment standard. We also agree with commenters that in general CDC should be responsible for recognizing DPP organizations, consistent with its recognition standards. However, as noted above, we intend to propose in future rulemaking interim CMS recognition standards that would permit DPP organizations that are seeking full CDC recognition and have demonstrated capacity to furnish DPP services to enroll in Medicare prior to January 1, 2018. We are considering performance

criteria that we could propose as part of any interim CMS standards that we would use to permit DPP organizations that have not yet achieved full CDC recognition to enroll as MDPP suppliers before the CDC standards are updated. For example, we are considering proposing that DPP organizations with pending CDC recognition would be required to meet a performance standard threshold of 60 percent participant attendance in at least 9 core sessions in months 1-6 and 60 percent participant attendance in at least 3 core maintenance sessions in months 7-12. In addition, we intend to consider options to ensure program integrity and mitigate fraud and abuse during the preliminary recognition stage. We encourage interested parties to submit comments on any updates to CDC's DPRP Standards when CDC publishes them for public comment.

Finally, in response to commenters, we do not intend to propose differential payments based on whether the supplier has full recognition. We also do not intend to make payments for MDPP services prior to January 1, 2018. We will also propose details on the payment structure in future rulemaking.

Final Decision: We finalize our proposal that an entity must have full CDC DPRP recognition as a requirement to enroll in Medicare as an MDPP supplier. Due to timing issues with CDC standards updates, we are not finalizing any proposals for preliminary recognition at this time. We intend to address this issue in future rulemaking.

c. Coach Requirements

We proposed to require personnel who would furnish MDPP services, referred to hereafter as "coaches," to obtain a National Provider Identifier (NPI) to help ensure the coaches meet CMS program integrity standards. We also considered requiring that coaches enroll in the Medicare program in addition to obtaining an NPI, and we solicited comment on this approach. Another alternative policy we considered was to require DPP organizations to collect and submit

information on the coaches who would furnish MDPP services, which could include identifying information such as first and last name and social security number (SSN). We proposed to require MDPP suppliers to submit the active and valid NPIs of all coaches who would furnish MDPP services on behalf of the MDPP supplier through a roster of coach identifying information. We proposed that if MDPP suppliers fail to provide active and valid NPIs of their coaches, or if the coaches fail to obtain or lose their active and valid NPIs, the MDPP supplier may be subject to compliance action or revocation of MDPP supplier status.

The following is a summary of the comments we received and our responses.

Comment: We received comments regarding coach enrollment into Medicare. Commenters overwhelmingly stated objections to coach enrollment, citing reasons including high turnover and the reality that many coaches work part time or as volunteers. Commenters also highlighted that since claims and payment are handled directly by the supplier, coaches have limited reasons to enroll. Other commenters noted that coaches lack medical licensure, indicating that only medical providers should enroll. And several commenters cited the burden that enrollment would impose on coaches, and that requiring this approach could limit coach participation and ultimately reduce beneficiary access to services.

The majority of commenters indicated that organizations alone should enroll in Medicare as MDPP suppliers, though one commenter proposed that diabetes prevention coordinators, who oversee the coaches as outlined in the CDC DPRP Standards, should enroll. A few commenters recommended that coaches enroll, stating that this would ensure our ability to protect the integrity of the Medicare program and have direct oversight over coaches furnishing the benefit. Other commenters cited consistent use of CMS processes such as enrollment for program integrity efforts rather than creating new processes. Several commenters highlighted the

opportunity for coaches to be directly paid for the services furnished.

Response: We agree with the commenters who stated that coaches should not enroll in Medicare and should not be submitting MDPP claims. Though we understand there may be program integrity advantages if coaches were to enroll, we do not believe the existing enrollment process is appropriate for coaches. Most notably, enrollment is for the purpose of permitting Medicare billing, and we have proposed that only MDPP suppliers, not coaches, would submit claims for MDPP services. We do not believe coaches should have the ability to submit claims for MDPP or be directly paid for the services furnished because CDC DPRP recognition is obtained at the organization level, not for the individual coach furnishing MDPP services. Additionally, we believe that the burden of enrolling and submitting claims, as well as the medical record retention requirements associated with claim submissions, would be too burdensome to place on individual coaches, and that suppliers are more appropriate and suitable to assume this responsibility. We did not propose enrolling diabetes prevention coordinators, but we believe the same rationale against requiring coaches to enroll would apply to these individuals as we did not propose that diabetes prevention coordinators would be able to bill for MDPP services.

Comment: We received many comments regarding whether coaches should obtain NPIs, with commenters split on whether CMS should require only suppliers, or both suppliers and coaches, to obtain NPIs. A few commenters alternatively suggested that diabetes prevention coordinators, not coaches, would be more appropriately suited to obtain NPIs. Most commenters did not provide a reason for supporting the proposal that coaches obtain an NPI, but those that did stated that having coaches obtain an NPI would serve to validate community health workers' role in health care. Many commenters expressed their support for coaches obtaining an NPI as an

alternative to enrolling in Medicare. One commenter indicated that given that MDPP services will be additional preventive services, the processes that would apply to other additional preventive services should also apply, and coaches who furnish these services should therefore obtain NPIs.

Commenters who opposed the requirement for coaches to obtain NPIs largely expressed that only health care providers should obtain NPIs. Some commenters believed that MDPP coaches do not meet the definition of health care provider under 45 CFR 160.103, and therefore coaches should not be allowed to obtain an NPI. Other commenters questioned how coaches could obtain NPIs, particularly when registered nurses (RNs) and other credentialed professionals can neither obtain NPIs nor enroll as Medicare suppliers. Several commenters recommended that CMS extend those same proposals for coaches to RNs and other medical professionals who currently lack the ability to obtain an NPI. As an alternative to obtaining NPIs, a number of commenters proposed that coaches should have specialized training.

Response: We did not propose any requirements for diabetes prevention coordinators, but we may consider this possibility for future rulemaking as appropriate. Given that coaches directly furnish MDPP services, we believe that for any process aiming to track and screen professionals working with an MDPP supplier, the coach will likely stand as the most appropriate individual to track and screen, as opposed to the coordinators who do not directly furnish MDPP services.

To commenters who did not believe that coaches would be eligible for an NPI, we note that 45 CFR part 162, subpart D specifies that health care providers, as defined in 45 CFR 160.103, may obtain NPIs. Among other things, a health care provider under 45 CFR 160.103 is a person or organization who furnishes health care in the normal course of business. Because 45

CFR 160.103 specifies that health care includes preventive services, we believe MDPP coaches provide health care and are therefore health care providers under 45 CFR 160.103 and eligible to obtain NPIs. We disagree that requiring coaches to obtain NPIs would impose an undue burden on coaches, even those who work as coaches part-time or as volunteers. Obtaining an NPI takes approximately 20 minutes and can be done easily online. We will further consider the impact of coach requirements for rural and tribal areas that lack reliable access to the internet and will consider adjusting policies in future rulemaking as appropriate.

Requests for CMS to address NPI issues and enrollment for other health care providers such as RNs are outside of the scope of this rulemaking for MDPP. Should RNs or other providers who currently lack an NPI decide to work as a coach, these individuals would be able to obtain an NPI on that basis for purposes of furnishing MDPP services.

Given the relatively low burden that obtaining NPIs places on coaches and important considerations for monitoring, evaluation, and program integrity, we will require every coach furnishing MDPP services on behalf of an MDPP supplier to obtain an active and valid NPI that will be submitted to Medicare on the supplier's updated roster of coaches. This roster of coach identifying information would be submitted alongside the MDPP supplier's enrollment application to be used for vetting and program integrity purposes. However, we did not propose specific standards for how we would use roster information in connection with MDPP supplier enrollment. We intend to propose such standards in future rulemaking, and will begin enrollment of MDPP suppliers once appropriate standards are in place.

Comment: We received general support from commenters for the proposal to track coaches using some form of identifiable information to help ensure the coaches meet CMS program integrity standards. Few commenters detailed in their response the type of information

that should be collected. While some commenters preferred using coach names and NPIs for tracking purposes, slightly more commenters preferred using identifiable information such as social security numbers (SSNs).

Response: We appreciate the support from commenters. Use of NPIs and SSNs would serve different purposes in vetting coaches against program integrity risks upon the supplier's enrollment in Medicare, as well as evaluation and monitoring purposes for performance and continuing program integrity efforts. In existing areas of Medicare's enrollment process where both NPIs and SSNs are used for individual providers who enroll into Medicare, SSNs serve the purposes of completing background checks, while NPIs serve an identifying and tracking purposes with regards to Medicare claims and actions. These two identifiers play distinct and important roles in ensuring the integrity of Medicare's programs and the safety of the beneficiaries served. Given commenters' openness to using both pieces of identifying information, we will finalize a requirement that MDPP suppliers submit the names, NPIs and SSNs of their coaches.

Upon enrollment, MDPP suppliers must submit, and update within 30 days of any changes, a roster of coaches, including individuals' first and last name, SSN and NPI to CMS along with its enrollment application to help ensure the coaches meet CMS program integrity standards. Changes that must be reported to us include adding identifying information for any coach beginning to furnish MDPP services on behalf of the supplier or removing a coach who ceases furnishing MDPP services on behalf of the supplier. We intend to address how this coach information might affect MDPP supplier enrollment and be used in enforcement actions in future rulemaking as appropriate. As noted previously, enrollment of MDPP suppliers will not begin until such standards are in place.

Comment: We received a number of comments on coach requirements under the MDPP expanded model. The majority of commenters stated that training should be required, some stipulating that specific trainers should be utilized. Within the discussion of training, some commenters stipulated that medical professionals should be exempt from any additional training imposed on coaches, while others stipulated that everyone – including medical professionals—should undergo training to become a coach. One commenter recommended that CMS create an audit process to ensure that training occurred. Several commenters urged us to consider creating a certification program for coaches. Commenters also referred to the CDC DPRP Standards for coach requirements and requested that CMS clarify whether formal lifestyle coaching is a requirement and specifically what constitutes the definition of trained coach to furnish the required curriculum. Other commenters asked whether we will require additional training sources or continuing education requirements above the CDC DPRP Standards in order to qualify as a coach.

Many commenters supported specific practitioners to serve as coaches, such as Certified Diabetes Educators (CDEs). Other commenters recommended that coaches should have clinician oversight. Similarly, other commenters suggested that we require for coaches to have clinicians as affiliates who can serve as a medical resource. A few commenters stated that coaches should have some form of credentials, particularly given that participants may have medical questions about weight loss that extend beyond a CDC-approved curriculum, which credentialed professionals are better equipped to handle. A number of commenters specifically requested that we recognize the value that CDEs can have in the MDPP expanded model and specify the role that they play in the management of lifestyle changes.

While we received many comments suggesting additional requirements for coaches, a

number of commenters also urged against adding additional requirements on coaches beyond CDC DPRP Standards.

Response: We do not, at this time, see any need to require additional training, certification, or clinician oversight or affiliation beyond the CDC DPRP Standards, particularly given that the initial DPP model test met the criteria for expansion without these requirements.

Though we agree that CDEs, RNs, and other credentialed professions can be effective MDPP coaches, the DPP model test showed that trained, non-credentialed coaches can effectively deliver the program. Additionally, we do not believe that the literature supports this claim that coaches with credentials would result in better participant performance than non-credentialed individuals trained to be coaches.[28, 29, 30, 31] Therefore, we do not believe credentials are necessary at this time, but may evaluate and revisit this proposal as necessary. Therefore, any individuals – with or without credentials – can become a coach provided that they meet CDC DPRP Standards and work for a MDPP supplier.

We will further consider commenters' suggestions regarding mechanisms to ensure that coaches have received high quality training, whether we will require coach certification, the impact credentials may have on coaches, and the possibility of clinician affiliation or oversight as we monitor and evaluate the expanded model.

Final Decision: We are finalizing the proposal that DPP organizations must enroll in Medicare to become MDPP suppliers, and that coaches will not enroll in Medicare for purposes of furnishing MDPP services. We are finalizing the proposal that coaches must obtain NPIs. We

[28] D Vojta et al., "A Coordinated National Model for Diabetes Prevention: Linking Health Systems to an Evidence-Based Community Program," *American Journal of Preventive Medicine* 44, no. 4 Suppl 4 (2013): S301-S306.
[29] Mohammed K. Ali et al., "How Effective were Lifestyle Interventions in Real-World Settings that were Modeled on the Diabetes Prevention Program?," *Health Affairs* 31, no.1 (2012): 67-75.
[30] L Ruggiero et al., "Community-Based Translation of the Diabetes Prevention Program's Lifestyle Intervention in an Underserved Latino Population," *The Diabetes EDUCATOR* 37, no. 4 (2011); 564-572.
[31] JA Katula et al., "The Healthy Living Partnerships to Prevent Diabetes Study 2-Year Outcomes of a Randomized Controlled Trial," *American Journal of Preventive Medicine* 44, no. 4S4 (2013): S324 –S332.

are requiring MDPP suppliers to submit the active and valid NPIs of all affiliated coaches and to update CMS within 30 days of a coach beginning to or ceasing to furnish MDPP services. We finalize that this roster of coaches submitted will include the first and last name, SSN, and NPI. We intend to propose policies specific to enrollment standards and enforcement actions, as they relate to the roster, in future rulemaking.

The final policies for coach requirements are set forth in §424.59.

d. Revocation of MDPP Supplier Enrollment

We proposed that all MDPP suppliers would be required to comply with the requirements of 42 CFR part 424. If an MDPP supplier has its Medicare enrollment revoked or deactivated for reasons unrelated to its loss of CDC DPRP recognition, that MDPP supplier would lose its ability to bill Medicare for MDPP services but would not automatically lose its CDC DPRP recognition. We proposed that existing Medicare providers and suppliers who lose CDC DPRP recognition would lose their Medicare billing privileges with respect to MDPP services, but may continue to bill for other non-MDPP Medicare services for which they are eligible to bill. We proposed that MDPP suppliers that have their Medicare billing privileges revoked or that lose billing privileges for MDPP may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498. We proposed to add a new §424.59 to our regulations to specify the suppliers who would be eligible for Medicare enrollment and billing for MDPP services. We solicited comment on these proposals.

The following is a summary of the comments we received regarding these proposals and our responses.

Comment: A few commenters agreed with the proposal that loss of CDC DPRP recognition should lead to loss of MDPP billing privileges. Some commenters specifically

agreed that revocation should be limited to MDPP privileges. Commenters also stated that the ability to appeal a revocation decision was important. One commenter expressed concerns that losing Medicare billing privileges would affect MDPP suppliers less than medical professionals, presenting a potential vulnerability to fraud. For medical professionals, Medicare provides a key source of income and livelihood, whereas non-traditional Medicare providers who primarily deliver non-health care related services like those in a community center would not necessarily be as affected by a revocation than a health clinic. The commenter did not suggest an alternative approach that could make losing Medicare billing more impactful for these organizations.

Response: We appreciate the support from commenters on our proposed revocation policies, including the right to appeal a revocation. Should we deny a prospective MDPP supplier's enrollment, we expect that appeal rights set forth in 42 CFR part 424 would apply, however we will address any provisions related to Medicare enrollment denial appeal rights in future rulemaking. We agree with commenters that should a supplier lose CDC DPRP recognition, the supplier's revocation would be only of the supplier's MDPP enrollment. We disagree that revocation of MDPP enrollment would affect existing providers and suppliers less than new MDPP suppliers. In both cases, the supplier would lose its ability to bill for MDPP services. We reiterate that all MDPP suppliers—whether a new Medicare supplier or a currently enrolled provider and supplier—must comply with the requirements of 42 CFR part 424, subpart P, including, but not limited to, enrollment bars. CMS notes that we did not propose a policy regarding the effective date of the revocation, and will do so in future rulemaking. We retain the authority to revoke any Medicare enrollment—MDPP supplier or otherwise—if a supplier does not comply with Medicare requirements.

Final Decision: We are finalizing our proposals that all MDPP suppliers must comply with the requirements of 42 CFR part 424, will have their MDPP supplier enrollment revoked upon loss of CDC DPRP recognition or noncompliance with Medicare requirements, and may appeal these decisions in accordance with the procedures specified in 42 CFR part 405, subpart H, 42 CFR part 424, and 42 CFR part 498.

The final revocation and appeal policies are set forth in §424.59.

e. Virtual MDPP Services

Currently, CDC-recognized DPP organizations deliver DPP services in-person or virtually via a telecommunications system or other remote technology. The majority of current DPP organizations furnish DPP services in-person, but an emerging body of literature[32,33,34,35] supports the effectiveness of virtual sessions furnished remotely. We proposed to allow MDPP suppliers to furnish MDPP services through remote technologies. As part of our evaluation of the MDPP expansion, to the extent feasible, we planned to evaluate the effectiveness of MDPP services, particularly in relation to virtual versus in-person services, and, using the evaluation data, modify or terminate this component of the expansion as appropriate. To permit such evaluation, we are considering specifying the nature of the virtual service and the site of the service in codes included on claims submitted for payment, as well as collecting information on the nature of the virtual service and the site of service at the beneficiary level from MDPP suppliers.

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[32] W Su et al., "Return on Investment for Digital Behavioral Counseling in Patients With Prediabetes and Cardiovascular Disease," *Preventive Chronic Disease* 13, no. E13 (2016).

[33] J Ma et al., "Translating the Diabetes Prevention Program Lifestyle Intervention for Weight Loss into Primary Care: a Randomized Trial," *JAMA Internal Medicine* 173, no. 2 (2013): 113-121.

[34] CS Sepah et al., "Translating the Diabetes Prevention Program into an Online Social Network: Validation Against CDC Standards," *The Diabetes Educator* 40, no. 4 (2014): 435-443.

[35] Y Fukuoka et al., "A Novel Diabetes Prevention Intervention Using a Mobile App: A Randomized Controlled Trial with Overweight Adults at Risk," *American Journal of Preventive Medicine* [serial online] 49, no. 2 (2015): 223-237.

We planned to monitor administrative claims for virtual services to identify any unusual and/or adverse utilization of the MDPP services. We solicited comment on specific monitoring activities or program integrity safeguards with respect to virtual services, in addition to the time period in which such enhanced monitoring activities should occur.

We noted that MDPP services provided via a telecommunications system or other remote technology will not be part of current Medicare telehealth benefits and have no impact on how telehealth services are defined by Medicare. We recognize that the provision of MDPP services by such virtual methods may introduce additional risks for fraud and abuse, and we plan to address specific policies in future rulemaking to mitigate these risks. We thus solicited comment on whether there are quality or program integrity concerns regarding the use of virtual sessions, or whether they offer comparable or higher quality MDPP services when compared to in-person services. We solicited comment on strategies to strengthen program integrity and minimize the potential for fraud and abuse in virtual sessions.

The following is a summary of the comments we received regarding these proposals and our responses.

Comment: In response to our proposals for virtual MDPP services, we received many insightful and informative public comments suggesting matters related to furnishing virtual services, various modes of furnishing virtual services, how effective these services are, and that the standards that apply to in-person sessions may not be applicable to virtual sessions. Commenters were overwhelmingly supportive of the proposal to allow virtual providers to participate, particularly to ensure adequate access to the benefit in underserved areas. Only one commenter noted that in-person services should be prioritized over virtual services. Commenters provided specific suggestions on how to mitigate fraud and abuse and evaluate these services by

using site of service codes on claims, and requiring technology based methods for weight loss reporting (for example, digital scales) versus self-reported methods.

Response: We appreciate the comments on the virtual furnishing of MDPP services. We noticed many differences between the way a virtual MDPP supplier and in-person supplier may operate, in addition to hybrid virtual and in-person programs. We do not have enough information to finalize this proposal at this time, but expect to continue gathering more information on the virtual delivery of DPP services. We appreciate the many insights and comments we received, particularly suggestions of strategies to maintain program integrity. We remain committed to including virtual providers and services in MDPP as soon as possible, but we intend to use future rulemaking to address detailed policies on virtual providers' eligibility to enroll, furnish and bill for MDPP services.

f. Information Technology (IT) Infrastructure and Capabilities

We proposed that in order to receive payment, MDPP suppliers would be required to submit claims to Medicare using standard claims forms and procedures. Claims would be submitted in batches that contain beneficiary Protected Health Information (PHI) and Personally Identifiable Information (PII), including the Health Insurance Claim Number (HICN). Most Medicare claims are submitted electronically except in limited situations. We provide a free software package called PC-ACE Pro32 that creates a patient database and allows organizations to electronically submit claims to Medicare Part A and B. We understand there are several other electronic claims submissions software packages available in the market for purchase. We encouraged current and prospective DPP organizations to investigate adopting these systems to enhance the efficiency of claims submission, and we sought comment on the capacity of DPP

organizations to integrate these systems into their workflows. We indicated that we would provide guidance to MDPP suppliers regarding the Medicare claims submission standards.

We proposed to require MDPP suppliers to maintain a crosswalk between the beneficiary identifiers they submit to CMS for billing purposes and the beneficiary identifiers they provide CDC for beneficiary level-clinical data. We proposed that MDPP suppliers provide this crosswalk to the CMS evaluator on a regular basis.

We proposed that MDPP suppliers maintain records that contain detailed documentation of the services furnished to beneficiaries, including but not limited to the beneficiary's eligibility status, sessions attended, the coach furnishing the session attended, the date and place of service of sessions attended, and weight. We proposed that MDPP suppliers maintain these records within a larger medical record, or within a medical record that an MDPP supplier establishes for the purposes of administering MDPP. Consistent with the requirement in §424.516(f) we proposed that these records be retained for 7 years from the date of service and that MDPP suppliers would provide CMS or a Medicare contractor access to these records upon request. We proposed to require MDPP suppliers to accurately track payments and resolve any discrepancies between claims and the beneficiary record within their medical record. We also proposed that MDPP suppliers would be required to maintain and handle any beneficiary PII and PHI in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), other applicable privacy laws, and CMS standards. We indicated that we would provide education and guidance to MDPP suppliers to mitigate the risk of data discrepancies and audits. We stated that we would address specific recordkeeping requirements and standards in future rulemaking as appropriate.

The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended CMS clarify what the medical record should include, whether the medical record should be paper or electronic, and whether suppliers should retain records of any referrals and diagnostic tests demonstrating beneficiary eligibility or simply document that one was presented at the time of enrollment. Commenters requested guidance on whether the medical record would require proof of lab work or if documentation of the values would suffice. One commenter noted that while beneficiaries' data should be held in an EHR, suppliers should be able to transfer this information in electronic, paper, or fax format to beneficiaries' other providers. Though commenters generally agreed with the recordkeeping requirements, including the duration of recordkeeping, many of these same commenters and others noted the burden that recordkeeping requirements might impose on community-based organizations. These commenters urged us to consider the implications that a high cost, HIPAA-compliant recordkeeping system might impose on such organizations, as well as the subsequent strain it would place on beneficiary access should the requirement be cost prohibitive. Additionally, a number of commenters urged that when making IT-related policy decisions, that we consider the lack of internet and issues with electricity in rural and tribal areas.

These commenters suggested clarifying the medical record requirement in such a way that would be economically feasible for community-based programs. Due to these concerns, a number of commenters suggested that we work with CDC or other entities to identify a low cost data and billing system. Other commenters went further to suggest that CMS work with CDC to streamline the two data reporting systems such that when coaches or suppliers input performance data on beneficiary sessions to CDC, the Medicare claim would automatically be generated. Others appreciated the reliance on existing claim forms and software and applauded CMS for not creating a new data submission system. A few commenters noted that given the cost burdens of

adequate IT, data, and recordkeeping systems, many community-based programs are likely to use third party integrators. These commenters did not advocate for a specific role for these integrators. One commenter, however, requested that MDPP suppliers be permitted to partner with and use the IT system of a healthcare entity to maintain records and submit claims for Medicare payment. Lastly, one commenter suggested that MDPP suppliers be required to take HIPAA-compliant training due to concerns about non-medical professionals housing HIPAA-compliant information.

Response: We wish to clarify that for purposes of MDPP, the medical record would need to contain information related to the MDPP services furnished to the beneficiary, in compliance with HIPAA and other applicable privacy laws, and CMS standards, such as documentation of the beneficiary's eligibility, including blood test results, sessions attended, the coach furnishing the session(s) attended, the date and location of service(s), and weight. We understand various forms of documentation exist depending on the type of blood test administered, and we will provide additional details on what specific records are required to demonstrate eligibility in future guidance and/or future rulemaking as appropriate. In response to commenters' questions on the format of these records, we encourage the use of electronic records, but do not require it for purposes of this expanded model. Further details on specific information that would qualify as auditable documentation of the supplier's record will be provided in guidance and/or future rulemaking as appropriate. Although we require entities to maintain these records for the purposes of auditing, medical reviews, or other CMS requests, we do not intend to require that suppliers submit additional data, outside what is on the claim, to CMS for the purpose of payment.

Although we understand it might be easier for suppliers to submit claims and performance data to one joint CMS-CDC data system, we believe that maintaining MDPP claims independent from CDC performance data would allow us to compare information submitted to CMS with those submitted to CDC to identify inconsistencies, as supported by certain commenters. Additionally, it is important to note that while all MDPP suppliers will be organizations that have CDC recognition, it is likely that not all organizations with CDC recognition will enroll in Medicare. Similarly, not all participants in the National DPP are Medicare beneficiaries. Thus, Medicare claims information will not be relevant to CDC's assessment of performance data. For the aforementioned reasons, we do not agree with commenters that a joint CDC-CMS data system would be appropriate. We appreciate that these recordkeeping requirements can impose burdens on MDPP suppliers, particularly those who have not previously had to comply with these types of recordkeeping requirements. While MDPP suppliers are responsible for complying with these requirements, MDPP suppliers can decide which resources to utilize in order to do so, including the use of a third party administrator or other entity.

Comment: Several commenters noted the current proposed requirements for recordkeeping do not apply to the nature of sessions furnished virtually. One commenter proposed alternative record keeping requirements that were consistent with the proposal, but would allow flexibility for suppliers who furnish MDPP services through virtual technologies. .

Response: We are deferring all decisions regarding virtual providers to future rulemaking as discussed in section III.J.7.e. of this final rule.

Comment: Numerous commenters agreed with the proposal that MDPP suppliers maintain a crosswalk between beneficiary identifiers submitted to CMS for billing and

beneficiary identifiers submitted to CDC for beneficiary-level clinical data. A few commenters disagreed, stating CMS and CDC should not impose this requirement on suppliers and should instead coordinate directly to alleviate further reporting requirements for MDPP suppliers. Regarding monitoring and program integrity comments, we received general support for this approach to compare CMS claims with CDC performance data. Several commenters requested further clarity on the crosswalk, its format, whether or not CMS would provide a template, the frequency with which suppliers would be required to submit the same data to CMS, and the need for the crosswalk to CDC data given that CMS is requiring all suppliers to retain records for auditing purposes, medical reviews, or other requests.

Response: We understand the desire to avoid undue burdens on MDPP suppliers. We intend for the crosswalk to alleviate the redundancy for suppliers submitting performance data to CMS that is already being sent to CDC. Since MDPP is an expanded model test, we are required to evaluate the effectiveness of the MDPP expansion, and this crosswalk will facilitate this evaluation. While we understand the recommendation to create the crosswalk directly with CDC, the CDC does not receive any personal identifying information (PII) on beneficiaries who participate in the National DPP that would enable CMS and CDC to directly create the beneficiary crosswalk. While we are requiring organizations to retain records for CMS-directed audits, a crosswalk between CMS and CDC data will enable CMS to conduct an evaluation on the effectiveness of MDPP, as well as provide any necessary documents during an audit, medical review, or other CMS request. The crosswalk therefore has a role both with program integrity purposes as well as for evaluating the expanded model's effectiveness, as required of any Innovation Center model. We intend to provide guidance to suppliers on how to set up the

crosswalk, and make any further adjustments or clarifications (for example, frequency of submissions) in future rulemaking, as appropriate.

Final Decision: We are finalizing as proposed the documentation retention requirements and requirements for suppliers to provide documents in the case of an audit, medical review, or other CMS request. The final policies are set forth in §424.59.

8. Policies for Future Rulemaking

a. MDPP Reimbursement Structure

We proposed to reimburse for MDPP services at the times and in the amounts set forth in the Table 41, with payment tied to the number of sessions attended and achievement of a minimum weight loss of 5 percent of baseline weight (body weight recorded during the beneficiary's first core session).

TABLE 41: MDPP Expansion Payment Model

	Payment per beneficiary (Non-cumulative)
Core Sessions	
1 Session attended	$25
4 Sessions attended	$50
9 Sessions attended	$100
Achievement of minimum weight loss of 5% from baseline weight	$160
Achievement of advanced weight loss of 9% from baseline weight	$25 (in addition to $160 above)
Maximum Total for Core Sessions	$360
Core Maintenance Sessions (Maximum of 6 monthly sessions over 6 months in Year 1)	
3 Core Maintenance Sessions attended (with maintenance of minimum required weight loss from baseline)	$45
6 Core Maintenance Sessions attended (with maintenance of minimum required weight loss from baseline)	$45
Maximum Total for Maintenance Sessions	$90
Maximum Total for First Year	$450
Ongoing Maintenance Sessions After Year 1 (minimum of 3 sessions attended per quarter/no maximum)	
3 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
6 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
9 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
12 Ongoing Maintenance Sessions attended plus maintenance of minimum required weight loss from baseline	$45
Maximum Total After First Year	$180

As proposed, Table 41 illustrates that payments would be heavily weighted toward achievement of weight loss over the 12-month core benefit, and no payments would be available after the first 6 months without achievement of the minimum weight loss. In the payment structure we proposed, claims for payment would be submitted following the achievement of core session attendance, minimum weight loss, maintenance (both core and ongoing) session attendance, and maintenance of minimum weight loss. For example, MDPP suppliers would not be able to submit another claim after core session one until the beneficiary has completed four sessions, and maintenance sessions (both core and ongoing) would not qualify for payment

unless minimum weight loss was achieved and maintained. Similar value-based payments are being offered by commercial insurers and accepted by DPP organizations. We sought comment on this payment structure. Additionally, we sought comment on whether to update payment rates annually through an existing fee schedule, such as the PFS, or establish a new fee schedule for MDPP suppliers.

We are deferring finalizing the proposed reimbursement structure to future rulemaking. In response to our solicitation, we received many comments. We intend to address these comments in future rulemaking.

b. Program Integrity

We recognize the potential for fraud and abuse by suppliers filing inaccurate claims and/or duplicative claims on the number of sessions attended or amount of weight loss achieved. We also recognize beneficiaries may move between MDPP suppliers, and we intend to address in future rulemaking as appropriate any requirements necessary to prevent duplication claims for MDPP services furnished by more than one MDPP supplier to the same beneficiary. We are also concerned about the potential for beneficiary inducement or coercion and the potential program risks posed by permitting a new type of organization to receive payment from Medicare for furnishing MDPP services. We also realize that there may be other risks to program integrity. We intend to develop policies to mitigate these risks and monitor the MDPP expansion, to ensure MDPP suppliers meet all applicable CMS program integrity and supplier enrollment standards, and will address them in future rulemaking, as necessary. We intend to develop system checks to identify when CMS may need to audit an MDPP supplier's records. We are considering ways to cross reference the data DPP organizations are currently required to report to the CDC to identify potential discrepancies with data submitted to CMS. We sought comment on such approaches.

Finally, MDPP suppliers would be subject to audits and reviews performed by CMS program integrity and/or review or audit contractors in addition to program-specific audits. We sought comment on these approaches and others to mitigate these risks and strategies to ensure program integrity.

In response to our solicitation, we received many comments. We intend to address these comments in future rulemaking.

c. Learning Activities

The CDC provides technical assistance to DPP organizations with CDC DPRP recognition to improve performance. We solicited comment on what additional technical assistance would be needed for providers and other organizations in order to expand the MDPP model.

In response to our solicitation, we received many insightful and informative public comments and will consider the input when developing our strategy for ensuring that organizations seeking to enroll in Medicare and furnish and bill for MDPP services have the information and guidance they need to do so.

d. Quality Monitoring and Reporting

We solicited comment on the quality metrics that should be reported by MDPP suppliers in addition to the reporting elements required on Medicare claims submissions outlined above (attendance and weight loss) or by the CDC DPRP. We solicited comment specifically on what quality metrics should be considered for public reporting (not for payment) to guide beneficiary choice of MDPP suppliers.

In response to our solicitation, we received many comments. We intend to address these comments in future rulemaking.