K. Changes to the Medicare Diabetes Prevention Program (MDPP) Expanded Model

1. Background

a. Authority for and Establishment of the MDPP Expanded Model

In the November 15, 2016 **Federal Register**, we issued a final rule to implement aspects of the Medicare Diabetes Prevention Program (MDPP) expanded model (81 FR 80459 through 80475 and 80552 through 80558) as part of the CY 2017 Physician Fee Schedule (PFS) final rule. Section 1115A(c) of the Act provides the Secretary with the authority to expand, through rulemaking (including implementation on a nationwide basis), the duration and scope of a model that is being tested under section 1115A(b) of the Act if certain determinations specified in the Act are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act. The MDPP expanded model is an expansion of CMS' Center for Medicare and Medicaid Innovation's (Innovation Center) Diabetes Prevention Program (DPP) model test under the authority of section 1115A of the Act. The Secretary expanded the DPP model test in duration and scope under the authority of section 1115A(c) of the Act. For further information on the DPP model test, and the associated National DPP administered by the Centers for Disease Control and Prevention (CDC), we refer readers to the CY 2017 PFS final rule and the following websites: https://Innovation.cms.gov/initiatives/Health-Care-Innovation-Awards/ and https://www.cdc.gov/diabetes/prevention/index.html.

The aim of the MDPP expanded model is to continue to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes as defined by the MDPP beneficiary eligibility criteria (finalized at §410.79(c)(1)). Services available through the MDPP expanded model are MDPP services furnished in community and health care settings by coaches, such as trained community health workers or health

professionals. We have designated services under the MDPP expanded model to be covered as additional preventive services under Medicare, as defined in section 1861(ddd) of the Act.

For a detailed discussion of the DPP model test and the development of aspects of the MDPP expanded model, we refer readers to the CY 2017 PFS proposed rule ("Proposed Expansion of the Diabetes Prevention Program (DPP) Model") (81 FR 46413 through 46418), and the CY 2017 PFS final rule (81 FR 80459 through 80475).

In the CY 2017 PFS final rule, we responded to and incorporated certain suggestions from the public comments we received that were within the scope of the MDPP proposals presented in the CY 2017 PFS proposed rule. We indicated in that final rule (81 FR 80459) that the MDPP expanded model would be implemented through at least two rounds of rulemaking. In the CY 2017 PFS final rule, we finalized MDPP policies that will enable CDC-recognized organizations to prepare for enrollment, including finalizing the framework for the MDPP expanded model, timeline and definitions for the MDPP expanded model (codified at §410.79(a) and (b)), beneficiary eligibility criteria (codified at §410.79(c) and (d)), supplier eligibility criteria and supplier enrollment requirements (codified at §424.59, proposed to be redesignated as §424.205). We also identified several issues, including some issues raised by commenters that we deferred to future rulemaking.

b. Summary of Provisions Finalized in the CY 2017 PFS final rule

In the CY 2017 PFS final rule (81 FR 80465 through 80468), we finalized the structure of MDPP services. We provided that the MDPP core benefit consists of at least 16 weekly core sessions over months 1 through 6 and at least 6 monthly core maintenance sessions over months 7 through 12, furnished regardless of weight loss (§410.79(b) and (c)(2)). We also finalized that Medicare will cover ongoing maintenance sessions after the 12-month core set of MDPP services

if beneficiaries achieve and maintain the required minimum weight loss of 5 percent. In the CY 2018 PFS proposed rule, we proposed to further revise the structure of MDPP services as a 3-year service period, generally contingent upon a beneficiary's attainment of two performance goals: achievement and maintenance of weight loss and attendance at a certain number of MDPP sessions (82 FR 34131 through 34132).

As used in this final rule, the term "MDPP services period" refers to the time period in which MDPP services are furnished under the MDPP expanded model over a minimum of 12 consecutive months and a maximum of 24 consecutive months from the date of the first core session the beneficiary attends. We use the term "set of MDPP services" to include the entirety of MDPP services available under the MDPP expanded model, including core sessions, core maintenance sessions, and, subject to §410.79(c)(3), ongoing maintenance sessions offered over the course of the MDPP services period. For purposes of this final rule and the expanded model, MDPP services are covered under the "additional preventive services" benefit category under section 1861(ddd)(1) of the Act and paid from the Medicare Part B Trust Fund. As indicated in the CY 2017 PFS, we intended to begin supplier enrollment before MDPP services became available, and we finalized an expanded model start date of January 1, 2018.

In the CY 2018 PFS proposed rule, we proposed a new start date for the furnishing of MDPP services within the expanded model of April 1, 2018 (82 FR 34157 through 34158). That is, MDPP suppliers will not be able to furnish MDPP services, or to receive payment for these services, prior to April 1, 2018. We note that we proposed the supplier enrollment and compliance policies become effective on January 1, 2018. This stated that the change to delay the furnishing of MDPP services would allow time for organizations to enroll in Medicare before they begin furnishing and billing for MDPP services.

In the CY 2017 PFS final rule (81 FR 80459), we described a possible payment structure for MDPP services, but deferred full development of the payment structure to future rulemaking. In section III.K.2.d. of this final rule, we discuss our payment structure for MDPP services. This finalized payment structure took into consideration the significant number of public comments we received in response to the possible payment structure we described in the CY 2017 PFS proposed rule, as well as comments received on the CY 2018 PFS proposed rule. We also proposed payment policies for instances in which an MDPP beneficiary switches MDPP suppliers in the CY 2018 PFS proposed rule.

In the CY 2017 PFS final rule (81 FR 80471 through 80474), we required CDC-recognized organizations that will bill Medicare for MDPP services to enroll in Medicare as MDPP suppliers. We also finalized the requirements for coaches furnishing MDPP services. We finalized policies regarding CDC Diabetes Prevention Recognition Program (DPRP) full recognition for MDPP suppliers and we indicated an intention to propose policies in future rulemaking regarding whether a DPP organization without full CDC recognition could enroll as an MDPP supplier. We are finalizing an interim MDPP preliminary recognition standard in section III.K.2.e. of this final rule. Also, in this section of this final rule, we are finalizing revisions to the supplier eligibility and enrollment requirements, including establishment of standards and implementation of appropriate program integrity safeguards. In section III.K.2.f. of this final rule, we are finalizing policies related to MDPP beneficiary engagement incentives furnished by MDPP suppliers.

In the CY 2017 PFS final rule (81 FR 80459), we deferred establishing policies related to organizations delivering "virtual" DPP services, where services are not furnished in person. In section III.K.3. of this final rule, we explain that the MDPP expanded model covers in-person

MDPP services (other than ad hoc virtual make-up sessions discussed in section III.K.2.c.iv.(3) of this final rule), and thus, explain why we are not currently finalizing any policies related to MDPP services furnished 100 percent virtually and state that we are considering a separate model under CMS's Innovation Center authority to test and evaluate virtual DPP services.

2. Policy Changes

a. Changes to Effective Date of MDPP Services

In the CY 2017 PFS final rule, we established at §410.79(a) that MDPP services would be available on January 1, 2018. In the CY 2018 PFS proposed rule, we proposed to change §410.79(a) to state that MDPP services would be available on April 1, 2018. We proposed this change because we want to ensure that MDPP suppliers have sufficient time to enroll in Medicare after the effective date of the CY 2018 PFS final rule.

Therefore, beneficiaries will not be able to receive MDPP services immediately on January 1, 2018 due to the time needed for supplier enrollment. For this reason, we proposed April 1, 2018 as the expanded model start date, which we believe allows a sufficient amount of time (90 days) for eligible suppliers to enroll in Medicare before furnishing and billing for MDPP services. As a result of this proposed change, we stated that the following regulatory provisions, if finalized, would be effective April 1, 2018: §414.84 related to payment for MDPP services; and §424.210 related to beneficiary engagement incentives. We proposed that all other sections, if finalized, will be effective on January 1, 2018, including the policies proposed in section III.K.2.e. of the proposed rule related to supplier enrollment and compliance. We invited public comments on these proposals.

The following is a summary of the public comments received on this new proposed expanded model start date and whether 90 days is a sufficient amount of time for organizations to enroll in Medicare and prepare to furnish and bill for MDPP services and our responses:

Comment: Many commenters supported the proposed model start date of April 1, 2018. The commenters stated that a 90-day delay from January 1, 2018, was both reasonable and necessary to ensure MDPP suppliers would be ready to deliver services by April 1, 2018. Other commenters stated that enrollment of DPP organizations into the MDPP as of January 1, 2018, would allow sufficient time for organizations to apply, receive a supplier determination, comply with requirements, and ultimately, operate starting April 1, 2018. One commenter appreciated the alignment of the MDPP's implementation in April 2018 with the CDC's recently-proposed DPRP standards that will allow DPP suppliers to prepare for enrollment as Medicare suppliers.

One commenter expressed concerns about delaying the availability of the services until April and recommended CMS keep the implementation date of January 1, 2018. The commenter stated that because the MDPP was first discussed in the 2017 rulemaking cycle and CMS had finalized a January 1, 2018 start date, CMS and suppliers alike had ample time to plan, enroll, and prepare to operationalize this program. The commenter suggested CMS work with speed and efficiency to make these services available on January 1, 2018, as the agency had previously finalized given the obesity and diabetes prevalence in the United States.

A few commenters suggested CMS delay the model start date beyond April 1, 2018, including several requests to delay until January 1, 2019. Most of the commenters stated the delay was necessary to allow Medicare Advantage (MA) organizations sufficient time to contract with MDPP suppliers thereby ensuring adequate coverage for their members. One commenter suggested delaying the start date to July 1st or October 1st 2018 to allow additional time for

suppliers to be trained and in place when the service becomes available to Medicare beneficiaries.

Response: We appreciate all of the comments received on the proposed new effective date for MDPP services and thank the commenters for their recommendations. We note that we cannot make the MDPP service available to beneficiaries until there are MDPP suppliers enrolled in Medicare who can meet beneficiary demand for the service. Suppliers have been awaiting detailed requirements in order to enroll into Medicare as MDPP suppliers. Those requirements are finalized in this rule which becomes effective January 1, 2018. In response to commenters recommending a January 1, 2019 start date, CMS does not believe it is prudent to further delay the availability of this preventive service for the majority of Medicare beneficiaries, who are in Fee for Services (FFS). Additionally, DPP stakeholders have been preparing to offer this service to Medicare beneficiaries since the service was first proposed in the CY 2017 PFS proposed rule and finalized in CY 2017 PFS final rule (81 FR 80459). There are currently over 1500 organizations actively pursuing or maintaining DPP recognition through the CDC's DPRP which includes nearly a 90 percent increase between September 2015 and March 2017 alone. These organizations have made significant investments in pursuit of recognition and represent a growing supply of organizations that meet the qualifications specified in this rule to deliver the DPP to Medicare beneficiaries. At §410.79(a), we are finalizing that MDPP services will be available under the MDPP expanded model as a Part B service for eligible Medicare beneficiaries beginning on April 1, 2018. Because MDPP services are a Part B service, all Medicare health plans (which include plans offered by Medicare Advantage Organizations, cost plans offered under sections 1833 and 1853 of the Act, and PACE organizations), are required to cover MDPP services for eligible beneficiaries. As a Part B service, Medicare health plans are

required to provide beneficiaries with coverage of all MDPP services using medical necessity criteria that authorize coverage on at least the same terms as Original Medicare. In the CY 2017 final rule (81 CFR 80468 through 80470) and in section III.K.2.c of this final rule, we establish specific beneficiary eligibility requirements that regulate the coverage of MDPP services as a basic benefit. Therefore, notwithstanding other requirements under this final rule, MA plans must authorize coverage of MDPP on at least the same terms as those established in §410.79(c) and (d) of this final rule. We note that Medicare health plans may generally also provide more generous coverage than Original Medicare as a supplemental benefit.

Comment: We received several comments related to our proposed delay of the start date for MDPP services from January 1, 2018 to April 1, 2018 that addressed whether such a delay would likewise delay the effective date for MA plans. The majority of commenters who provided comments on the delay with respect to MA plans recommended that CMS further delay the start date for MDPP services beyond the April 1 date, recommending new start dates ranging from June 1, 2018 to January 1, 2019. Concerns underlying the request for this additional delay were related to the number of MDPP suppliers available to contract with MA plans for MDPP services, the short timeline in which to negotiate and implement contracts with MDPP suppliers for an April 1 start date, and other operational challenges underlying the implementation of a new covered service between the November 2017 publication of the MDPP final rule and the April 1, 2018 start date. Other commenters supported the delayed start date in MDPP services from January 1, 2018 to April 1, 2018, citing the need for additional time to contract with MDPP suppliers and their desire to align with the proposed start date for Original Medicare.

Response: While we understand that Medicare Advantage Organizations have significant concerns regarding their ability to construct a network of adequate coverage for MDPP, we

remind MAOs that, as a Part B service, §422.112 permits MA plans to limit coverage to services from a network of providers so long as the MAO ensures that all covered services—which will include MDPP services—are available and accessible under the MA plan; an MAO must arrange for out-of-network access to specialty care when network providers are unavailable or inadequate to meet enrollees' medical needs. We further note that for section 1876 cost plans, §417.416 requires that an Health Maintenance Organization or Comprehensive Medical Plan must furnish required services—which will include MDPP services—to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity. Therefore, we decline to accept commenters' recommendations to further delay the effective date for MA plans. As indicated in a November 23, 2016 Health Plan Management System (HPMS) memo, because MDPP is a Part B service, all Medicare health plans, including plans offered by Medicare Advantage plans, are required to cover the service for eligible beneficiaries. In this section, we are finalizing that MDPP services will be available under the MDPP expanded model as a Part B item/service for eligible Medicare beneficiaries, in both Original Medicare and Medicare health plans, beginning on April 1, 2018. Additional information on this topic will be released in future guidance, as appropriate.

Comment: In addition to a number of comments supporting a delay to the original start date for MDPP services of January 1, 2018, we received several comments requesting that CMS provide additional guidance and information on the implementation and operationalization of MDPP in the Medicare Advantage setting, with most comments focused on the impact of the

proposed delay in the start date for MDPP services to April 1, 2018 on the implementation of MDPP services in Medicare Advantage.

Response: In response to requests from MAOs to provide additional guidance on the implementation of MDPP in MA, we have provided a number of responses to MAOs seeking clarification on the implementation of MDPP in the preamble of this final rule. As appropriate, we will provide additional information to MAOs on the implementation of MDPP in future guidance.

Comment: Several commenters expressed concern that Evidence of Coverage documents developed by MA plans, which were required to be delivered to MA enrollees by September 30th of 2017 prior to the finalization of this rule, may have been published without including MDPP services as an available covered service or may have indicated that MDPP services would be available per the January 1, 2018 date finalized in the CY 2017 final rule and not the April 1st, 2018 date in the CY 2018 proposed rule.

Response: At the time these EOCs were published, the MDPP Expanded Model was to become effective January 1, 2018 with a proposed rule to change the effective date to April 1, 2018; therefore, an EOC that indicates a January 1, 2018 start date for MDPP services was accurate at the time it was published. As we are finalizing our proposed effective date change to April 1, 2018 in this final rule, MA plans that have not included MDPP services in beneficiary documentation such as an EOC or have provided an effective date of January 1, 2018 should consult §422.111(d) and follow existing guidance at Medicare Managed Care Manual 60.7 "Other Mid-Year Changes Requiring Enrollee Notification."

After considering the public comments, we are finalizing, at §410.79(a), the policy as proposed with an effective date of April 1, 2018 for furnishing MDPP services. Based on the

many comments received in support of the proposed date, we believe the 90-day period will allow eligible organizations adequate time to enroll in Medicare as MDPP suppliers and furnish the services to eligible beneficiaries beginning April 1, 2018.

b. Changes to the Set of MDPP Services

In the CY 2017 PFS final rule, we established the parameters of MDPP services. The policies and terms in this final rule seek to clarify, build on, and at times change these previously finalized policies. In particular, we proposed to refine and add terms related to the different aspects of "MDPP services." In the CY 2018 PFS proposed rule, we proposed to refine the term "MDPP services" to refer to structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum (§410.79(b)). The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

In the preamble to the CY 2017 PFS final rule, we referenced the set of MDPP services covered under the expanded model as the "MDPP benefit." In the CY 2018 PFS proposed rule, we proposed to update this terminology. In cases where we would have previously referred to the term "benefit" to describe the entire set of MDPP sessions covered under the MDPP model, we proposed to use the phrase "set of MDPP services." "Set of MDPP services" means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and ongoing maintenance sessions, offered over the course of the MDPP services period (proposed §410.79(b)).

In cases where we would have previously used the term "benefit" to describe a period of time, we proposed to refer to the "MDPP services period." The MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in §410.79(c)(2)(i) and, subject to §410.79(c)(3), one or more ongoing maintenance session intervals during the ongoing services period described in §410.79(c)(2)(ii) (§410.79(b)). The duration of the MDPP services period is discussed further in section III.K.2.c.iv. of this final rule. As noted throughout this section, the term "benefit" would no longer be used. We proposed to remove the term "MDPP core benefit" from the list of definitions.

In the CY 2017 PFS final rule, we included a definition for "core sessions" that referred to the set of core sessions covered under the MDPP expanded model. We proposed to revise the definition for "core sessions," and instead define the singular "core session" as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for core sessions (§410.79(b)). We believe that having a definition for the individual core session would be more uniform with other MDPP definitions, which are defined in the singular form. We proposed to revise the definition of "core maintenance session" as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval, is approximately 1 hour in length, and adheres to a CDC-approved DPP curriculum for maintenance sessions (under §410.79(b)).

We proposed to revise the definition of an "ongoing maintenance session" as an MDPP service that is furnished by an MDPP supplier to an MDPP beneficiary during an ongoing

maintenance session interval; is approximately 1 hour in length and adheres to a CDC-approved DPP curriculum for maintenance sessions (§410.79(b)). The time period over which MDPP suppliers offer ongoing maintenance sessions, which differs from our previously finalized policy, is discussed in section III.K.2.b.i. of this final rule.

We proposed to add a definition for "MDPP session," which means a core session, a core maintenance session, or an ongoing maintenance session (§410.79(b)).

We invited public comments on these proposals.

The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed support for the revised definitions and one commenter stated they were familiar with the terms "core" and "maintenance" in their current practice. Some commenters appreciated that the terms were aligned with the Centers for Disease Control and Prevention approved DPP curriculum with the addition of ongoing maintenance sessions. One commenter recommended CMS redefine the MDPP Services Period to include a core services period of 1 year and an ongoing maintenance services period of 1 year with the proposed 3-year MDPP payment model adjusted to reflect such changes. One commenter stated that CMS proposes that the core services period consist of two primary subsets: (a) core sessions, which consist of 16 sessions offered at least one week apart during months one through 6, and (b) core maintenance sessions, which are provided during months 7 through 12. Because a Medicare beneficiary could, as a technical matter, complete the 16 sessions by the end of month 4, the commenter requested that CMS clarify the proposed regulatory language to take into account the fact that core maintenance sessions could be provided during months 5 through 12 (as opposed to only during months 7 through 12). In other words, the commenter was requesting

that CMS clarify that months 5 through 6 could include either core sessions or core maintenance sessions, depending on the beneficiary and the pace at which that beneficiary participates in the MDPP. One commenter stated they were pleased that eligible beneficiaries will now be offered 16-weekly core sessions and 6 monthly core maintenance sessions regardless of their level of weight loss during the first 12 months.

Response: We appreciate the comments received on the proposed definitions for the MDPP Services Period. As we discuss more in section III.K.2.b.i of this final rule, we are finalizing that the ongoing maintenance services period will only be 1 year, and therefore, we agree with the comment to redefine the MDPP Services Period to include a core services period of 1 year and an ongoing maintenance services period of 1 year and will be modifying the definition to account for this change. Lastly, we clarify that monthly core maintenance sessions cannot begin prior to month 7 during the first 12 months because a core maintenance session interval is defined as occurring in months 7 through 12 of the MDPP services period. We understand that beneficiaries will complete the core sessions at different paces and some may complete 16 weekly sessions in the first 4 months; however, 16 weekly sessions is the minimum number of sessions to be furnished during months 1-6. Our definition of the MDPP Services Period being finalized at §410.79(b) and (c)(2)(i), specifies that MDPP suppliers must furnish at least 16 core sessions during months 1-6 and that these core sessions must be offered at least 1 week apart. This definition allows flexibility to suppliers in terms of the frequency that core sessions may be offered. Suppliers can offer core sessions less frequently than weekly so they are spread more evenly across months 1-6 or they can offer them weekly. If a supplier chooses to offer them weekly and a beneficiary completes 16 sessions in months 1 through 4, the supplier will need to offer additional sessions during months 5 and 6 in order to avoid a 2-month break in

service for the beneficiary. In this case, the number of additional core sessions offered is left to the discretion of the supplier. However given the evidence from the CDC's DPRP that it takes an average of 17 DPP sessions attended for an individual in the DPP to exceed the required minimum weight loss[8], and the importance of the first 6 months in achieving weight loss as discussed in more depth in section K.III.2.d.iii.(3) of this final rule, we believe most beneficiaries who attend 16 sessions by month 4 would require high engagement during those 2 months in order to achieve or maintain weight loss by month 7.

Comment: Although unrelated to the current proposals regarding changes to the MDPP set of services, many commenters expressed support for Medicare's expansion of MDPP services as a Part B additional preventive service, and one commenter requested that CMS encourage Medicare Advantage Organizations to cover MDPP as they do other preventive and screening services. However, one commenter stated that the mandate of the MDPP beyond Medicare Part B to Medicare Advantage and PACE plans unduly restricts these plan providers and requested the ability to seek a waiver that would remove the requirement that an MA plan provide MDPP services if the MA plan is able to show that alternative prediabetes outreach is available to plan enrollees that may better fit the plan's service delivery model.

Response: We clarify in this final rule that under 42 CFR 422.100(a), MAOs offering MA plans must provide enrollees in that plan with coverage of all basic benefits, which are defined at §422.100 (c)(1) as all Medicare-covered services, except hospice services. In the CY 2017 PFS final rule, we finalized our proposal to expand the duration and scope of the DPP model test through the MDPP expanded model under section 1115A(c) of the Act, as well as our proposal to designate MDPP services as "additional preventive services" as defined by section

[8] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

1861(ddd) of the Act. Thereafter, in a November 23rd, 2016 HPMS memo, we stated that, as a Part B additional preventive service, MDPP services will be covered for eligible Medicare beneficiaries under Medicare health plans. We reiterate here that this includes Medicare Advantage plans. The commenter did not offer an explanation as to why the requirement that Medicare Advantage plans provide MDPP services to enrollees is more restrictive than coverage of any other new or existing Part B covered service that would be required under §422.100(a), and we can see no reason that MDPP, in particular, would be more restrictive on plan providers than previous Part B services provided to enrollees as basic benefits under §422.100(a). Furthermore, while we applaud MA plans that currently provide prediabetes outreach, we note that there is no current mechanism by which CMS may review existing prediabetes outreach or programs and then make a determination to waive particular MA plans from the requirements of §422.100(a) as they relate to MDPP services. As such, we decline to do so here. We note that MA plans are free to provide existing prediabetes services and outreach that do not qualify as MDPP services as a supplemental benefit available to enrollees.

Comment: We received requests from commenters to provide flexibility to modify the curriculum that MA plans must provide to MA enrollees to meet the MDPP services coverage requirement. One commenter requested the removal of a specific curriculum element--the requirement that ongoing maintenance sessions be approximately one hour in length. Both commenters requested clarification as to whether MA plans may provide modified curriculums for MDPP services provided to MA enrollees so long as they are similar to the CDC DPRP curriculum described at §410.79(b).

Response: Although these commenters did not comment on any specific proposals on the changes to the MDPP set of services, we believe it is appropriate to respond to provide

clarifications in this final rule with respect to MDPP services more generally. We decline to accept the commenter's recommendation to remove the requirement that MDPP suppliers must provide ongoing maintenance sessions that are approximately one hour in length. In the CY 2017 PFS final rule, we agreed with commenters that our former proposal of a one-hour requirement may be too rigid when compared against CDC-approved DPP curricula that vary in approach and mode of delivery. We noted 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. As stated in the CY 2017 PFS final rule, 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 declined to adopt it for MDPP because having auditable requirements is a critical component of our program integrity efforts (81 CFR 80468). We believe our previous amendment to the session duration (formerly §410.79(c)(2)(i) and (c)(2)(ii), and redesignated at §410.79(b) in this final rule) is satisfactory and that our rationale applies equally to MDPP suppliers providing MDPP services to MA enrollees. Therefore, we are not modifying the requirement that ongoing maintenance sessions must be "approximately one-hour in duration."

We also decline to adopt commenters' recommendation to permit MA plans flexibility in providing MDPP services so long as the curriculum is similar to the CDC DPRP curriculum described at §410.79(b) as we believe adequate flexibility is already available to any MDPP supplier. As finalized in this final rule, MDPP services must meet the definition established at §410.79(b) defining MDPP services as "structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among

Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle." We also finalized in the CY 2017 PFS final rule that MDPP suppliers may, consistent with their CDC DPRP recognition, use either the CDC-preferred curriculum as designated by the CDC DPRP Standards or an alternative curriculum approved for use in DPP by the CDC (81 CFR 80467). The CDC preferred curriculum is available at http://www.cdc.gov/diabetes/ prevention/lifestyle-program/ curriculum.html. Therefore, MDPP suppliers, including those contracting with an MA plan or an MA plan itself when that MAO is enrolled in Medicare as an MDPP supplier, may choose to develop and use an alternative curriculum for MDPP services so long as the MDPP supplier has first had the curriculum approved by the CDC DPRP.

Comment: We received one comment that requested additional clarification on how MA plans will be required to report encounters for MDPP services to CMS.

Response: This question was asked in the context of a general request for CMS to provide additional guidance to MA plans regarding the implementation of MDPP in MA. Given this context, we believe that this could be a question about reporting this specific type of data to CMS under §422.310, which requires MA plans to report data (for risk adjustment purposes) about services provided to MA enrollees. While unrelated to the changes to the set of MDPP services, we note that the application of §422.310 in this context is not within the scope of the MDPP rule. We believe that there is no reason to treat MDPP services differently from other services furnished by an MA plan for which the data requirements of §422.310 apply. We further note that additional guidance to MA organizations will be forthcoming.

After considering the public comments, we will finalize all definitions as proposed with the exception of the MDPP Services Period. In response to public comments, we are finalizing the definition of the MDPP Services Period as consisting of a core services period of 1 year and an ongoing maintenance services period of 1 year at (§410.79(c)(2)).

i. Ongoing Maintenance Session Time Limit

In the CY 2017 PFS final rule, we finalized that "MDPP eligible beneficiaries" (a term we proposed to remove and replace with "MDPP beneficiary," as described further in section III.K.2.c. of this final rule) would have Medicare coverage for ongoing maintenance sessions for an unspecified length of time, provided that they maintained the required minimum weight loss, which is 5 percent weight loss from baseline. Based on public comments indicating the limited administrative and operational capability of many MDPP suppliers to provide ongoing maintenance sessions for an individual indefinitely (81 FR 80467), we stated our intent to propose a limit on the number or duration of ongoing maintenance sessions to be covered in the set of MDPP services in future rulemaking.

In the CY 2018 PFS proposed rule, we proposed a 2-year limit on Medicare coverage for ongoing maintenance sessions (§410.79(c)(2)(ii)). The CMS Chief Actuary noted in the certification of the expansion of the DPP model test that continued participation in a DPP after 3 years has generally been untested. In addition, a DPP clinical trial conducted by the National Institutes of Health from 1996 to 2001 followed participants in a DPP for 3 years and found that, at the end of the study, diabetes incidence was reduced by 58 percent in the group that received a DPP lifestyle intervention when compared to the placebo group.[9] Based on the lack of evidence about DPP services beyond 3 years and evidence of positive effects from DPP participation for 3

[9] Available at http://www.nejm.org/doi/full/10.1056/NEJMoa012512.

years, in the CY 2018 PFS proposed rule, we proposed a total MDPP services period of up to 3 years (consisting of 1 year of core sessions and core maintenance sessions, followed by up to 2 years of ongoing maintenance sessions, (§410.79(b)).

We considered alternatives to this proposal, such as limiting Medicare coverage for ongoing maintenance sessions to 1 year, which would limit the total MDPP services period to 2 years. Because the CDC DPRP does not require organizations to offer ongoing maintenance sessions, we also considered not covering ongoing maintenance sessions at all, which would limit the total MDPP services period to 1 year. However, we believe that beneficiaries can benefit from maintenance sessions beyond the 6 months of core maintenance sessions because weight loss is difficult to achieve and can be even more difficult to sustain. We believe that the behavior changes necessary to sustain weight loss will be more deeply ingrained through beneficiary participation in ongoing maintenance sessions. Existing evidence also supports the effectiveness of participation in a DPP through 3 years.

We did not consider alternatives that would extend Medicare coverage for ongoing maintenance sessions beyond 2 years, and therefore, create an MDPP services period that would last longer than 3 years. Therefore, we proposed to continue to include ongoing maintenance sessions, but with a limit of up to 2 years. As stated earlier, we believe there is not enough evidence available to support the effectiveness of participation in a DPP beyond 3 years. We also believe, based on public comments received in response to the CY 2017 PFS proposed rule, that many suppliers have limited administrative and operational capacity to offer MDPP ongoing maintenance sessions indefinitely to all MDPP beneficiaries who maintain eligibility. As noted in section III.K.2.e.iv.4 of this final rule, an example of a capacity limit could include a situation where an MDPP supplier has met its class size maximum and therefore could not accept

additional beneficiaries. We invited public comments on our proposal and the alternatives we considered.

The following is a summary of the public comments received on our proposal and the alternatives we considered and our responses:

Comment: We received several comments on the proposed time limit for ongoing maintenance sessions. Many commenters recommended limiting ongoing maintenance sessions to 1 year and defining the MDPP Set of Services as a 2- year service period. The majority of these commenters suggested that a 2-year service period better aligned with the evidence base, reduced supplier risk and administrative burden, and still allowed for adequate time for ongoing support to participants. One commenter stated that they support general limits to ongoing maintenance sessions, but expressed that by adding a third year to the overall MDPP services period, CMS is further expanding the DPP model test and the CDC National Diabetes Prevention Program curriculum without sufficient evidence to show that the benefit to beneficiaries would outweigh the burden on suppliers to continue to staff a third year of the program. Another commenter stated the scientific evidence to suggest an additional 24 months for ongoing maintenance sessions following the achievement of the 5 percent weight loss is unclear. In addition, some commenters expressed concern about MDPP suppliers delivering sessions to dwindling numbers of individuals over time and stated this was not a cost-effective approach, and could diminish the morale among those attending the ongoing maintenance sessions. One commenter suggested opportunities for MDPP beneficiaries to elect sessions beyond month 24 (possibly covered by the beneficiary's own funds). Another commenter stated they recognize the importance of ongoing maintenance classes, but find it unrealistic to have participants commit to

a 3-year program. They stated that in their experience it is difficult to maintain retention in a 12-month program, and the effectiveness of the sessions furnished in a third year would diminish.

Response: Upon consideration of the comments received, we agree that limiting the ongoing maintenance sessions to 12 months following the 12-month core program will reduce administrative burden and financial risk for suppliers while still providing 1 year of ongoing support and maintenance to help solidify behavior change in MDPP participants. Although there is evidence to support the effectiveness of participation in a DPP through 3 years, we acknowledge that evidence does not specifically address whether our proposed 2 years of ongoing maintenance is superior to 1 year of ongoing maintenance in establishing long-term behavior change or reduced incidence of type 2 diabetes. However, we maintain our belief that evidence supports requiring ongoing maintenance sessions after the core services period as discussed in a subsequent response to comments in this section.

In addition, we appreciate the commenters who pointed out that the absence of new curriculum for ongoing maintenance sessions posed a significant threat to the continued engagement of beneficiaries for a full 24 months. We agree with the assertion made by commenters that the core maintenance curriculum could become too repetitive during a second year of ongoing maintenance resulting in increasingly lower levels of participation among beneficiaries during later intervals. Based on the comments received on our proposals, we also better understand how this could contribute to dwindling enrollment during the ongoing maintenance years and how dwindling enrollment could create significant financial hardships for suppliers. We agree that it would be difficult and possibly economically unsustainable to secure space, staff coaches, and produce materials for classes that were not well attended due to a steady decrease in participants over the course of the ongoing maintenance period. From these

comments, we believe finalizing a 2-year requirement for the ongoing services period could have a negative impact on the number of DPP organizations that choose to enroll as MDPP suppliers due to the estimated financial hardships of this requirement.

Therefore, we believe that a modification to our policy to require 1 year of ongoing maintenance following the core services period is both supported by current evidence and responds to the practical considerations of implementing MDPP services by MDPP suppliers.

Comment: A few commenters recommended that ongoing maintenance sessions be available in perpetuity with some suggesting a restructuring of the ongoing maintenance sessions. One commenter suggested that CMS reconsider its proposed 2-year time limit on Medicare coverage for ongoing maintenance sessions. This commenter stated an appreciation for CMS' intent to control costs, but suggested that some Medicare beneficiaries may continue to benefit from MDPP for longer periods of time. Another commenter suggested that all beneficiaries who complete the program should be eligible for a lifetime of maintenance support independent of weight loss goal achievement. The commenter suggested the delivery of ongoing maintenance sessions could be restructured to include 2-3 sessions per year as needed.

Response: We disagree with the commenters that recommended we make ongoing maintenance sessions available in perpetuity. There is no evidence to suggest that ongoing maintenance sessions offered in perpetuity would provide any additional health benefit to Medicare beneficiaries. Similarly, and taking other public comments into account, there is no evidence to demonstrate a demand from beneficiaries for ongoing maintenance sessions in perpetuity. Lastly, there is no evidence to support that 2-3 sessions per year would be adequate for maintaining weight loss, and we do not believe this level of engagement is sufficient to warrant continued coverage of the MDPP services (please see more detailed discussion on

session attendance during the ongoing services period in section III.K.2.c.iv.(b) of this final rule).

Comment: Some commenters supported the proposed 2-year time limit for ongoing maintenance sessions. One commenter supported CMS's proposal to provide 2 years of ongoing maintenance sessions for a total of 3 years of MDPP services. This commenter stated that patients require ongoing support to make long-lasting behavioral changes, and since appropriate care plans and interventions may change over time, this item is most important for continued patient and program success. Another commenter stated that it is helpful, too, to cover the 2 years of maintenance after the core and core maintenance part of the DPP. The commenter stated that people do not change and maintain significant behavioral changes without this added opportunity for maintenance and support.

Response: We agree that maintaining significant behavioral change is challenging and requires ongoing maintenance and support. The evidence is less clear in terms of exactly how long ongoing maintenance is needed to sustain significant behavior change. Given this lack of clarity on the optimal length of maintenance coupled with the many comments we received from DPP organizations and other DPP stakeholders with keen insight into the delivery of DPP, we have chosen to finalize one of our alternatives and limit ongoing maintenance to 1 year.

Comment: Some commenters did not support the inclusion of ongoing maintenance sessions at all. Many of these commenters suggested that DPP organizations may not have the capacity to deliver ongoing maintenance sessions as proposed by CMS, and at this time, there is not a CDC curriculum for this program phase. Another commenter stated that ongoing maintenance beyond 12 months should not be required by MDPP suppliers as a condition for payment. A few commenters suggested that while individuals often need ongoing support to

maintain behavior change, individuals start dropping out of programs at 12 months. Other commenters recommended that CMS more closely align the MDPP services period with the CDC Diabetes Recognition Program curriculum and requirements which do not include any ongoing maintenance sessions. One commenter stated that to date, the evidence-base regarding DPP has been based on a 1-year program, and therefore, recommend that the program should remain a 1-year program. Lastly, a few commenters appreciated the importance of ongoing maintenance sessions in supporting the sustainability of participant outcomes but stated that the proposed level of reimbursement under the MDPP would not support the cost of additional human and material resources that would be needed to follow Medicare participants for an additional 2 years.

Response: We disagree that the evidence-base regarding DPP has been based on a 1-year program. In developing our length of service proposals, we performed an extensive literature review of the evidence, consulted with current DPP providers, the CDC's National Diabetes Prevention Program (DPP) staff, physicians, and a large commercial insurer. This research provided us with the evidence to support anywhere from a 1-year DPP program to a 3-year DPP program. We acknowledge that the CDC's National DPP does not currently extend beyond a 12-month program; however, as a payer, we are interested in taking an approach, which has been supported by the existing evidence base and public commenters, that we believe is most likely to sustain the behavior change beyond 12 months.

After considering the public comments, we are finalizing the length of the MDPP Services Period as a 2-year MDPP services period, specifically finalizing that after year 1, suppliers of MDPP would have to offer 1 year of ongoing maintenance sessions to beneficiaries who continue to meet attendance/weight loss goals. Finalizing this alternate proposal reduces

administrative burden and financial risk to suppliers while providing up to 1 year of additional support to beneficiaries. Based on our research and echoed by many of the public comments, we received in response to our CY2018 PFS proposed rule, we believe 12 months of ongoing maintenance should solidify the behavior change and help to ensure that weight loss outcomes are sustained.

ii. MDPP Services Period Clarifications

At §410.79(b), we proposed to remove the existing definition of "maintenance session bundle," and to establish new definitions for "core maintenance session interval," and "ongoing maintenance session interval," which we believe will more directly reflect the structure of the set of MDPP services, as well as support the policies in this final rule. Through these definition changes, we were seeking to clarify the differences between the two types of intervals. We proposed to define "core maintenance session interval" as one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least 1 core maintenance session per month. We proposed to define "ongoing maintenance session interval" as one of the up to eight consecutive 3-month time periods during the ongoing services period described in §410.79(c)(2)(ii), during which an MDPP supplier offers at least 1 ongoing maintenance session to an MDPP beneficiary per month.

We made the proposal to use the term "interval" instead of "bundle" because the performance payments are tied to attendance and weight loss performance goals and, in aggregate, constitute the payment to MDPP suppliers for furnishing MDPP services during the MDPP services period, but they do not provide specific payments for a particular subset of sessions. Therefore, we believe that the term "bundle" is not appropriate for describing

performance payments for these time intervals. The new terms would allow us to more appropriately describe the relationship of the performance payments to the specific time periods where performance is measured. Furthermore, we proposed to define "make-up session" as a core session, a core maintenance session, or an ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session (§410.79(b)). We proposed to define "virtual make-up session" as a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions (§410.79(b)). Policies describing the parameters of make-up sessions and virtual make-up sessions are described further in section III.K.2.c.iv.(3) of this final rule.

We proposed an additional term that helps describe key aspects of the MDPP expanded model: "performance goal." This term refers to an attendance or weight loss goal that an MDPP beneficiary must achieve during the MDPP services period for an MDPP supplier to be paid a performance payment (§414.84(a)). Because we proposed this term that more broadly speaks to the performance goals of this expanded model, we proposed to remove the definition of "maintenance of weight loss." We also proposed to move the definition of "coach" from §410.79(b) to §424.205(a) (we proposed in section III.K.2.e to redesignate §424.59, Requirements for Medicare Diabetes Prevention Program suppliers to §424.205). We proposed to revise the definition of "MDPP supplier" to mean an entity that is enrolled in Medicare to furnish MDPP services as provided in §424.59 (redesignated as §424.205).

We did not receive comments on the proposed revisions to these definitions, and therefore, we are finalizing these revisions as proposed with the exception of the definition for "ongoing maintenance session interval." In order to align with the finalization of the MDPP

Services Period as a 2-year period, we are finalizing the definition of the ongoing maintenance session interval as one of the up to four consecutive 3-month time periods during the ongoing services period described in §410.79(c)(2)(ii), during which an MDPP supplier offers at least 1 ongoing maintenance session to an MDPP beneficiary per month.

c. Changes Related to Beneficiary Eligibility

In the CY 2017 PFS final rule, we established the eligibility criteria for Medicare beneficiaries to have coverage of the set of MDPP services, codified at §410.79(c)(1) and (d), respectively. We previously finalized that an individual who met these criteria would be referred as an "MDPP eligible beneficiary." However, in the CY 2018 PFS proposed rule, we proposed to remove this term, and instead, add the definition of "MDPP beneficiary" to mean a Medicare beneficiary who meets the criteria specified in §410.79(c)(1)(i), who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in §410.79(c)(3) (§410.79(b)). We believe that this revised definition will provide more clarity about when a beneficiary qualifies to receive MDPP services. We proposed to remove the definition of "MDPP eligible beneficiary" to avoid confusion between the two definitions, and we proposed conforming changes to §410.79 to remove the term "MDPP eligible beneficiary" and use the term "MDPP beneficiary" in its place, where appropriate.

In the CY 2017 PFS final rule (81 FR 80470), we specified at §410.79(c)(1) that Medicare beneficiaries are eligible for MDPP services if they meet all of the following criteria:

- Are enrolled in Medicare Part B.
- 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 (please see our discussion of BMI parameters in the CY 2017 PFS final rule at 81 FR 80468).

- Have, within the 12 months prior to attending the first core session, a hemoglobin A1c test with a value between 5.7 and 6.4 percent, a fasting plasma glucose of 110-125 mg/dL, or a 2-hour plasma glucose of 140-199 mg/dL (oral glucose tolerance test).
- Have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes).
- Do not have end-stage renal disease (ESRD).

In the CY 2018 PFS proposed rule, we proposed changes to these eligibility criteria at §410.79(c)(1) to clarify the eligibility limitations related to previous type 1 or type 2 diabetes diagnosis (described further in section III.K.2.c.ii. of this final rule), move and edit the regulation text that specifies that each beneficiary can only receive the set of MDPP services once in their lifetime (described further in section III.K.2.c.iii. of this final rule), and make changes so that the provisions are specific to an individual beneficiary. We also clarify some of the eligibility criteria.

Comment: We received a variety of comments on referral pathways for MDPP services, though we did not specifically propose any new policies regarding referrals. Some commenters supported the policy that CMS allow multiple referral pathways for beneficiaries, including self-referral, referral by a physician, and referral from community-based organizations. One commenter who supported these multiple referral pathways also noted that beneficiaries who self-refer or are referred by community programs to MDPP may not fully benefit from care coordination by their primary care provider on their diabetes care. This commenter urged CMS to consider a mechanism to ensure that the beneficiary's primary care provider be notified of the beneficiary's participation in MDPP in cases where the primary care provider is not the referring person or entity.

MedPAC opposed the policy of multiple referral pathways, preferring instead that only a clinician referral be allowed, and required, for each MDPP beneficiary. MedPAC noted that clinician referrals would help ensure clinical appropriateness of MDPP services or integration with other medical services and health maintenance goals. They were also concerned that multiple referral pathways would assist in leading to broad expansion of MDPP services and up-take, far beyond the population for which it is appropriate. MedPAC offered the example of an MDPP supplier conducting an MDPP session for a large group of beneficiaries at a nursing home, without consideration of whether a general weight loss target is clinically appropriate for each beneficiary in that group. Other commenters noted that there was no mention in the proposed rule of a provider referral mechanism or reimbursement, and recommended creating patient referral codes.

Response: We note that in the CY 2017 PFS final rule we finalized that Medicare beneficiaries who meet the MDPP eligibility criteria may obtain MDPP services by self-referral, community-referral, or health care practitioner-referral. Since we did not propose any changes to the referral policy in this rule, we are not finalizing any changes to this policy, but reemphasize our position regarding beneficiary referrals to and from MDPP services. We note that MDPP is a preventive service. Given that preventive services are generally underutilized,[10] facilitating broad access to MDPP services is important. In addition, the MDPP expanded model has been certified by the CMS Office of the Actuary to be cost-saving, and therefore, we believe eliminating barriers, such as clinician referrals, will facilitate access to this cost-saving preventive service.

[10] See, for example: Partnership for Prevention, "Preventive Care: A National Profile on Use, Disparities, and Health Benefits," *Robert Wood Johnson Foundation* (2007), https://www.rwjf.org/content/dam/farm/reports/reports/2007/rwjf13325; Maciosek, et. al, "Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost," *Health Affairs* 29, no. 9 (2010): 1656-1660, http://content.healthaffairs.org/content/29/9/1656.full.pdf+html; Farley, et. al, "Deaths Preventable in the U.S. by Improvements in Use of Clinical Preventive Services," American Journal of Preventive Medicine 38, no. 6 (2010): 600-609, http://www.sciencedirect.com/science/article/pii/S0749379710002072.

We also note that Medicare beneficiaries can always consult with their health care provider about whether MDPP services are clinically appropriate for the beneficiary.

We acknowledge the concerns from MedPAC regarding uptake of MDPP services beyond the population for which it is appropriate. We believe the requirement for MDPP suppliers to maintain CDC preliminary or full recognition will provide some level quality assurance. Specifically, maintenance of CDC recognition will require MDPP suppliers to continue to achieve performance standards based on attendance and average weight loss among participants. If an MDPP supplier chose to enroll large numbers of individuals who were clinically inappropriate for MDPP (for example, who lack the cognitive capability to implement the behavior changes), these practices may drive down their average performance data, and negatively affect the supplier's ability to maintain CDC recognition. Nevertheless, we are establishing monitoring mechanisms such that if a supplier was offering MDPP services to large numbers beneficiaries for whom the services may not be appropriate, we could identify this supplier and take appropriate administrative action.

Comment: Two commenters asked whether MA plans can modify beneficiary eligibility requirements for MA enrollees. The first commenter asked for clarification on whether an MA plan may impose additional eligibility requirements for MA enrollees, such as the requirement that an enrollee have a primary care physician referral to access MDPP services or to require a blood test prior to authorizing MDPP services. The second requested that we provide MA plans with the flexibility to provide or arrange for MDPP services as deemed appropriate by the plans, which the commenter identified as the standard for other Parts A and B services.

Response: While we did not propose any additional policies regarding referrals or alternative MDPP beneficiary eligibility criteria, we respond to commenters here to clarify this

issue. Under §422.100(a), MA plans are required to provide enrollees in that plan with coverage of Medicare-covered services. As a Part B Medicare-covered service, §422.100(f) requires CMS to ensure that an MA plan's coverage of MDPP services meets CMS fee-for-service rules described in this final rule and the CY 2017 PFS final rule. Additionally, §422.101(b)(2) requires MAOs to comply with general coverage guidelines included in original Medicare manuals and instructions unless superseded by MA regulations or guidance in connection with coverage of basic benefits.

In response to commenter's request to require physician referrals for MDPP services, we note that previous MDPP guidance, the CY 2017 PFS final rule, intentionally does not include a requirement for a physician referral to be eligible for coverage. In that rule, we finalized that we would not require any specific type of referral for the MDPP expanded model test in order to ensure broad program access (81 CFR 80471). In finalizing this policy, we noted that we understood the value of coordinating results from the MDPP with a beneficiary's primary care provider, however, we declined to 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. Furthermore, regarding commenter's request to allow MA plans to arrange for MDPP services as deemed appropriately by the plan, we understand the commenter to be requesting that MA plans be permitted to arrange for MDPP services as deemed medically necessary by the plan, as is the current standard. While general coverage guidelines included in original Medicare manuals and instructions may permit MAOs to arrange for other Parts A and B services as deemed medically necessary by the plan, in the CY 2017 final rule (81 CFR 80468 through 80470) and in this section of this final rule we explicitly designate a set of criteria for determining eligibility for MDPP services. Therefore, to ensure access to MDPP

services as a Medicare covered service is consistent with coverage available in Original Medicare, we decline to permit MA plans to modify the eligibility requirements established in this final rule when determining the eligibility of a plan enrollee for coverage of MDPP services.

Comment: Some commenters raised concerns that obtaining documentation for clinical blood values from beneficiaries to determine their eligibility prior to furnishing MDPP services will present challenges to MDPP suppliers. One commenter in particular raised concerns with requiring blood tests from every beneficiary, citing this as a structural barrier for beneficiary participation and a burden on MDPP suppliers who may not be able to afford to delay MDPP sessions for individuals who are missing the required documentation. This commenter recommended that CMS adopt CDC's National DPP requirement that at least 50 percent of participants qualify for the DPP based on blood values, and allow the remaining 50 percent to participate based on a risk assessment. This commenter also noted that the National DPP allows blood values to be collected and documented after an individual begins DPP sessions, and requested that CMS allow MDPP beneficiaries up to 30 days after the first core session to provide their blood test results given that the beneficiary meets all other MDPP eligibility criteria.

Response: We note that we finalized beneficiary eligibility criteria, including criteria for blood test results, in the CY 2017 PFS final rule. Since we did not propose any changes to the blood test requirements in this rule, we are not finalizing any changes but are clarifying our policy. We acknowledge that the CDC enforces the blood test eligibility criteria at the organizational level. However, since Medicare will be paying for individuals receiving a service, it is necessary that we enforce eligibility on an individual basis as well. We also acknowledge that CDC allows blood values to be collected and documented after an individual begins DPP

sessions. We considered allowing this policy for MDPP beneficiaries. However, if a beneficiary began MDPP services and was later determined ineligible due to their blood values, we have no way to prevent an MDPP supplier from charging the beneficiary for the services already received. We do not want to allow situations where a beneficiary could potentially be held liable for a service he/she thought was covered by Medicare, so we are not pursuing a change to this policy.

As we did not propose any substantive changes to the beneficiary eligibility policies, including referral pathways and blood test documentation, we are not finalizing any changes to these policies.

i. Clarifying MDPP Eligibility Criteria Related to Gestational Diabetes and End-Stage Renal Disease (ESRD)

In the CY 2018 PFS proposed rule (82 FR 34133), we noted that we are not excluding beneficiaries with a prior history of gestational diabetes from eligibility for MDPP services, while beneficiaries with a prior history of a diagnosis of type 1 or type 2 diabetes are ineligible. The eligibility criteria are intended to identify a beneficiary at high risk for the development of type 2 diabetes in an individual that has not been diagnosed with type 1 or type 2 diabetes. Gestational diabetes is a condition that develops during pregnancy and typically resolves after delivery, although an individual with a history of gestational diabetes is at increased risk of subsequent type 2 diabetes development and may benefit from the set of MDPP services. Because of the clinical differences between gestational diabetes and type 1 or type 2 diabetes, we determined that it was appropriate not to exclude a beneficiary with a prior history of gestational diabetes from eligibility for MDPP services.

We also proposed (82 FR 34133) that a beneficiary who is diagnosed with ESRD after having begun receiving MDPP services would lose eligibility. We do not believe MDPP services are appropriate for beneficiaries with ESRD because beneficiaries with ESRD require dialysis, and the nutrition requirements for individuals on dialysis are very specific and therefore the MDPP curriculum will not apply.[11] We believe that a beneficiary receiving MDPP services who develops ESRD will be best suited by ceasing to receive MDPP services and receiving attention by other health care professionals specifically suited to address his or her condition. Additionally, individuals with ESRD were not included in the DPP model test. We noted that suppliers can use the online HIPAA Eligibility Transaction System (HETS) to verify if a beneficiary has ESRD by checking his or her eligibility status as a Part B or ESRD Medicare beneficiary. Suppliers can find more information on this system at https://www.cms.gov/hetshelp/. We recognized that some Medicare beneficiaries may have other serious conditions, such as heart disease or cancer, and therefore may also have specific dietary requirements. We recommended that beneficiaries with complex dietary needs consult their health care provider as to whether they should participate in MDPP.

In summary, we noted that a beneficiary must maintain Medicare Part B coverage and not have ESRD throughout the duration of the MDPP services period to remain eligible to receive coverage for MDPP services. In conjunction with our proposal in the proposed rule related to diabetes diagnosis (explained further in section III.K.2.c.ii. of this final rule), we noted that a beneficiary must meet the eligibility requirements related to prediabetes and diabetes (including

[11] WE Mitch, "Beneficial responses to modified diets in treating patients with chronic kidney disease," *Kidney International Supplements* April, 94 (2005): S133-5, https://www.ncbi.nlm.nih.gov/pubmed/15752230. J Rysz et al., "The Effect of Diet on the Survival of Patients with Chronic Kidney Disease," *Nutrients* 9, no. 5 (2017): E495, https://www.ncbi.nlm.nih.gov/pubmed/28505087. ME Chen et al., "Correlations of dietary energy and protein intakes with renal function impairment in chronic kidney disease patients with or without diabetes," *The Kaohsiung Journal of Medical Sciences* 33, no. 5 (2017):252-259, https://www.ncbi.nlm.nih.gov/pubmed/28433072.

BMI, blood test results, and no diagnosis of diabetes other than gestational diabetes) as of the date of attendance at the first core session.

We invited public comments on these clarifications. The following is a summary of the public comments received on these clarifications and our responses:

Comment: Commenters noted their support for the clarifications related to gestational diabetes and End-Stage Renal Disease (ESRD) eligibility criteria. One commenter requested that CMS integrate checks on ESRD at the federal level. Another commenter requested that CDC and CMS align eligibility criteria related to gestational diabetes. The commenter noted that CDC does not allow individuals who previously had gestational diabetes to participate in DPP, whereas CMS does allow beneficiaries who previously had gestational diabetes to participate in MDPP. One commenter requested clarification on whether an individual with a history of gestational diabetes must still meet prediabetes and BMI eligibility requirements to participate in MDPP.

Response: We appreciate commenters' support for the clarifications about gestational diabetes and ESRD eligibility criteria. CMS currently has a system that suppliers can use to check whether an individual has Medicare coverage by way of ESRD, called the HIPAA Eligibility Transaction System (HETS). Suppliers can find more information on this system at https://www.cms.gov/hetshelp/. Medicare suppliers can also determine this information by contacting their Medicare Administrative Contractor (MAC). We note, however, that the HETS system may only identify beneficiaries entitled to Medicare by way of ESRD, as described in §406.13 of this chapter. Beneficiaries who are entitled to Part B benefits by aging into Medicare, who then develop ESRD, are not captured as having ESRD in HETS. Therefore, we clarify that MDPP suppliers can rely on self-reported ESRD status for beneficiaries who age into Medicare.

We view this process as similar to the other self-reported eligibility criteria we noted in the CY 2017 final rule (81 CFR 80469), including a history of type 1 or type 2 diabetes diagnosis. As noted in §424.205(d)(11), before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. This information must include beneficiary eligibility requirements under §410.79(c)(1), which include ESRD status and history of type 1 or type 2 diabetes diagnosis. We intend to include in guidance that this disclosure should inform beneficiaries to report this information to their MDPP supplier.

In response to the commenter who noted a discrepancy in eligibility criteria between CDC and CMS regarding individuals with a previous diagnosis of gestational diabetes, we believe that the commenter was mistaken. CDC has always allowed women with a previous diagnosis of gestational diabetes to participate in the National DPP. If a woman has a previous diagnosis of gestational diabetes and meets the BMI and age criteria, she is eligible for the National DPP and would not need a blood test or an elevated risk test score.[12] Similarly, if a Medicare beneficiary has had a previous diagnosis of gestational diabetes and meets all other MDPP eligibility criteria, the beneficiary is eligible to receive MDPP services, as described at §410.79(c)(1)(i)(E).

We also note that the DPRP Standards allow women who become pregnant and develop gestational diabetes to continue participation in the national DPP. Similarly, we clarify if a Medicare beneficiary becomes pregnant and develops gestational diabetes while receiving MDPP services, that beneficiary may continue participation in MDPP (as long as the beneficiary

[12] Centers for Disease Control and Prevention, "Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operation Procedures," *CDC* (2015), https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf.

continues to meet the applicable performance goals required for eligibility). We encourage commenters to look to the final 2018 DPRP Standards, when available, for any updated information on how gestational diabetes is treated for the purposes of CDC performance data reporting.

Because we did not propose any policies, we are not making any modifications to the beneficiary eligibility criteria related to gestational diabetes and ESRD, at §410.79(c)(1)(i)(E) and (c)(1)(i)(F), respectively.

ii. Diabetes Diagnosis during the MDPP Services Period

In the CY 2017 PFS final rule, we finalized at §410.79(c)(1) that to be eligible for coverage for the set of MDPP services, a Medicare beneficiary must have prediabetes, as shown through a qualifying BMI and blood test results, and must have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes). We received public comments in response to the CY 2017 PFS proposed rule that asked whether a beneficiary would remain eligible for the set of MDPP services if the beneficiary developed type 2 diabetes during the MDPP services period. In the CY 2017 PFS final rule, we deferred action in response to these public comments and are now addressing them in this final rule.

We proposed in the CY 2018 PFS proposed rule (82 FR 34133 through 34134) that the diabetes diagnosis exclusion applies only at the time of the first core session (that is, if a beneficiary develops diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services). Specifically, we proposed to revise the eligibility requirements for MDPP services to state that a beneficiary has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes (§410.79(c)(1)(i)(E)). This policy proposed was based in part on the fact

that the DPP model test, which demonstrated cost savings, did not exclude from the model individuals who developed type 2 diabetes. Additionally, whereas suppliers can check HETS to verify if a beneficiary has Medicare coverage by way of ESRD, and can rely on self-report for beneficiaries who age into Medicare and then develop ESRD, we believe requiring a supplier to reassess other beneficiary eligibility criteria such as diabetes status and blood test results, and subsequently removing those who no longer meet the eligibility criteria is impractical and unduly burdensome.

Alternatively, we considered deeming any beneficiary who develops diabetes during the MDPP services period to be ineligible to continue to receive coverage for MDPP services because these services are intended to be preventive. If a beneficiary progresses to type 2 diabetes, other treatment options, such as Diabetes Self-Management Training (DSMT), may be more appropriate than services that seek to prevent a condition the beneficiary already has. However, it is important to note that the receipt of MDPP services does not preclude a beneficiary from accessing other treatments for diabetes during the time period that the beneficiary is covered for MDPP services. An MDPP beneficiary who ultimately also receives DSMT at some time during the MDPP services period because he or she develops diabetes after beginning the set of MDPP services will receive different types of information and training. For example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and life style changes including blood sugar monitoring, insulin usage, medication management, and crisis management. In contrast, MDPP services will be furnished by trained coaches who teach beneficiaries with prediabetes how to lower their risk of progressing to type 2 diabetes with methods that do not include medication or other interventions for beneficiaries diagnosed with diabetes. Despite some common elements, the interventions for

the MDPP expanded model and the DSMT benefit target different populations and furnish different services.

We sought public comments on our proposal and whether individuals who develop type 2 diabetes during the MDPP services period should continue to be eligible for coverage of MDPP services for the full duration of the MDPP services period.

The following is a summary of the public comments received on the proposal that if a beneficiary develops type 2 diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services and our responses:

Comment: The majority of commenters supported the proposal to allow beneficiaries who develop diabetes while receiving MDPP services to continue to be eligible for MDPP for the remainder of the MDPP Services Period. The commenters noted that MDPP services will continue to be beneficial to beneficiaries with diabetes, that the MDPP curriculum varies from other Medicare-covered diabetes curriculum, such as DSMT, and that it would be impractical and unduly burdensome for suppliers to continually verify a beneficiary's diabetes status and blood test results. Of those who supported the proposal, some commenters requested that MDPP suppliers also refer beneficiaries who develop diabetes to their health care provider while other commenters requested that MDPP suppliers inform the beneficiary of Medicare-covered diabetes services, such as DSMT. Some commenters remained neutral on the proposal, either requesting further clarification or recommending that CMS continue testing this policy to ensure beneficiary access, clinical goals, and program savings. One commenter disagreed with the proposal and recommended that individuals who develop diabetes only remain eligible for MDPP services until the end of the type of session the beneficiary is receiving (that is, core sessions, core maintenance sessions, or ongoing maintenance sessions). This commenter suggested that MDPP

suppliers be required to refer beneficiaries who develop diabetes to medical nutrition therapy and DSMT services, noting concern that these beneficiaries may not receive the necessary referrals and underutilize these benefits.

Response: We agree with the commenters who noted that MDPP services will continue to be beneficial to beneficiaries with diabetes, that the MDPP curriculum varies from other Medicare-covered diabetes curriculum, such as DSMT, and that it would be impractical and unduly burdensome for suppliers to continually verify a beneficiary's diabetes status and blood test results. We also note that the DPP model test, which demonstrated cost savings, did not exclude from the model individuals who developed diabetes. We clarify, for those who recommended continued testing, that CMS will monitor this policy over time and make adjustments if necessary. We clarify that we believe it is most appropriate for MDPP suppliers to recommend that beneficiaries who develop diabetes during the MDPP services period see their primary health care provider who is best suited to develop a treatment plan for beneficiaries, which could include continuation or discontinuation of MDPP services, or other diabetes-related health care services such as DSMT. As finalized in last year's final rule, and discussed further at section III.K.2.c of this final rule, however, we are not requiring MDPP suppliers to refer beneficiaries to health care providers. Additionally, an MDPP supplier (and the MDPP beneficiary) may be unaware that the beneficiary has developed diabetes, and therefore, we do not believe that mandatory referrals are appropriate. We note that the receipt of MDPP services does not preclude a beneficiary from accessing other treatments for diabetes during the time period that the beneficiary is covered for MDPP services, but emphasize the importance of beneficiaries who develop diabetes to consult with their health care provider on the most appropriate treatment plan for their diabetes, which may or may not include MDPP services.

Comment: Some commenters noted data reporting discrepancies between CDC and CMS. They noted that the proposed 2018 DPRP standards suggest that DPP programs no longer submit data to CDC on participants that have received a type 2 diabetes diagnosis while receiving DPP services, whereas CMS will continue to collect data on, and pay for services for, these individuals. Commenters noted that this will cause a gap in MDPP suppliers' required crosswalk between a beneficiary's DPRP data and billing documentation for CMS. Commenters recommended that CDC and CMS align their data submission guidelines to best track and support these beneficiaries.

Response: We appreciate the comments on this difference in data submission requirements. As with other parts of the MDPP expanded model, we are coordinating closely to align with CDC to ensure there are not major discrepancies between our programs. We encourage commenters to look to the final 2018 DPRP standards, when available, for any updated information on data reporting regarding individuals who develop type 2 diabetes while receiving DPP services.

Comment: Some commenters noted incorrect information in the CY 2018 PFS proposed rule. In discussing the alternative considered to our proposed diabetes diagnosis policy, we stated, "[f]or example, a beneficiary receiving DSMT furnished by certified diabetes educators acquires knowledge for self-care and life style changes including blood sugar monitoring, insulin usage, medication management, and crisis management" (emphasis added). Commenters brought to our attention that the National Standards for Diabetes Self-Management Education and Support do not require health professionals to hold a certification in diabetes education to offer DSMT services and recommended we replace "certified diabetes educators" with a more appropriate phrase, such as "health professionals who have experience in diabetes education."

Response: We appreciate commenters bringing this to our attention.

In response to the comments, we are finalizing our proposal, without modification, that the diabetes diagnosis exclusion applies only as of the date of attendance at the first core session, (that is, if a beneficiary develops diabetes during the MDPP services period, it would not affect the beneficiary's eligibility to continue receiving MDPP services) at §410.79(c)(1)(i)(E).

iii. Once-Per-Lifetime Set of Services

In the CY 2017 PFS final rule, we specified that coverage for the set of core MDPP services is available only once per lifetime for each MDPP beneficiary (codified at §410.79(d)(1)). In the CY 2018 PFS proposed rule, we proposed to delete §410.79(d)(1) and move this provision to §410.79(c)(1)(i)(B) to place it with other MDPP beneficiary eligibility criteria. We also proposed to edit this provision to specify that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once per lifetime per MDPP beneficiary (82 FR 34134). Since we had proposed to limit the ongoing services period to 2 years (which we are finalizing as 1 year), we believed that this revision is necessary to clarify that coverage for the entire set of MDPP services is subject to this limitation--otherwise, the once-per-lifetime limitation has no practical effect because an MDPP beneficiary could continue to attend ongoing maintenance sessions long after the MDPP beneficiary has completed the core services period. In addition, for the reasons stated previously, we do not have evidence to support coverage of MDPP services for more than 3 years. We also are clarifying that the once-per-lifetime coverage limit applies to a beneficiary who receives a set of MDPP services under the MDPP model expansion. This limitation would not apply to beneficiaries who participated in a DPP as part of the DPP model test unless they

receive the set of MDPP services under the MDPP expanded model. We invited public comments on our proposal.

The following is a summary of the public comments received on the proposed provision that coverage for the full set of MDPP services, inclusive of ongoing maintenance sessions as opposed to only core MDPP services, is available only once-per-lifetime per MDPP beneficiary and our responses:

Comment: The majority of commenters opposed the once-per-lifetime limit on MDPP services, generally, including the previously finalized once-per-lifetime limit on the core set of services finalized in the CY 2017 PFS final rule and the proposed limit on the ongoing services. Some commenters only supported the lifetime limit if maintenance sessions were to be available for all beneficiaries regardless of weight loss, or if all beneficiaries who complete the core services can receive 2-3 maintenance sessions per year. Other commenters recommended that beneficiaries be able to access MDPP services annually, similar to what is allowed in some private plans. Commenters who opposed the once-per-lifetime limit stated that the limit will decrease access to MDPP services, especially for those beneficiaries that need the most assistance. These commenters noted that behavior changes take time and often require multiple attempts or ongoing support. They additionally noted that major life events may prevent a beneficiary from participating.

Some commenters recommended that beneficiaries be allowed to re-enroll in MDPP services. Others recommended providing exceptions to the once-per lifetime limit in the case of a major life event, allowing a 6- to 12-month waiting period for a beneficiary to re-enroll in MDPP after stopping (similar to Medicare's obesity counseling benefit), or both approaches. One commenter recommended that CMS allow MDPP beneficiaries to participate in an introductory

session where beneficiaries can learn the requirements of the program and coaches can assess a beneficiary's readiness for change before initiating core sessions. The commenter recommended that CMS allow a beneficiary the opportunity to withdraw within 30 days from the start of the core services period without triggering the once-per-lifetime limitation so that those MDPP beneficiaries who may not be ready to complete the program may withdraw from MDPP and participate at a later time. Another commenter suggested that CMS and CDC identify and encourage the use of a validated "readiness to change" assessment instrument and a "life stress" assessment instrument to engage beneficiaries in a shared decision-making process so that individuals commit to the MDPP at a time they are most likely to succeed in the program. Some commenters also encouraged CMS to study the effect of allowing beneficiaries to enroll in the program multiple times.

Response: We recognize that behavior changes take time and often require multiple attempts or ongoing support. We also understand concerns that major life events may prevent a beneficiary from participating during the MDPP services period. However, we finalized in the CY 2017 PFS final rule that the core set of MDPP services would only be available once-per-lifetime per MDPP beneficiary (previously at §410.79(d)(1); now at §410.79(c)(1)(i)(B)). The MDPP model expansion was designed to permit access to MDPP services to the greatest extent possible within the limits of how MDPP could be expanded. We also believe that having MDPP services available once-per-lifetime will better engage beneficiaries to make behavior changes than if they could re-start services again at any time. We believe that this same rationale applies to ongoing maintenance sessions and continue to believe the once-per-lifetime limit is the most appropriate policy at this time, particularly given the added flexibilities beneficiaries have to use make-up sessions.

In finalizing the once-per-lifetime limitation on MDPP services in the CY 2017 PFS final rule, we added in flexibility for beneficiaries by not including any attendance requirements for beneficiary eligibility in the first year of core services following the first core session. Therefore, beneficiaries can attend as many or as few sessions as the beneficiary wishes in the first year, and as long as they meet the 5 percent weight loss goal in months 10-12, they are eligible for ongoing maintenance sessions. If an unexpected or life-altering event does occur during the core services period, the beneficiary is not required to attend a certain number of sessions. The beneficiary can take a break and begin attending MDPP sessions again within the first year. The beneficiary could also still be eligible for ongoing maintenance sessions, as long as the beneficiary begins attending sessions again and meets the 5 percent weight loss goal in months 10-12. Additionally, in this rule, we are finalizing the ability for beneficiaries to attend in-person or virtual make-up sessions if they miss a regularly scheduled session. We believe that these policies provide flexibility for beneficiaries who experience difficulty attending sessions during both the core services and ongoing services periods in light of the once-per-lifetime service limitation.

We appreciate the comments received recommending the allowance of an introductory session and 30-day window to withdraw, as well as the use of an assessment tool to assess if the beneficiary is ready to start MDPP services, so that the beneficiary can understand the eligibility requirements and determine if he or she is ready to begin. We note that suppliers may speak to beneficiaries about their readiness while assessing them for eligibility or before the beneficiary begins MDPP services. This could include the use of any tools that the supplier may have to help a beneficiary make their own determination about whether to commit to the MDPP services period or not. However, MDPP suppliers may not use these tools to screen beneficiaries for their perceived ability to successfully complete the MDPP performance goals. Selecting beneficiaries

based on these purposes would not comply with the MDPP supplier standard proposed (and which we are finalizing) in §424.205(d)(8), which prohibits an MDPP supplier from denying an MDPP beneficiary access to MDPP services during the MDPP services period, including on the basis of the beneficiary's weight, health status, or achievement of performance goals, with few exceptions. We also note that in §424.205(d)(11), which we are finalizing in this final rule, the supplier standards require MDPP suppliers to provide an MDPP beneficiary information about the MDPP set of services prior to beginning furnishing such services. This information must include eligibility requirements throughout the MDPP services period, including the once-per-lifetime limitation. We believe that this information will supply the beneficiary with the necessary information to make an informed decision on whether to begin MDPP services.

We acknowledge commenters' concerns on life altering events precluding a beneficiary's participation and understand that there will be circumstances that preclude an individual from participating. As stated previously, we believe the ability for a beneficiary to attend in-person and virtual make up sessions could assist in some of these circumstances. Additionally, because only 2.4 percent of participants in the DPP model test re-enrolled in the model while the model test was still active, we believe that the number of beneficiaries requesting to re-enroll in MDPP will be quite small. However, we plan to monitor the once-per-lifetime limitation to consider whether an exceptions policy for beneficiaries who experience life-altering events is necessary, and if appropriate, we will address this issue in future rulemaking.

In the CY 2017 PFS final rule, we stated that beneficiaries could self-report to MDPP suppliers that they had not previously received MDPP services. We recognize that self-reported information may not be the most reliable source for MDPP suppliers to use before submitting claims for MDPP beneficiaries, and there is a risk that information that is inaccurately self-

reported could result in the denial of payments for MDPP services. In the CY 2018 PFS proposed rule, we noted that we were considering ways MDPP suppliers would be able to reliably verify if a beneficiary has received MDPP services from another supplier, such as through a standardized tracker (82 FR 34134), and we sought public comments on any additional ways MDPP suppliers could access this information. We noted that we intend to provide administrative guidance on any resources to assist MDPP suppliers in identifying beneficiaries' previous receipt of covered MDPP sessions, as appropriate.

The following is a summary of the public comments received on ways that MDPP suppliers can reliably verify if a beneficiary has received coverage of MDPP services from another supplier and our responses:

Comment: Commenters generally raised concerns about the use of beneficiary self-reported data, noting that such data is often unreliable. Commenters also noted that verifying previous MDPP service use would require a sophisticated tracking system and urged CMS to work with MDPP suppliers to ensure accurate tracking of eligibility and progress through the MDPP services period. To this end, we received comments on a variety of ways for MDPP suppliers to verify if a beneficiary has previously received MDPP services from another supplier.

Some commenters requested that CMS document whether an individual has previously received MDPP services, and make this information available to MDPP suppliers to check a beneficiary's previous MDPP service use, at the federal level. One commenter suggested that CMS could build a beneficiary-level database that would contain information about MDPP status. The database could include the beneficiary's first name, last name, and birthdate so that MDPP suppliers could look up a beneficiary based on those three variables in order to identify his or her eligibility and program status based on time-to-date and MDPP sessions already

furnished in the MDPP services period. The commenter recommended against the use of social security numbers in this context, due to data security concerns. For looking up beneficiaries where those three pieces of information identify multiple individuals, the commenter suggested that a hotline could be set up and MDPP suppliers could call in to verify eligibility of a specific beneficiary for MDPP services. Another commenter similarly recommended building a master database for MDPP suppliers to use to verify MDPP use, and that CMS permit self-reporting until such a database exists. One commenter noted that CMS could consider leveraging state and local health information exchanges, where they exist, to transfer beneficiary information on MDPP service use.

Commenters were divided on CMS designing a paper tracker, such as the one mentioned in the CY 2018 PFS proposed rule, that beneficiaries could take with them to a new supplier to share information. One commenter recommended that CMS develop such a tracker to assist in data sharing between MDPP suppliers. However, this commenter also noted that for potential, small, and new DPP suppliers that typically have limited staff, the administrative processes involved with such a tracker may be burdensome. Another commenter raised concerns about such a tracker, noting that beneficiaries could lose their trackers and possibly modify results.

Response: We appreciate the suggestions on ways that MDPP suppliers can determine a beneficiary's prior use of MDPP services for the purposes of verifying eligibility. We recognize that self-reported data is not always reliable; however, we did state in the CY 2017 PFS final rule that beneficiaries could self-report to MDPP suppliers about their previous MDPP service use.

We agree that a beneficiary-level data system could provide a useful way for MDPP suppliers to check whether an MDPP beneficiary had previously received MDPP services both before a beneficiary starts receiving MDPP services and when an MDPP beneficiary switches

MDPP suppliers. When we considered creating such a data system, we recognized that it would need to contain data beyond what we will receive in claims data (such as baseline weight), and therefore, would require that MDPP suppliers continuously submit updated beneficiary information to us to populate the system. We believe that creating such a system would post a significant burden that would outweigh the benefit for MDPP suppliers. Moreover, other commenters have urged us to pursue a more streamlined interaction between CDC and CMS DPP-related data systems.

Given these various stakeholder views and our considerations about what a data system would entail, we believe that creating an additional data system for MDPP suppliers to verify beneficiary eligibility would be inconsistent with commenters' general requests for fewer, rather than additional, data submission requirements (please see more information at III.K.2.d.v of this final rule). Thus, we do not intend on creating a beneficiary-level data system at this time. Instead, we are exploring an electronic mechanism using claims data and existing CMS systems that MDPP suppliers could access to verify beneficiaries' prior receipt of MDPP services and plan to provide additional information on this mechanism in future guidance, as appropriate. In addition, we are still considering developing a paper tracker that an MDPP beneficiary can take with them between suppliers to prevent disruption in MDPP services. However, as described in section III.K.2.d.v of this final rule, a supplier accepting a new beneficiary in the middle of his or her services period would need to obtain the beneficiary's previous MDPP records to verify data such as baseline weight or weight loss from baseline that is necessary before the new supplier could submit any performance payments. Obtaining this documentation would be necessary to satisfy the MDPP supplier requirement at §424.205(g) that an MDPP supplier shall maintain documentation that includes services furnished and body weight measurements.

Comment: We received several comments regarding the MDPP's once-per-lifetime limit and its application and operationalization within Medicare Advantage. One commenter asked whether an MA plan could provide introductory classes or offer a waiting period after a beneficiary has received MDPP services before the once-per-lifetime limit is implicated, or if MA plans could provide accommodations for extenuating circumstances that may interfere with a beneficiary's ability to complete the program as an exception to the once-per lifetime requirement.

Response: As in Original Medicare, the once-per-lifetime limit is implicated for an MA enrollee upon the receipt of MDPP services. The rationale for this policy can be found in the CY 2017 PFS final rule (81 CFR 80470) and section III.K.2.c.iii of this final rule. Under §422.100(a), MA plans are required to provide enrollees in that plan with coverage of Medicare-covered services. As a Part B Medicare-covered service, §422.100(a) requires MA plans to provide coverage of MDPP services to plan enrollees. Additionally, §422.100(f) goes on to require that CMS must ensure that an MA plan's coverage of MDPP services meets CMS fee-for-service rules, which are described here in this final rule and the CY 2017 PFS final rule. These rules explicitly require that, to be eligible for coverage for MDPP services, a beneficiary must not have previously received the set of MDPP services in his or her lifetime. Therefore, the once-per-lifetime per beneficiary limit applies equally to MA enrollees, and we decline to permit MA plans to implement a "waiting period" after an enrollee has received MDPP services without implicating the lifetime limit on MDPP services. We note, however, that nothing in this final rule or the CY 2017 PFS final rule (81 CFR 80170 through 80562) prevents an MA plan from making available to its enrollees additional or more extensive MDPP-like services as a supplemental benefit. For instance, where an MA plan believes that its prediabetic enrollees

could benefit from introductory classes that, while not MDPP services, would allow the enrollee to decide whether to go on to receive MDPP services, an MA plan may elect to provide those classes as a supplemental benefit. Similarly, where an enrollee has begun MDPP services and is unable to complete the program due to extenuating circumstances, an MA plan may elect to make available to that enrollee other, MDPP-like services as a supplemental benefit.

Comment: Two commenters suggested that CMS facilitate data sharing among MDPP suppliers, such as by constructing a master database that MDPP suppliers and Medicare Advantage Organizations could consult to determine whether a given Medicare beneficiary or MA enrollee previously received MDPP services. Commenters indicated that such data sharing abilities would be useful when a beneficiary moves from Original Medicare to an MA plan or between MAOs. Without this database, one commenter recommended that CMS permit self-reporting from beneficiaries as a means for MA plans to determine whether the beneficiary has or has not utilized the once-per-lifetime set of services when determining a beneficiary's eligibility for MDPP services.

Response: As discussed in this section, we are exploring existing CMS systems that MDPP suppliers could access to verify if beneficiaries have previously received MDPP services and intend to release additional details through guidance. We intend that this would also allow any MDPP supplier that is furnishing MDPP services to an MA enrollee to determine whether a given beneficiary has previously received MDPP services under Original Medicare, regardless if the MDPP supplier seeking the verification is the plan itself or has contracted with an MA plan to provide MDPP services to enrollees. We emphasize that when determining whether an enrollee is eligible for MDPP services, MA plans should treat the once-per-lifetime limit for

MDPP as they would similar services, such as mammograms, that are available on a time-limited basis. Additional information on this matter will be released in future guidance, as appropriate.

After consideration of the public comments, we are finalizing the once-per-lifetime limitation on MDPP services as proposed at §410.79(c)(1)(i)(B). However, we plan to monitor this policy to consider whether an exceptions policy for beneficiaries who experience life-altering events is necessary, and if appropriate, we will address this issue in future rulemaking. We did not make any proposals regarding ways that MDPP suppliers can reliably verify if a beneficiary has received coverage of MDPP services from another supplier, and intend to release future guidance on this, as appropriate.

iv. Eligibility throughout the MDPP Services Period

In the CY 2017 PFS final rule, we specified the minimum number and frequency of sessions that MPP suppliers must offer to MDPP beneficiaries (codified at §410.79(c)(2)(i) and (c)(2)(ii)). We finalized that MDPP suppliers must furnish ongoing maintenance session intervals to MDPP eligible beneficiaries who have maintained 5 percent weight loss from their baseline weight as measured during the previous maintenance session interval. As defined at §410.79(b), "baseline weight" is the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

However, because in the CY 2018 PFS proposed rule, we proposed to tie payment for MDPP services to the beneficiary's achievement of performance goals, we proposed additional changes to tie the beneficiary's eligibility for continued coverage of ongoing maintenance session intervals to his or her achievement of performance goals, namely requiring a minimum level of attendance (82 FR 34134 through 34135). Because our proposed policies for payment and coverage differ somewhat, we are addressing them separately below.

(1) MDPP Services Period

As discussed in section III.K.2.b. of this final rule, we are revising §410.79(c)(2), which describes MDPP services periods, to specify that the MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in §410.79(c)(2)(i) and, subject to §410.79(c)(3), up to 4 ongoing maintenance session intervals during the ongoing services period described in §410.79(c)(2)(ii).

We proposed to revise §410.79(c)(2) to specify that there are 2 service periods in which Medicare will cover MDPP services for a beneficiary: the core services period; and the ongoing services period (82 FR 34134 through 34135). Together these would make up the MDPP services period. The core services period is the first 12 months of the MDPP services period, and consists of core sessions and core maintenance sessions. There are 16 core sessions that are offered at least a week apart in months 1 through 6, beginning on the date of attendance at the first core session. Core maintenance sessions are offered at least once per month in months 7 through 12 of the core services period. We proposed to move the requirements for MDPP suppliers to offer these services to §424.205(d)(10) because they are more appropriately included among other requirements for MDPP suppliers. Consistent with our policies finalized in the CY 2017 PFS final rule, we do not condition coverage for the core services period upon weight loss or attendance. However, we note that an MDPP beneficiary must attend at least 1 core session to initiate the MDPP services period.

These proposals were consistent with CDC's 1-year curriculum, divided into two 6-month periods. We recognize that framing the MDPP services period in terms of months may cause some confusion because the CDC terminology uses weeks. However, we stated that we

believe that framing the MDPP services period in months would better align with our payment structure. We did not make eligibility for the core maintenance sessions contingent upon an attendance-based performance goal; because the CDC DPP curriculum covers 12 months of sessions, we stated that we believe that coverage for the 12 months of the core services period should be available to all MDPP beneficiaries, regardless of attendance. The 12-month CDC DPP curriculum is based on evidence from the original DPP randomized clinical trial, and the curriculum used in that trial, which achieved a 58 percent reduction in type 2 diabetes risk (with 71 percent reduction in those over age 60).[13]

As discussed in section III.K.2.e.iv.4 of this final rule, MDPP suppliers must offer a minimum of 16 core sessions, no more frequently than once each week, in months 1 through 6, and at least 1 core maintenance session each month in months 7 through 12 of the core services period. However, some MDPP suppliers may choose to furnish more than the minimum number of sessions, and these coverage parameters would allow beneficiaries to receive more than the minimum number of sessions if the MDPP supplier elects to furnish them.

We did not receive comments on the proposed description revisions for the MDPP services periods, and therefore, are finalizing these proposals at §410.79(c)(2). However, we note that we are finalizing changes at §410.79(c)(2) to reflect that we are finalizing shortening the ongoing services period from 2 years to 1 year. We are also finalizing the movement of requirements for MDPP suppliers to offer these services to §424.205(d)(10) because they are more appropriately included among other requirements for MDPP suppliers.

[13] WC Knowler et al., "Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin," New England Journal of Medicine 346, 6 (2002): 393-403, https://www.ncbi.nlm.nih.gov/pubmed/11832527. The Diabetes Prevention Program (DPP) Research Group, "The Diabetes Prevention Program," Diabetes Care 25, 12 (2002): 2165-2171, http://care.diabetesjournals.org/content/25/12/2165.long.

(2) Ongoing Services Period

As discussed in section III.K.2.b.i. of this final rule, we proposed at §410.79(c)(2)(ii) that the ongoing services period consists of up to eight 3-month ongoing maintenance session intervals offered during months 13 through 36 of the MDPP services period; however, we are modifying this proposal to finalize that the ongoing services period consists of up to *four* 3-month ongoing maintenance session intervals offered during months *13 through 24* of the MDPP services period. Medicare's coverage of the ongoing services period is subject to limitations discussed subsequently in this section.

(a) Eligibility for the Ongoing Services Period

Our existing regulations at §410.79(b) state that Medicare will cover MDPP services in the first 12 months of the MDPP services period, without regard to a beneficiary's achievement of performance goals, whereas §410.79(d)(2) specifies that, for coverage of ongoing maintenance sessions, the beneficiary must have achieved weight loss of 5 percent from his or her baseline weight. In the CY 2018 PFS proposed rule, we proposed to delete §410.79(d)(2) and move this provision to §410.79(c)(1) with other MDPP beneficiary eligibility criteria. We also proposed to add paragraph (c)(1)(ii) to §410.79 to specify that beneficiaries must also attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period and achieve or maintain required minimum weight loss at a minimum of one in-person session during the final core maintenance session interval to be eligible for coverage of the first ongoing maintenance session interval. We proposed to establish that a beneficiary must attend at least one in-person core maintenance session in months 10 through 12 of the MDPP services period because, as stated in the CY 2017 PFS final rule, an MDPP beneficiary must achieve at

least 5 percent weight loss from baseline at least once during the previous maintenance session interval to have coverage of an ongoing maintenance session.

Because we proposed that weight measurements used for determining beneficiary eligibility for coverage or supplier payment must be taken in person by an MDPP supplier at an MDPP core maintenance or ongoing maintenance session (§410.79(c)(1)(iv)), a beneficiary must attend at least one in-person core maintenance session during months 10 through 12 to have his or her weight measured to determine whether he or she qualifies for coverage of the first ongoing maintenance session interval. We believe that in-person measurements are the most feasible method for weight ascertainment at this time for services where the beneficiary would have regular in-person sessions with the MDPP supplier. We believe that self-reported weight loss is not reliable for the purposes of determining continued coverage of MDPP services for a beneficiary. We invited public comments on these proposals.

The following is a summary of the public comments received on eligibility for the ongoing services period and our responses:

Comment: We received a variety of comments on our proposal that weight measurement must be taken in-person at an MDPP session, although they were in relation to the proposed policy regarding virtual make-up sections discussed in section III.K.2.c.iv.3.b of the proposed rule (82 FR 34136 through 34137). Some commenters supported the proposal, while others requested alternate forms of weight measurement, such as via Bluetooth-enabled scales or self-reported weight.

Response: As discussed further in section III.K.2.c.iv.3.b of this final rule, while we recognize the use of Bluetooth-enabled scales for virtual weight reporting in some DPP programs, we believe that virtual weight reporting is not appropriate or necessary for a

predominantly in-person model (we are using the term "Bluetooth-enabled" as we understand it described in the CDC DPRP as a scale that uses a cellular, wireless, Bluetooth, or other electronic connection to automatically send weight data to the supplier). Except for the limited number of virtual-make up sessions, MDPP sessions are required to be offered and attended in person and corresponding weight are also required to be taken in-person. We also believe that self-attested weight measurement is generally unreliable, and therefore believe that in-person weight measurement is the most reliable and appropriate form of weight measurement for the MDPP expanded model.

After consideration of the comments received, we are finalizing the eligibility criteria for the ongoing services period as proposed at §410.79(c)(1)(ii). We are also finalizing changes to the definition of "ongoing maintenance session interval" at §410.79(b) to reflect shortening the ongoing services period from 2 years to 1 year.

(b) Eligibility for Ongoing Maintenance Session Intervals 2 through 8

In addition to achieving weight loss performance goals, as previously finalized in the CY 2017 PFS final rule §410.79(d)(2) (now finalized at §410.79(c)(1)(ii) and (c)(1)(iii)), we proposed that beneficiaries must also meet an attendance-related performance goal in order for Medicare to cover ongoing maintenance session intervals. We proposed to add paragraph (c)(1)(iii) to §410.79 to specify that for coverage of ongoing maintenance session intervals 2 through 8, an MDPP beneficiary must attend at least three ongoing maintenance sessions during the previous ongoing maintenance session interval, at least one of which must be an in-person ongoing maintenance session to record an in-person weight measurement, in addition to maintaining 5 percent weight loss from baseline at least once during the previous ongoing maintenance session interval.

We believe that adding an attendance-related performance goal during the ongoing services period is important because it will provide an incentive to keep MDPP beneficiaries engaged after the core services period. MDPP beneficiaries who meet the specified attendance and weight loss goals will have Medicare coverage of ongoing maintenance sessions, which are a part of the set of MDPP services, but not a part of the CDC DPP curriculum. We believe that the subsequent attendance goal requirements during ongoing maintenance session intervals will motivate beneficiaries to take on more individual responsibility for their behavior changes over time because coverage of these services is dependent upon their attendance and achievement and maintenance of weight loss.

In addition, this policy closely aligns with our policy for supplier payment for ongoing maintenance session intervals. As described further in section III.K.2.d.iii.5. of this final rule, we proposed that a supplier would be paid for furnishing an ongoing maintenance session interval only if the MDPP beneficiary both attended three sessions, as well as maintained a 5 percent weight loss from baseline measured at least once in that interval. However, in light of our proposal to pay MDPP suppliers upon the beneficiary's attendance of three ongoing maintenance sessions (in addition to maintaining at least a 5 percent weight loss), we believe that we similarly need to have attendance goals for beneficiaries to continue to have coverage of ongoing maintenance sessions and mitigate the supplier's risk of providing services without payment. Without requiring attendance, an MDPP beneficiary who maintained 5 percent weight loss but only attended two ongoing maintenance sessions in an ongoing maintenance session interval would be eligible for coverage of ongoing maintenance sessions, but the supplier would not receive payment for furnishing that ongoing maintenance session interval. In effect, the MDPP supplier could be required to furnish up to 12 months (finalized in this final rule at

§410.79(c)(2)(ii)) of MDPP services without payment. For this reason, we proposed to require beneficiaries to attend all three sessions within an ongoing maintenance session interval to have coverage of the subsequent interval.

We considered an alternative where a beneficiary would have continued coverage of ongoing maintenance session intervals if he or she attends at least one in-person ongoing maintenance session during an ongoing maintenance session interval, as long as that beneficiary maintained at least 5 percent weight loss from baseline at least once during that interval. However, we do not believe that this alternative would align with our proposed supplier payment requirements for ongoing maintenance sessions discussed in section III.K.2.d.iii.5 of this final rule, which would require suppliers to furnish, and the beneficiary to attend, all three sessions of the ongoing maintenance session interval for the supplier to receive payment for that interval. We invited public comments on our proposal and the alternative we considered.

The following is a summary of the public comments received on our proposal to add attendance requirements for beneficiary eligibility for ongoing maintenance session intervals 2-8 and our responses:

Comment: The majority of commenters noted that beneficiary eligibility requirements for ongoing maintenance session intervals are too strict and requested flexibility in eligibility requirements for the ongoing services period. Some commenters noted that the eligibility requirements would be especially difficult for certain populations, such as those that face socio-economic barriers or individuals in rural areas who may lack transportation options or other services required to attend MDPP sessions.

Many commenters noted that requiring perfect attendance at ongoing maintenance sessions (that is, 3 out of 3 ongoing maintenance sessions per interval) places too much burden

on beneficiaries. These commenters noted that requiring perfect attendance at ongoing maintenance sessions is an unrealistic expectation, given that certain life events, often beyond the beneficiary's control, could prevent the beneficiary from attending a session. These commenters noted that this fact, combined with the limited number of allowed virtual make-up sessions and the once-per-lifetime limitation on MDPP services, could limit beneficiary access to MDPP services. These factors have the potential to permanently disqualify the beneficiary from receiving additional MDPP services, even if the beneficiary maintained weight loss. Additionally, commenters noted that MDPP suppliers may need to offer additional ongoing maintenance sessions beyond the minimum to ensure that beneficiaries meet attendance goals; however, offering these extra sessions would be costly and may limit MDPP supplier participation, further limiting beneficiary access.

Commenters who provided this information on the challenge of having perfect attendance often recommended allowing beneficiaries to maintain eligibility if they attend 2 out of 3, rather than 3 out of 3, ongoing maintenance sessions per interval, in addition to maintaining 5 percent weight loss. Some commenters recommended that beneficiaries only be required to attend 1 out of 3 ongoing maintenance sessions per interval, in addition to maintaining 5 percent weight loss, to be eligible for the next interval.

Response: After consideration of the public comments received with respect to beneficiary eligibility for ongoing services, we acknowledge that requiring a beneficiary to have perfect attendance to be eligible for the next interval is strict, and that allowing some flexibility is reasonable. When considering comments on this policy, we considered how changing attendance requirements for eligibility would affect beneficiaries' engagement and our ability to determine whether the maintenance of weight loss is attributable to the sessions attended during

the ongoing services period. As noted in our proposal, we considered an alternative of requiring at least 1 session attended per interval; however, we do not believe that requiring attendance at only 1 MDPP session per interval provides enough MDPP sessions to be attributable to the outcome of maintained weight loss. A beneficiary who can only attend 1 session over the course of 3 months may be engaged in other activities that are contributing more to his or her weight loss maintenance than MDPP, and we do not believe continued coverage of ongoing maintenance sessions is appropriate in this case. However, we believe that weight loss maintained by a beneficiary who attends at least 2 monthly sessions (with the option of attending all 3 sessions offered by an MDPP supplier within an interval) can be reasonably attributed to the receipt of ongoing maintenance services. Suppliers have the option (but are not required) to offer both in-person and virtual make-up sessions, which offer the beneficiary additional flexibility with attendance. If a beneficiary is not able to attend a regularly scheduled ongoing maintenance session, the beneficiary may have the ability to attend a make-up session at another time (as described in section III.K.1.c.iv.(3) of this final rule).

We also understand based on comments that there could be scenarios in which attendance at an in-person monthly session may be challenging and impractical for a beneficiary, due to transportation barriers or some other life event, and if the supplier did not offer make-up sessions (because they are not required), the beneficiary could lose coverage for the next interval even if they are engaged and maintain weight loss. We also understand that if MDPP suppliers believe additional ongoing maintenance sessions beyond the monthly sessions are needed to ensure that beneficiaries meet attendance goals, this would be costly and potentially limit supplier participation. Although make-up sessions are an option for MDPP suppliers, we share the

concern commenters raised about the potential burden placed on suppliers to make accommodations for beneficiaries who miss a session in order to maintain their eligibility.

Since the performance goals of the MDPP expanded model are more heavily weighted towards outcomes (that is, weight loss) than process measures (that is, attendance), and the specific outcome during the ongoing services period is maintenance of weight loss, which is required both for the ongoing maintenance session interval performance payment and coverage of the next ongoing maintenance session interval, we believe reducing the attendance requirements by 1 session allows sufficient flexibility to beneficiaries and suppliers without misattributing a beneficiary's maintenance of weight loss to other activities occurring outside of MDPP, during the ongoing services period. While in section III.K.2.d.iii.(3) of this final rule we describe our final policy which increases the attendance-based performance payment amounts for core sessions, we believe that placing more emphasis on weight loss maintenance, rather than attendance, during the ongoing services period maintains the integrity of the program while providing beneficiaries and suppliers more flexibility. We believe this modification will still provide an incentive to keep MDPP beneficiaries engaged after the core services period.

We note that we are aligning these eligibility requirements with our finalized payment structure, described more in section III.K.2.d.3 of this final rule. As discussed in section III.K.2.c.iv.2.b of the CY 2018 PFS proposed rule, we find it important to align attendance goals for beneficiaries to maintain eligibility for ongoing maintenance sessions with performance goals required for payment during ongoing maintenance sessions. Without requiring the same number of attendance goals, an MDPP beneficiary who maintained 5 percent weight loss but only attended two ongoing maintenance sessions in an ongoing maintenance session interval would be eligible for coverage of ongoing maintenance sessions, but the supplier would not receive

payment for furnishing that ongoing maintenance session interval. In effect, the MDPP supplier could be required to furnish up to 12 months (finalized in this final rule at §410.79(c)(2)(ii)) of MDPP services without payment. To alleviate this concern, we are aligning our finalized payment policies, described more in section III.K.2.d.3 of this final rule, to align with our finalized eligibility policies.

After consideration of the public comments, we are finalizing that an MDPP beneficiary must attend at least 2 ongoing maintenance sessions per ongoing maintenance session interval (and achieve a 5 percent weight loss during at least one in-person session during the interval) to be eligible for subsequent ongoing maintenance session interval after the first. This policy will be finalized at §410.79(c)(1)(iii).

Comment: A number of commenters requested modification to a previously finalized policy that stated that ongoing maintenance sessions are available only if the MDPP eligible beneficiary has achieved maintenance of weight loss (a policy finalized previously at §410.79(d)(2); now at §410.79(c)(1)). Many of these commenters noted that a 5 percent weight loss seemed too high and recommended alternatives to the 5 percent weight loss goal to determine continued eligibility for ongoing maintenance session intervals, such as attendance alone or HbA1c level. One commenter suggested allowing beneficiaries to reach the 5 percent weight loss goal once every 6 months, rather than 3 months, to maintain eligibility for the next ongoing maintenance session interval.

Response: We appreciate commenters' concerns that maintaining 5 percent weight loss during each ongoing maintenance session interval to be eligible for the next interval will be difficult for some beneficiaries. We also appreciate the comments received that suggest lowering the weight loss criteria or using different criteria. However, we note that we finalized our weight

loss policy in the CY 2017 PFS final rule (previously at §410.79(d)(2); now at §410.79(c)(1)) as it relates to eligibility for ongoing maintenance sessions, and did not propose any adjustments to the 5 percent weight loss goal in this year's proposed rule. In last year's final rule, we noted that the requirement that beneficiaries 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. Therefore, we are not changing the requirement that beneficiaries must maintain the 5 percent minimum weight loss in order to be eligible for ongoing maintenance sessions. To account for the fact that weight does fluctuate, and to allow beneficiaries more flexibility, we finalized last year that beneficiaries need only meet the 5 percent weight loss goal at 1 session during a 3-month interval. We believe that this allows beneficiaries the opportunity for weight fluctuation within an interval, while maintaining the MDPP goals of continued lifestyle change over time.

Comment: We received comments that CMS should grant flexibility to certain tribal health programs to determine their own diabetes prevention measures of success. These commenters noted that the 5 percent weight loss goal is too stringent and that weight loss alone does not adequately reflect the overall progress a participant is making toward lasting lifestyle changes and the prevention of diabetes. These commenters also recommended separate categories for weight loss goals for men and women, citing sedentary lifestyle and metabolism barriers of Native women, and that Native women struggle with weight loss more than Native men because of hormonal body changes and gradual lean muscle loss that come with age.

Response: We appreciate this request for flexibility from tribal communities. However, we note that the MDPP expanded model is an expansion of the DPP model test, which was based

on the CDC National DPP. We are relying on measures that were shown to be successful in the DPP model test, which includes the same percentage achievement of weight loss for men and women, and the MDPP expanded model relies on these measures for eligibility during the ongoing services period. However, we will continue consultation with tribal communities and attempt to address their concerns as appropriate.

After consideration of the public comments, we are finalizing that an MDPP beneficiary must only attend 2 ongoing maintenance sessions per ongoing maintenance session interval (and maintain 5 percent weight loss during one in-person session) to be eligible for the next ongoing maintenance session interval. This policy will be finalized at §410.79(c)(1)(iii).

(c) Limitations on the Set of MDPP Services

In the CY 2018 PFS proposed rule, we proposed to add §410.79(c)(3) to specify that coverage of the MDPP services period would end upon completion of the core services period for a beneficiary that is not eligible for the first ongoing maintenance session interval as proposed under §410.79(c)(1)(ii); that is, if the beneficiary does not attend at least 1 in-person core maintenance session during the second core maintenance session interval and/or does not achieve the required minimum weight loss during this interval (82 FR 34136). For any beneficiary who is eligible for at least 1 ongoing maintenance sessions interval, but who does not meet the requirements for coverage of a subsequent interval based on failure to meet attendance or weight loss goals proposed at §410.79(c)(1)(iii), the beneficiary's coverage of the set of MDPP services would end upon completion of his or her current ongoing maintenance session interval. It is important to note that performance payments, discussed in section III.K.2.d.iii.5. of this final rule, will be tied to the achievement of the same performance goals a beneficiary must meet to have coverage for the ongoing maintenance session intervals. Therefore, if an MDPP

beneficiary does not meet weight loss or attendance goals to have coverage of the subsequent ongoing maintenance session interval, the supplier will not receive payment for that ongoing maintenance session interval or any subsequent performance payments related to that beneficiary.

We did not receive comments on our proposal to add specifications on when coverage of the MDPP services period ends, and therefore, are finalizing our policies as proposed at §410.79(c)(3). We note that we are finalizing changes at §410.79(c)(3) to reflect shortening the ongoing services period from 2 years to 1 year (so now there are only four intervals).

(d) Beneficiaries Who Change MDPP Suppliers during the MDPP Services Period

In the CY 2017 PFS final rule (81 FR 80470), we confirmed that a beneficiary may change MDPP suppliers at any time. However, we deferred to future rulemaking specific policies to address coverage of and payment for MDPP services when beneficiaries change MDPP suppliers. In the CY 2018 PFS proposed rule, we clarified that a beneficiary may change MDPP suppliers at any time during his or her MDPP services period, subject to beneficiary eligibility requirements (82 FR 34136). Based on evidence from the CDC DPRP, we believe that the instances of beneficiaries changing MDPP suppliers will be relatively infrequent. However, we intend to monitor how often beneficiaries change MDPP suppliers, as well as MDPP suppliers' billing patterns to detect any aberrant billing patterns suggestive of fraudulent or discriminatory practices. Payment policies related to when a beneficiary changes MDPP suppliers are discussed in section III.K.2.d.v. of this final rule.

The following is a summary of the public comments received on our clarifications about beneficiaries changing suppliers and our responses:

Comment: We received some comments noting that beneficiaries may switch suppliers more often than we anticipate, given the mobility of the "baby boom" generation and the fact that many seniors are "snowbirds," traveling south for the winter. Other commenters requested clarification about when MDPP beneficiaries may switch suppliers.

Response: We clarify that beneficiaries are generally not required to switch suppliers. However, if the beneficiary chooses to switch MDPP suppliers, the beneficiary may do so at any time and for any reason within the MDPP services period (which includes both the core services period and ongoing services period).

Since we did not propose any changes to the policy that beneficiaries may change suppliers at any time during the MDPP services period, we are not finalizing any changes to this policy.

(3) Make-Up Sessions

(a) General Requirements.

In the CY 2018 PFS proposed rule, we proposed at §410.79(d)(1) that suppliers may offer make-up sessions to an MDPP beneficiary who missed a regularly scheduled session (82 FR 34136 through 34137). We proposed to define, at §410.79(b), "make-up session" to mean a core session, core maintenance session, or ongoing maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session, core maintenance session, or ongoing maintenance session. We proposed that make-up sessions may be delivered in person or virtually, although virtual make-up sessions are subject to additional requirements in this rule (and the term "virtual make-up session" is separately defined). We proposed the availability of make-up sessions to be consistent with CDC's DPRP Standards and

to ensure that MDPP beneficiaries have the opportunity to receive the full DPRP curriculum, even if they are unable to attend a particular regularly scheduled MDPP session.

We proposed that the curriculum delivered during a make-up session must address the same CDC-approved DPP curriculum topic as the session that the beneficiary missed (§410.79(d)(1)(i)). To be consistent with CDC's proposed 2018 DPRP Standards,[14] we proposed that the MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session (proposed at §410.79(d)(1)(ii)), and the MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week at §410.79(d)(1)(iii)).

(b) Virtual Make-Up Sessions

There is a growing area of research examining the effectiveness of DPP delivered virtually. CDC began recognizing Virtual DPP organizations in 2015 and emerging evidence suggests that virtual delivery of DPP services can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants.[15] Since CDC's DPRP Standards permit virtual make-up sessions, and we recognize that MDPP beneficiaries may encounter situations where they are unable to attend in-person make-up sessions, we proposed to allow MDPP suppliers to offer a limited number of virtual

[14] Available at https://www.federalregister.gov/documents/2017/07/14/2017-14792/proposed-data-collection-submitted-for-public-comment-and-recommendations

[15] See, for example: F Chen et al., "Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease." PLoS ONE 11, 10 (2016), https://doi.org/10.1371/journal.pone.0163627. W Su et al., "Return on Investment for Digital Behavioral Counseling in Patients With Prediabetes and Cardiovascular Disease." Preventing Chronic Disease 13 (2016), http://dx.doi.org/10.5888/pcd13.150357. J Ma et al., "Translating the Diabetes Prevention Program lifestyle intervention for weight loss into primary care: a randomized trial." JAMA Intern Med. 173, 2 (2013): 113-21, https://www.ncbi.nlm.nih.gov/pubmed/23229846. CS Sepah et al., "Translating the diabetes prevention program into an online social network: Validation against CDC standards." The Diabetes Educator 40, 4 (2014): 435-443, https://www.ncbi.nlm.nih.gov/pubmed/24723130.

make-up sessions (§410.79(d)(2)). We proposed to define "virtual make-up session" in §410.79(b) as a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions. All requirements in §410.79(d)(1) apply to virtual make-up sessions. In addition, we proposed that virtual make-up sessions are subject to additional requirements.

First, as indicated by the applicable definition, we proposed virtual make-up sessions must be furnished in a manner consistent with CDC's DPRP Standards for virtual sessions (§410.79(d)(2)(i)). To align with CDC's DPRP Standards, virtual make-up sessions refer to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and a coach via a computer, laptop, tablet, smart phone, or other device with Internet access. This modality requires that the MDPP beneficiary have an Internet connection to participate in all aspects of the virtual make-up session;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires that the MDPP beneficiary have an Internet connection for some aspects of the virtual make-up session, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require that the MDPP beneficiary have an Internet connection for any of the aspects of the virtual make-up session.

By defining MDPP virtual make-up sessions as being consistent with CDC's DPRP Standards for virtual sessions, we allowed our proposed definition to change over time as such standards are updated.

Second, we proposed that a supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request (§410.79(d)(2)(ii)). A supplier may not cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries virtually. However, the supplier may cancel a regularly scheduled MDPP session and offer the session to all MDPP beneficiaries in person. We believe that this is necessary to ensure that the MDPP expanded model remains a model predominantly furnished in person. Individual beneficiary needs may be accommodated, but suppliers should not use virtual make-up sessions as a means to move toward virtually-delivered MDPP sessions more generally.

Third, to further ensure that MDPP services are largely furnished in-person, we proposed at §410.79(d)(2)(iii) that a supplier may offer: (a) no more than 4 virtual make-up sessions within the core services period to an MDPP beneficiary, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and (b) no more than 3 virtual make-up sessions that are ongoing maintenance sessions to an MDPP beneficiary during any rolling 12-month time period. At §410.79(d)(3), we proposed that these same limitations on the number of virtual make-up sessions also apply for the purposes of determining whether a beneficiary has attended a sufficient number of MDPP sessions in order to be eligible for ongoing maintenance sessions (§410.79(c)(1)) and for assessing whether a beneficiary has met the attendance-related performance goals used to determine whether an MDPP supplier is eligible to receive a performance payment (§414.84(b)). The limitation on the number of virtual make-up sessions is not applicable to in-person make-up sessions.

We assume not all suppliers will have the ability to offer virtual make-up sessions, and we are not requiring suppliers to offer virtual make-up sessions. Conversely, an MDPP supplier could offer only virtual make-up sessions and no in-person make up sessions if the supplier chooses as long as the proposed limits for these sessions are not exceeded. We believe that allowing fewer than these proposed number of virtual make-up sessions will make it difficult for suppliers to meet DPRP Standards, and therefore remain enrolled as an eligible MDPP supplier. However, the DPP model test only offered in-person sessions (no virtual sessions) and therefore the MDPP expanded model is intended to predominantly offer services in person. Allowing more than the proposed number of virtual make-up sessions would not support an evaluation of an in-person MDPP model, as described further in this section. We sought comment on our proposals and specifically on the proposed limitations on virtual make-up sessions.

We considered the following alternatives to this proposal. We considered not allowing any make-up sessions to be furnished virtually. However, we believe that this would place undue restrictions on MDPP suppliers who are willing and offer virtual make-up sessions to MDPP beneficiaries, particularly if these are offered to other DPP participants who are not Medicare beneficiaries.

We also considered allowing an MDPP supplier to furnish between 1 and 3 sessions within the core services period and either 1 or 2 ongoing maintenance sessions each year as virtual make-up sessions per MDPP beneficiary. However, we believe that allowing fewer sessions to be furnished as virtual make-up sessions than proposed would not provide sufficient flexibility for MDPP suppliers to meet CDC's DPRP Standards, which require organizations to meet attendance requirements for their panel of participants. Organizations may struggle to meet DPRP attendance requirements without the flexibility to provide virtual make-up sessions.

We also considered permitting suppliers to offer any number of virtual make-up sessions, and for attendance at any number of virtual make-up sessions to count toward attendance goals. However, as stated previously, since the DPP model test only offered DPP services in person, the MDPP expanded model is intended to predominantly offer MDPP sessions in person as well. Therefore we believe that it is important to limit the number of virtual make-up sessions so that MDPP beneficiaries are predominantly receiving MDPP sessions in person.

We proposed that the payment policies detailed in section III.K.2.d. of this final rule apply to virtual make-up sessions. Specifically, as indicated in sections III.K.2.c.iv and III.K.2.d.iii.10.b. of this final rule, weight measurements used for the purposes of determining the achievement or maintenance of weight loss for weight loss performance payments, or for determining eligibility for coverage of ongoing maintenance sessions, would be required to be taken at an in-person session, not during a virtual make-up session. As noted at §410.79(d)(3), make-up sessions are counted toward performance goals for both eligibility and payment, which specify that at least one ongoing maintenance session per ongoing maintenance session interval must be attended in person for the purposes of in-person weight measurement. We sought public comments on these proposals and the alternatives considered.

The following is a summary of the public comments received on our proposals regarding make-up sessions, and specifically on the limitations on virtual make-up sessions, and our responses:

Comment: We received some comments on make-up sessions generally, both virtual and in-person. One commenter supported CMS' proposal to allow for same day make-up sessions, finding them to be operationally feasible by allowing patients to come early or stay late to make up a session. Another commenter noted that furnishing to the beneficiary a maximum of one-

make-up session on the same day as a regularly scheduled session may pose a barrier to beneficiaries if they cannot make the regular session on the same day and recommended an option to allow a window for make-up sessions of 1-2 business days for either virtual or in-person make-up sessions. A third commenter generally agreed with the proposed definitions and options for make-up sessions, noting that the proposal was feasible to provide and would encourage beneficiaries to receive the necessary educational component and coach support.

Response: We appreciate commenters' support of the proposals. In response to the commenter who noted that furnishing a maximum of one-make-up session on the same day as a regularly scheduled session may pose a barrier to beneficiaries if they cannot make the regular session on the same day, we believe that the commenter was misunderstanding the proposal. Make-up sessions are not required to be offered on the same day as a regularly scheduled session. However, to be consistent with CDC's proposed 2018 DPRP Standards,[16] if the MDPP supplier wishes to offer a make-up session on the same day as a regularly scheduled session, we clarify our intent is for suppliers may furnish a maximum of one make-up session on the same day as a regularly scheduled session. The intent of this policy is to allow most make-up sessions to be scheduled on different days than regularly scheduled session, since beneficiaries may not be able to attend a make-up session on the same day as a regularly scheduled session. The only limitations on when make-up sessions can be offered is that any core make-up session is considered a core session, and therefore must occur during months 1-6. Similarly, any core maintenance make-up session is considered a core maintenance session and must occur during months 7-12.

[16] Available at https://www.federalregister.gov/documents/2017/07/14/2017-14792/proposed-data-collection-submitted-for-public-comment-and-recommendations

Comment: The majority of commenters who commented on these policies supported the use of virtual make-up sessions. The additional commenters requested clarification about weight measurement for, and monitoring of, virtual make-up sessions. Of those who supported the use of virtual make-up sessions, there were an equal number of comments supporting and opposing the proposed limitations on virtual make-up sessions (that is, that a supplier may offer no more than 4 virtual make-up sessions within the core services period, of which no more than 2 may be core maintenance sessions; and no more than 3 virtual make-up sessions that are ongoing maintenance sessions during any rolling 12-month time period). Those who supported the limitations noted that the limits would foster compliance and adherence to program goals. Those who opposed the limitations requested that CMS either raise the allowed number of virtual make-up sessions or allow exceptions to the proposed limitations on virtual make-up sessions if the beneficiary cannot come in person. These commenters stated that an increased number of allowed virtual make-up sessions would increase access to MDPP services and improve beneficiary choice of supplier, and noted that the use of virtual DPP has a strong evidence base.

Response: While we recognize that there is an emerging evidence base demonstrating effectiveness of virtual DPP, we do not believe that we should allow a greater number of virtual make-up sessions than proposed, or allow exceptions to the proposed limitations at this time. As noted in this rule, the DPP model test only offered in-person sessions (no virtual sessions) and therefore the MDPP expanded model is intended to predominantly offer services in person. Allowing more than the proposed number of virtual make-up sessions would not support an evaluation of an in-person MDPP curriculum. However, we believe it is appropriate to permit some virtual make-up sessions because, as discussed in this rule, we understand, based on research into current practices at CDC DPRP recognized DPP providers, that it is difficult for

DPP suppliers to meet DPRP recognition without the allowance of at least some virtual make-up sessions, and organizations must meet DPRP Standards to become MDPP suppliers. Therefore, in order to have a sufficient number of MDPP suppliers to ensure access to MDPP services, and to also ensure fidelity with the original DPP model test, we believe that a supplier's ability to furnish a limited number of virtual make-up sessions is necessary.

Comment: One commenter requested clarification on monitoring the use of virtual make-up sessions. The commenter asked if there will be an additional HCPCS code or modifier used to indicate virtual visits since there is a proposed limit to the number of visits the beneficiary can receive virtually.

Response: We do plan to monitor virtual make-up sessions through the claims system to indicate when a beneficiary has received the maximum number of virtual make-up sessions permitted. In order to collect information on virtual make-up sessions, we are creating a modifier that suppliers will include on claims to indicate the use of virtual make-up sessions. This modifier is discussed further in section III.K.2.d.iii.10.c of this final rule. We intend to provide information on how to use this modifier on claims submitted by MDPP suppliers in conjunction with other billing instructions in future guidance.

Comment: We received multiple comments on weight measurement for virtual make-up sessions. Some commenters supported the proposal that weight measurement must be taken in person. One commenter encouraged the allowance of beneficiary attestation for weight measurement associated with virtual make-up sessions, including reporting via Bluetooth-enabled scales, which allows the weight measurement taken on the scale to be transmitted to the supplier. This commenter also recommended that CMS allow weight measurements to be taken at any in-person visit with any member of a care delivery team (regardless of whether the weight

measurement is with the MDPP supplier) as long as the weight measurement occurs within a month of the associated core maintenance session or ongoing maintenance session.

Response: While we recognize the use of Bluetooth-enabled scales for virtual weight reporting in some DPP programs, we believe that virtual weight reporting is not appropriate or necessary for a predominantly in-person model. Except for the limited number of virtual-make up sessions, MDPP sessions are required to be offered and attended in person and corresponding weight are also required to be taken in-person. We also believe that self-attested weight measurement is generally unreliable,[17] and therefore, believe that in-person weight measurement is the most reliable and appropriate form of weight measurement for the MDPP expanded model.

We appreciate the commenter's request for flexibility by allowing weight measurement to be taken in-person, but outside of an MDPP session, by any member of a care delivery team within a month of the MDPP session. However, we believe that requiring weight measurement to be taken by an MDPP supplier during an MDPP session is the most appropriate and reliable method for weight measurement to ensure accuracy. We have not proposed any program integrity safeguards about transferring weight measurement between providers, suppliers, or care delivery teams, nor do we expect MDPP suppliers to have systems in place to facilitate such information transfer. We also believe that weight must be measured on the same date and at the time of the MDPP session to ensure that weight measurement falls within the correct time frame or interval for the purposes of eligibility and payment. If a member of the beneficiary's care delivery team is also part of the MDPP supplier's organization, for example serving as the DPP

[17] See, for example: Gorber, et. al, "A Comparison of Direct vs. Self-Report Measures for Assessing Height, Weight and Body Mass Index: A Systematic Review," *Obesity Reviews* 8, no. 4 (July 2007): 307-26, https://www.ncbi.nlm.nih.gov/pubmed/17578381; Engstrom, et. al, "Accuracy of Self-Reported Height and Weight in Women: An Integrative Review of the Literature," *Journal of Midwifery and Women's Health* 48, no. 5 (Sept-Oct 2003): 338-45, https://www.ncbi.nlm.nih.gov/pubmed/14526347; Lin, et. al, "Accuracy and Reliability of Self-Reported Weight and Height in the Sister Study," *Public Health Nutrition* 15, no. 6 (June 2012): 989-999, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3511620/.

coordinator or coach, then this type of arrangement is appropriate, as long as the conditions for weight measurement are met.

Comment: One commenter sought clarification on if a beneficiary who completed a virtual make-up session could come in to an MDPP supplier in person at another time to have their weight measured and counted for that session. The commenter noted that this may be particularly important if that weight measurement is needed for the MDPP supplier to submit a claim for payment.

Response: As noted in proposed §410.79(c)(1)(iv), which we are finalizing as proposed, weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session. Additionally, as discussed in section III.K.2.d.iii.10.b of this final rule, we also are finalizing at §414.84(b) that all performance payments associated with weight loss require weight measurement to conducted in person at an MDPP session. We believe it is important that weight measurements occur on the date of an MDPP session so that they fall within the correct interval for the purposes of eligibility and payment. Thus, a beneficiary could not complete a virtual make-up session and come in to an MDPP supplier in person at another time to have his or her weight measured and counted for that session.

We re-emphasize that that virtual make-up sessions cannot be used to record weight for the purposes of beneficiary eligibility for or during ongoing services period or payment, due to the concerns we have laid in this section out regarding any measurement that is not taken in person. This is why we are finalizing in this final rule, discussed in section III.K.2.c.iv.a and III.K.2.c.iv.b, that a beneficiary must attend at least one in-person core maintenance session during the final core maintenance session interval and at least one in-person ongoing

maintenance session during each ongoing maintenance session interval in order to have weight recorded in person for the purposes of eligibility and payment (§410.79(c)(1)(ii) and (c)(1)(iii)).

After consideration of the public comments received, we are finalizing our proposals on make-up sessions at §410.79(d). We are finalizing changes to these policies to reflect shortening the ongoing services period from 2 years to 1 year.

d. Payment for MDPP Services

i. MDPP Payment Discussion in Prior Rulemaking

In the CY 2017 PFS proposed rule (81 FR 46415 through 46416), we discussed a potential MDPP payment structure and the associated payment amounts and sought information from the public to inform future MDPP proposals. We received a number of public comments on these topics and considered this information in the development of our proposals for the MDPP payment structure, payment amounts, and related issues.

ii. Conceptual Framework for Payment for MDPP Services

We proposed to pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. We proposed a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. Performance payments would be made to MDPP suppliers periodically during the course of a beneficiary's MDPP services period based upon a number of factors, including the beneficiary's completion of a specified number of MDPP sessions and the achievement of the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes, rather than

individual payments being made upon the furnishing of any service as is typical of FFS payment methodologies in the Medicare program.

The aggregate amount of the performance payments proposed would equal the total performance-based payment amount for the set of MDPP services during the MDPP services period, including core sessions, core maintenance sessions, and ongoing maintenance sessions. Even though these performance payments would be made periodically and in amounts that would not be evenly distributed across the course of sessions furnished during the MDPP services period, payment for each session would be included in the total performance-based payment amount. For example, the proposed performance payment of $25 that would be paid to MDPP suppliers upon furnishing the first MDPP core session is relatively large on a per-session basis compared to other attendance-based performance payments (as calculated on a per-session basis) ranging from approximately $3 to $20 made during the MDPP services period. However, the performance payment for the first core session would make payment for some of the MDPP supplier resources used in furnishing the first session, as well as make a partial prospective payment attributable to the MDPP supplier furnishing subsequent sessions.

Once the required minimum weight loss is achieved and the 12-month core services period, described at proposed §410.79(c)(2)(i), concludes, we would make additional 3-month interval performance payments for ongoing maintenance sessions when the required minimum weight loss is maintained, whereas no additional interval performance payments would be made for ongoing maintenance sessions if the required minimum weight loss is not maintained. Finally, when a beneficiary achieves a significant percentage of weight loss, specifically a level of 5 percent (the required minimum weight loss) or 9 percent, we proposed to make additional performance payments to the MDPP supplier. This proposal would provide performance

payments in addition to the performance payments we may have already made for the previous MDPP sessions furnished to the beneficiary because those sessions resulted in the beneficiary achieving the weight loss performance goal.

In total, based on our consultation with DPP organizations holding commercial contracts, review of information related to DPP organizations that currently hold or are in the process of obtaining CDC recognition, and comments received on the discussion of the payment structure and payment amounts for the set of MDPP services included in the CY 2017 PFS proposed rule (81 FR 46415 through 46416), we believed that the proposed performance-based payment methodology would pay MDPP suppliers appropriately for the resources used in furnishing MDPP services throughout the MDPP services period. We noted that we sought public comment on the payment structure and payment amounts for the set of MDPP services in the CY 2017 PFS proposed rule, and we used the information provided by commenters in developing the proposed performance-based payments included in the CY 2018 PFS proposed rule (82 FR 34138 through 34152).

In the proposed performance-based payment structure, it is important to note that a beneficiary's performance goals would not be considered in the same way for beneficiary coverage and supplier payment during each specific period within the MDPP services period. During the core services period, a beneficiary would not be required to achieve attendance and/or weight loss performance goals for coverage of MDPP services, although a beneficiary would be required to achieve specified performance goals for an MDPP supplier to receive performance payments during this period. In contrast, achieving performance goals would be required for both coverage of MDPP services and performance payments during the ongoing services period.

For example, a supplier would be required to offer a minimum of 16 core sessions during the core services period according to §410.79(c)(2)(i), but a beneficiary would not need to achieve an attendance or weight loss performance goal to be eligible for coverage of core maintenance sessions. However, MDPP supplier performance payments during the core services period would be based on the beneficiary's achievement of attendance and/or weight loss performance goals. During the ongoing services period, achievement of performance goals would affect both coverage and supplier payment. We noted that a beneficiary would need to attend at least 1 core session to initiate the core services period, and attend at least 1 core maintenance session during the final core maintenance session interval to determine whether he or she has achieved the required minimum weight loss to have coverage of ongoing maintenance sessions. Because we proposed, as discussed in section III.K.2.d.iii.4 of the proposed rule (82 FR 34143 through 34145) to make a performance payment for core maintenance sessions only when the beneficiary attends at least 3 sessions within a 3-month interval, it is possible that an MDPP supplier would not be paid a separate performance payment for the second core maintenance session interval, but the beneficiary would still have coverage of the first ongoing maintenance session interval. This would occur if the beneficiary attended only 1 or 2 core maintenance sessions during the second core maintenance session interval and achieved or maintained the required minimum weight loss as measured at 1 of those 2 sessions.

iii. Performance Payments for MDPP Services

(1) Overview of Public Comments on Discussion of Payment for MDPP Services in Prior Rulemaking

Commenters on the discussion of payment for MDPP services in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) expressed a variety of perspectives on the

performance-based payment methodology presented in that proposed rule. We describe the comments on the prior discussion as background for our proposals for the performance-based payment methodology for MDPP services that was included in the CY 2018 PFS proposed rule (82 FR 34137 through 34155).

In summary, commenters on the CY 2017 PFS proposed rule recommended that a sustainable payment rate structure for MDPP services should mirror performance-based payment models in the existing employer marketplace. They requested that we not tie Medicare payment to weight loss or that we make separate weight loss and attendance payments; that we tie payment to aggregate, rather than individual, beneficiary weight loss; or that we tie payment to other factors besides or in addition to weight loss. Some commenters requested that we provide information on how the payment rates included in the CY 2017 PFS proposed rule discussion were determined due to their concerns that the amount of MDPP payments was not consistent with payments for other similar services. Multiple commenters urged that higher payments be made at the beginning of the MDPP services period to cover program start-up costs, that we decrease supplier financial risk by providing sufficient payment for beneficiaries who do not achieve weight loss performance goals, and that we implement risk-stratification of payments to reduce the risk of MDPP suppliers preferentially seeking to furnish MDPP services to low-risk beneficiaries most likely to achieve weight loss and avoiding high-risk beneficiaries.

The proposed MDPP payment structure in the CY 2018 PFS proposed rule was generally similar to that which was discussed in the CY 2017 PFS proposed rule (81 FR 46415 through 46416). However, the proposed performance payment amounts for core sessions, core maintenance session 3-month intervals, and ongoing maintenance session 3-month intervals differed somewhat based on our consideration of the comments received in response to the CY

2017 PFS proposed rule in the context of our policy goal to prioritize the achievement and maintenance of the required minimum weight loss that is associated with a reduction in the incidence of type 2 diabetes. We proposed a payment structure for MDPP services that is performance-based in relation to two meaningful performance goals.

First, the proposed payment structure valued beneficiary weight loss most significantly. Weight loss is a key indicator of success among individuals enrolled in a DPP due to the strong association between weight loss and reduction in the risk of type 2 diabetes.[18] Second, the proposed payment structure valued beneficiary attendance because, in the DPP model test, session attendance was associated with greater weight loss. According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds, while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. Body mass index was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions.[19]

In addition to weight loss, we considered linking other criteria such as hemoglobin A1c level to MDPP performance payments, or using aggregate, instead of individual, weight loss for MDPP payments. However, the MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in

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

[19]Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. Awardee-Level Findings: YMCA of the USA; 2016. Table 17. Average/Frequencies Health Outcomes of all Participants through Q11, p. 36. RTI Project Number 0212790.010.001.004, Contract HHSM-500-2010-00021I. Sponsored by the Centers for Medicare & Medicaid Services.

that model. Therefore, we did not propose to use hemoglobin A1c blood values in the performance-based payment methodology for MDPP services under the MDPP expanded model, which is based on certification of the DPP model test. We further noted that the CDC does not require post-MDPP services hemoglobin A1c blood values to be determined as part of its 2015 DPRP Standards or its proposed 2018 DPRP Standards, and we aim to align with the CDC's DPRP Standards as much as possible. While 5 percent weight loss is considered a performance measure for CDC recognition, the CDC does not examine pre-post DPP differences in hemoglobin A1c as part of its DPRP Standards.

The proposed MDPP payment structure would incentivize MDPP suppliers to prioritize the achievement and maintenance of beneficiary weight loss by furnishing MDPP services, and provide a balance between performance-based payments related to weight loss and session attendance. We believed that it would be inappropriate for payment to be tied to attendance alone because weight loss is more directly associated with a reduction in the incidence of type 2 diabetes than attendance at MDPP sessions. We further believed that the proposed performance-based payment structure based on individual beneficiary success, rather than average weight loss across all MDPP beneficiaries who receive MDPP services from an MDPP supplier, would maximize the focus of MDPP suppliers on the achievement of the performance goals for all beneficiaries, including those beneficiaries who experience challenges with achieving attendance and/or weight loss performance goals. Therefore, we did not believe it would be appropriate to use aggregate beneficiary information (that is, average weight loss) in the proposed performance-based payment methodology.

(2) Overall Approach to Setting Performance Payment Amounts

We proposed to establish the rules governing payment for MDPP services at new §414.84. At proposed §414.84(a), we proposed to define "performance goal" as an attendance or weight loss goal that an MDPP beneficiary must achieve for an MDPP supplier to be paid a performance payment. We proposed to define "performance payment" as a payment to an MDPP supplier for furnishing certain MDPP services when an MDPP beneficiary achieves the applicable performance goal. These definitions were used in our proposals for payment of MDPP services.

To align with the once-per-lifetime policy, we proposed at §414.84(b) that each performance payment made based on attendance of a specified number of core sessions, for a specific 3-month core maintenance or ongoing maintenance interval during the MDPP services period, or for achieving a weight loss performance goal, would be made only once per MDPP beneficiary.

The following is a summary of the public comments received on the proposals for the definitions of performance goal and performance payment for MDPP services and our responses:

Comment: Several commenters recommended that CMS use additional outcome measures other than weight loss or use other measures of performance in addition to attendance as performance goals in the performance-based payment methodology for MDPP services. The commenters urged CMS to use laboratory values, such as a reduction in hemoglobin A1c or fasting blood glucose, either in addition to or instead of weight loss as measures of a DPP organization's effectiveness, noting that changes in these laboratory values would reflect improvement in the blood values that are used to diagnose diabetes. The commenters reasoned that if a DPP organization can help a beneficiary improve on these lab values, the beneficiary's risk of type 2 diabetes would be reduced. One commenter added that although body weight was

the measurement of success in the DPP Randomized Control Trial and is a DPRP standard, due to it being a non-invasive and cost-effective measurement of reduction in risk of type 2 diabetes, there is also an evidence-based correlation between a reduction in hemoglobin A1c value and the risk of developing type 2 diabetes. Another commenter, who cited that its own DPP organization has experienced numerous examples of individuals who did not meet the milestone of a 5 percent weight loss but were able to reduce their hemoglobin A1c value into a lower prediabetes zone or, in some instances, to a normal range, recommended that the proposed weight loss performance payments be tied to weight loss *or* a reduction in hemoglobin A1c.

Other commenters expressed concern that the focus on weight loss as the MDPP supplier's outcome valued in the performance-based payment methodology could lead to weight cycling, which could in turn lead to health risks for beneficiaries other than type 2 diabetes. The commenters claimed that weight loss and attendance are confounded measures when both are used as performance goals in the payment methodology because they are linked. They urged CMS to avoid double counting by using attendance alone as the performance goal for performance payments instead of both weight loss and attendance.

Some commenters encouraged CMS to focus the performance goals valued in the payment methodology on improving beneficiary behaviors rather than weight loss. Several commenters recommended that certain DPP organizations, including tribal health programs, have the flexibility to determine their own diabetes prevention measures of success that would be the performance goals upon which payment would be based. In addition to advocating that CMS utilize hemoglobin A1c blood values to assess DPP outcomes, a few commenters suggested that CMS consider adopting other variables, including reduced hypertension risk, lower BMI, increased intake of healthy foods, increased rate of physical activity, or successful reduction of

other risk factors. The commenters claimed that incorporating these variables in the MDPP expanded model performance-based payment methodology would reflect beneficiary adherence to healthy behaviors taught in the DPP curriculum. One commenter recommended that CMS supplement performance payments for core sessions with an additional payment for those sessions that include physical activity, in order accommodate and recognize beneficiaries who may fluctuate in weight loss due to thyroid and hormonal imbalances, stress, sleep disorders, or gastrointestinal issues, but who are otherwise achieving improved healthy behaviors through physical activity. Finally, another commenter urged CMS to explore, via a pilot, additional measures that reflect a possible mechanism associated with an MDPP supplier's success in furnishing MDPP services, such as increased beneficiary self-efficacy or activation and reduced social isolation, which the commenter noted would be likely to have spillover benefits for general health.

Response: We appreciate the commenters' recommendations about additional outcomes and other parameters that could be used as performance goals in the MDPP expanded model payment model to recognize a DPP organization's success that benefits the health of beneficiaries. As we stated in the proposed rule (82 FR 34189), we considered linking other criteria such as hemoglobin A1c level to MDPP performance payments. However, the MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures. Although elevated hemoglobin A1c levels were included as part of the beneficiary eligibility criteria in the DPP model test, hemoglobin A1c levels were not evaluated post-intervention in that model so we do not have information from the DPP model test about the relationship between hemoglobin A1c levels and reductions

in Medicare expenditures upon which a determination about whether the MDPP expanded model meets the statutory requirements for expansion could be made. In addition, the CDC does not require post-MDPP services hemoglobin A1c blood values to be determined as part of its 2015 DPRP Standards, or the proposed 2018 DPRP Standards, and we aim to align with the CDC's DPRP Standards as much as possible. Therefore, we will not use hemoglobin A1c blood values as a performance goal in the performance-based payment methodology for MDPP services.

In response to the commenters who expressed concern about the potential for negative health effects of a focus on weight loss as a performance goal for the MDPP expanded model, we note that certification of the DPP model test was based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures, and the DPP Randomized Control Trial showed that people at risk for developing type 2 diabetes can prevent or delay the onset of type 2 diabetes by losing a modest amount of weight through diet and exercise. The CDC's DPRP Standards, where 5 percent weight loss is considered a performance measure, were developed with this science in mind. Therefore, we continue to believe that weight loss is an appropriate performance goal for use in the MDPP expanded model performance-based payment methodology.

In addition, while we acknowledge that there is an association between attendance and weight loss, the two performance goals proposed for use in the MDPP payment methodology, we remain committed to valuing weight loss in the methodology based on the evidence that achievement of the required minimum weight loss leads to a reduction in the incidence of type 2 diabetes. Weight loss is a key indicator of success among individuals enrolled in a DPP due to

the strong association between weight loss and reduction in the risk of type 2 diabetes.[20] The MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that demonstrated that weight loss was associated with reductions in Medicare expenditures. We note that while there is a positive association between attendance at MDPP sessions and weight loss, which underpins the rationale for offering MDPP services to Medicare beneficiaries in the MDPP expanded model, attendance is not a full proxy for the required minimum weight loss outcome that leads directly to a reduction in the incidence of type 2 diabetes. For example, while in the DPP model test the number of DPP sessions attended had a statistically significant marginal effect on the percent of weight loss, session attendance did not fully account for the percent of weight loss.[21] Specifically, the average effect of attending one additional session was a 0.43 percentage point increase in weight loss. However, the results showed that a participant who attended 9 or more sessions on average experienced a 6.24 percentage increase in weight loss compared to participants attending fewer than 9 sessions, which is a higher percentage point increase in weight loss than would be predicted based on the number of sessions attended alone. Therefore, we continue to believe it is appropriate to use both attendance and weight loss as the MDPP expanded model performance goals in the MDPP performance-based payment methodology, so we are finalizing these performance goals.

For the same reasons that we are not using hemoglobin A1c as a performance goal for the MDPP expanded model, we also will not include any of the other additional parameters

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

[21]RTI International.Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Third Annual Report Addendum 2017: Awardee-Level Findings: YMCA of the USA. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring Third Annual Report — March 2017.

recommended by the commenters to value a DPP organization's success in the MDPP performance-based payment methodology, nor will we allow each DPP organization to develop its own measures of success for Medicare payment purposes under the MDPP expanded model. None of these parameters related to healthy beneficiary behaviors, such as an increased rate of physical activity or increased intake of health foods, were evaluated in the DPP model test to assess their potential relationship to reductions in Medicare expenditures. Therefore, they are not being adopted for use in the MDPP expanded model because they were not used in the determination that the MDPP expanded model meets the statutory requirements for expansion. However, we encourage each MDPP supplier to assess the needs and experiences of the beneficiaries it serves in the context of the MDPP services furnished by the supplier to create, implement, and evaluate its own DPP organization's performance metrics, including process and outcome measures, in the context of the goals of the MDPP expanded model so that the MDPP supplier can identify areas of success and opportunities for improvement in its DPP services.

We will not supplement performance payments for core sessions with additional payments for specific modalities (such as physical activity) offered during sessions, because the MDPP expanded model methodology is already performance-based in nature. Although health behavior changes, including dietary changes and physical activity, are components of the DPP curriculum taught during sessions, the MDPP expanded model was certified based on the close link between weight loss outcomes and a reduced incidence of type 2 diabetes and lower Medicare expenditures. Therefore, it would not be appropriate for us to specifically value in the performance-based payment methodology intermediate health behavior changes such as physical activity changes. Moreover, we are finalizing the requirements for the MDPP expanded model in this final rule, and therefore, are not pursuing through this rulemaking other models or pilots

that reflect possible additional mechanisms associated with an MDPP supplier's success in reducing a beneficiary's incidence of type 2 diabetes.

After considering the public comments received, we are finalizing the proposals, without modification, for the definitions of performance goal and performance payment at §414.84(a).

(a) Total Amount and Distribution of Performance Payments Across the Set of MDPP Services

As displayed in Table 28, we proposed a maximum total performance payment amount per beneficiary for the set of MDPP services of $810. This amount is the aggregate of the maximum proposed performance payments for core sessions, core maintenance sessions, and ongoing maintenance sessions furnished to MDPP beneficiaries who achieve weight loss of at least 9 percent over the proposed 36 months of the MDPP services period. This performance payment amount would be made for a minimum of 46 MDPP sessions required to be offered to the beneficiary in the set of MDPP services. Although CMS would make performance payments to MDPP suppliers at intervals throughout the MDPP services period in varying amounts, payment for each session furnished would be included in the total performance payment amount a supplier was paid for the set of MDPP services furnished to an MDPP beneficiary.

Although we did not propose that payment for MDPP services utilize a fee-for-service payment methodology, we noted that, estimated on a per-session basis, the maximum MDPP payment amount for achievement of all the performance goals would equate to approximately $18 per session. For comparison, Medicare pays under the PFS approximately $10 (excluding physician work and malpractice) for CPT code 98962 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients), a service that may bear some resemblance to an MDPP session furnished by an MDPP

supplier, although an MDPP session would be furnished by a coach (not necessarily a health care professional), has a duration of 1 hour, and has no explicit limitation on group size.

However, this estimated per-session MDPP payment amount would result only from the furnishing of MDPP services to those beneficiaries who achieve all of the attendance and weight loss performance goals under the proposed performance-based payment methodology for MDPP services. For beneficiaries who do not achieve all of the performance goals, the estimated per-session MDPP payment amount would generally be significantly lower, with the amount based upon the actual attendance and weight loss performance of the beneficiary. The differences between the estimated MDPP per-session payment amounts and between the MDPP and PFS payment amounts would result from the proposed performance-based methodology for MDPP services based on the MDPP beneficiary's achievement of performance goals, that differs from the PFS where payments are based on suppliers' relative resources used to furnish services. We believed that the estimated per-session MDPP payment amounts under our proposal for beneficiaries who achieve specified attendance and weight loss performance goals were appropriate in the context of a performance-based payment methodology for the set of MDPP services.

Finally, we noted that there are also some administrative costs that MDPP suppliers would bear to enroll in Medicare and ensure compliance with the requirements for furnishing MDPP services. The total MDPP performance payment across all Medicare beneficiaries would provide some payment for the resources that would be used by MDPP suppliers to meet the administrative requirements for furnishing MDPP services.

In terms of the proposed distribution of the maximum total performance payment amount for MDPP services across the types of performance payments, as discussed in detail in sections

III.K.2.d.iii.(3) and (4) of the proposed rule (82 FR 34141 through 34145) and displayed in Table 28, we proposed that, for those beneficiaries achieving the highest core services period performance goals, approximately 13 percent of the maximum of $810 would be paid for attendance at core sessions during the initial 6 months of the core services period, while approximately 15 percent would be paid for core maintenance sessions during months 7 to 12 of the core services period. We believed that payment of a similar percentage of the maximum total performance payment amount during the initial 6 months of the core services period for beneficiaries who meet attendance performance goals and during months 7 to 12 for beneficiaries who meet both weight loss and attendance performance goals would be appropriate to balance performance payment for attendance and weight loss throughout the core services period.

In addition, as discussed in detail in section III.K.2.d.iii.(5) of the proposed rule (82 FR 34145 through 34146), we proposed that approximately 49 percent of the maximum of $810 would be paid for ongoing maintenance sessions over a 24-month period, or 24.5 percent per each 12-month period, for those beneficiaries who maintain the required minimum weight loss. The focus of ongoing maintenance sessions is on maintenance of weight loss that has already been achieved, and there would typically be an established relationship between the MDPP supplier and the MDPP beneficiary during the ongoing services period. Therefore, the totality of MDPP sessions furnished during this 24-month period would result in a slightly lower performance payment per 12-month period than the totality of those sessions furnished when the required minimum weight loss is achieved during the 12 months of the core services period, when 28 percent of the maximum total performance payment amount would be paid.

Finally, due to the importance of weight loss as a meaningful outcome of MDPP services because of its association with a reduction in the incidence of type 2 diabetes, as discussed in detail in section III.K.2.d.iii.(6) of the proposed rule (82 FR 34146), we proposed that 23 percent of the maximum total performance payment amount would be paid for weight loss performance payments to provide additional payments for MDPP sessions that are effective (that is, lead to specified percentages of weight loss). We noted that, in the DPP model test, 44.7 percent of participants achieved 5 percent weight loss, which under our proposal would result in a weight loss performance payment of approximately 20 percent of the maximum total performance payment amount.[22] Moreover, according to estimates from CDC's DPRP, approximately 12 percent of program participants attending at least 2 sessions achieved 9 percent or greater weight loss.[23]

Table 28 summarizes the proposed maximum total amount and distribution of performance payments for the set of MDPP services.

TABLE 28: Proposed Maximum Total Amount and Distribution of Performance Payments for the Set of MDPP Services

Type of Performance Payment	Maximum Performance Payment for Achieving Attendance and/or Weight Loss Performance Goals	Percentage of Maximum Total Performance Payment Amount
Core sessions	$105	13%
Core maintenance session intervals	$120	15%
Ongoing maintenance session intervals	$400	49%
Weight loss	$185	23%
Total performance payment	**$810**	**100%**

We invited public comments on our proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services.

[22]National Council of Young Men's Christian Associations, Measurement and Monitoring Report. CMS Health Care Innovation Awards, Round One, Sixteenth Quarterly Reporting Period (16QR), April, May, and June 2016.
[23]CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

The following is a summary of the public comments received on the proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services and our responses:

Comment: Many commenters supported the proposal of a performance-based payment methodology for MDPP services based on the performance goals of session attendance and weight loss. The commenters agreed that incentivizing MDPP suppliers, including coaches, and MDPP beneficiaries to work toward achievement of these performance goals would be valuable to the success of MDPP services in reducing the incidence of type 2 diabetes among MDPP beneficiaries. Several commenters further stated that the MDPP expanded model is consistent with other value-based payment models and would be an improvement over fee-for-service payment, although they acknowledged that the proposed payment structure was more complicated.

A few commenters recommended that CMS make a payment for each MDPP session, at least for the first 12 months of the MDPP services period. In addition, several of the commenters urged CMS to couple this payment policy with a bonus for achievement of the required minimum weight loss at the end of the core services period. Another commenter requested that CMS provide information on how the proposed performance payment amounts were determined, similar to information published in the Medicare PFS rules for any services covered under the Part B Medicare program. The commenter observed that the proposal for the MDPP expanded model contained extensive information on payment amounts but did not clearly explain the derivation of the proposed performance payment amounts. One commenter stated that services reported under the Medicare program using CPT code 98962 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized

curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients), a CPT code CMS referenced in the proposed rule, have been proven to be ineffective in changing behavior, yet the supplier is paid the full PFS amount regardless of outcomes. The commenter noted that trained DPP coaches have shown excellent results and, therefore, should be paid equal to or more on an hourly basis as the service reported under this CPT code, which the commenter stated would equate to $20 per hour.

One commenter urged CMS to reconfigure the proposed performance-based payment methodology to allow for add-on payments based on practice size and geographic location. The commenter noted that an additional payment for solo or small practices, as well as for practices in rural or underserved areas, would significantly expand the reach and effectiveness of MDPP services and enable primary care physicians to continue to drive the health care system through a focus on preventive services that reduce costs and improve care.

Another commenter recommended that CMS pay all MDPP suppliers, or at a minimum community-based organizations and small suppliers, based on aggregate, rather than individual, beneficiary performance on attendance and weight. Several commenters emphasized their perspective that performance-based payment that relies heavily on individual patient outcomes would be most likely to succeed when directed at large institutions with multiple sources of revenue where reallocation, cross-subsidy, and assuming financial risk are possible. The commenters noted that small MDPP suppliers would be unlikely to be able to support performance-based payment structures such as CMS proposed for the MDPP expanded model that are premised on a very low payment per evidence-based service, with small sample sizes that make performance payments based on individual beneficiary achievement of performance goals unreliable.

Another commenter noted that evidence to support the effectiveness of pay-for-performance through using the achievement of individual patient outcomes to financially incentivize the appropriate delivery of evidence-based services is mixed. The commenter claimed that there are some reports of no impact on the delivery of evidence-based services and other reports of initial improvements that fail to be sustained in comparison with changes in the practices of other providers over time. The commenter stated that pay-for-performance methodologies for individual health care providers have largely been based on process measures about the delivery of appropriate services, rather than the patient outcomes that result. They concluded that moving to pay-for-performance for an outcome measure like weight loss for Medicare payment as CMS proposed for the MDPP expanded model is an experimental rather than an evidence-based payment strategy, while MDPP services themselves are evidence-based and, therefore, should be paid through an evidence-based approach.

Response: We continue to believe that a comprehensive performance-based payment methodology is appropriate for the MDPP expanded model, where all payments are made in direct relation to the achievement of performance goals, rather than on a per-session basis. The MDPP performance-based payment methodology makes available performance payments for the achievement of weight loss, specifically the required minimum weight loss in the first 12 months of the MDPP services period and the achievement of 9 percent weight loss any time during the MDPP services period. This is consistent with the recommendations of several commenters that a weight loss "bonus" be available, although we are not accompanying weight loss performance payments with per-session payments as further recommended by those commenters.

Given the differences between such a performance-based payment methodology and payment under the FFS Medicare payment methodologies, we are not able to provide

information on determining MDPP performance payment amounts that is similar to information published in the Medicare PFS rules for other Part B services where payments are related to the relative resources used by suppliers to furnish those services, nor are comparisons to payment on an hourly basis with PFS services possible. The MDPP expanded model uses a fundamentally different payment methodology than the FFS Medicare payment methodologies because it provides a balance of performance-based payments related to weight loss and session attendance, and does not use a resource-based payment methodology for MDPP services. We respond specifically to comments on the proposed distribution of performance payments across the set of MDPP services in the subsequent response in this section and provide more information about our final performance payment and bridge payment amounts in sections III.K.2.d.iii.(3) through (6) and III.K.2.d.v. of this final rule.

Under the performance-based methodology, we believe it is appropriate to pay MDPP suppliers, regardless of size or geographic location, the same performance payment for each beneficiary who achieves the same performance goals because achievement of the required minimum weight loss leads to a reduced incidence of type 2 diabetes for beneficiaries.

Moreover, payment of performance payments based on aggregate beneficiary achievement of performance goals would not sufficiently incentivize MDPP suppliers to engage all beneficiaries in working to achieve the performance goals of the MDPP expanded model. We acknowledge that MDPP suppliers furnishing MDPP services to a small number of beneficiaries may experience more payment variation than larger suppliers under our proposed methodology that relies on the achievement of performance goals by individual beneficiaries to determine the payment amounts. However, we maintain our strong interest in incentivizing MDPP suppliers to work to engage all beneficiaries in achieving the attendance and weight loss performance goals

of the MDPP expanded model, despite our understanding that this may put some suppliers at greater financial risk than others. Therefore, we will not provide performance payments based on aggregate beneficiary achievement of performance goals.

We note that the MDPP expanded model was determined to meet the statutory requirements for expansion, with certification of the DPP model test based on findings that weight loss was associated with reductions in Medicare expenditures. In response to the commenter who was concerned that the MDPP expanded model performance-based payment methodology is not evidence-based, we emphasize that we intend to evaluate the MDPP expanded model, which will pay for MDPP services under this payment methodology, using a combination of encounter and claims data to analyze the long-term utilization of services by beneficiaries who have received MDPP services. Moreover, 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.

Comment: While many commenters supported the proposed maximum performance payment of $810 per MDPP beneficiary, multiple commenters opposed the proposed distribution of performance payments over the set of MDPP services. The commenters noted that the sum of the proposed performance payments for the first 12 months of the MDPP services period was too low, especially for beneficiaries who did not achieve the required minimum weight loss but to whom MDPP suppliers would be required to offer sessions throughout that time period. The commenters noted that the MDPP payment structure should take into account the weight loss trajectory of typical individuals receiving DPP services, where weight loss occurs slowly over

many months, and should also ensure ongoing financial support for the MDPP supplier that must provide access to MDPP services and teach the DPP curriculum to beneficiaries while the beneficiaries are working to lose weight.

Many commenters acknowledged that they anticipated significant attrition of MDPP beneficiaries over the maximum 36-month MDPP services period. The commenters expected that MDPP suppliers would not receive the full $400 that CMS proposed as the maximum aggregate performance payment for ongoing maintenance session intervals in the ongoing services period during months 13 to 36 as Medicare beneficiaries reduced their participation in MDPP services because they were no longer eligible for coverage based on their lack of adherence to attendance requirements over the long duration of the period. Most commenters with this perspective also urged CMS either not to include ongoing maintenance sessions in the MDPP expanded model or to reduce the proposed 24 months of the ongoing services period to 12 months. Under both scenarios, the commenters urged CMS to redistribute the performance payments that would have been made for ongoing maintenance session intervals to increase performance payments during the first 12 months of the MDPP services period, especially to core session performance payments.

Multiple commenters requested that MDPP suppliers be paid when MDPP supplier resources are used. They stressed that MDPP suppliers incur significant cost prior to the first core session, including hiring and training coaches, printing the CDC curriculum and nutrition logs, and potentially securing class space. The commenters claimed that most MDPP supplier costs (for example, administration, staffing, beneficiary engagement, marketing, materials, and recruitment) are expended up front in the initial 6 months of the MDPP services period, regardless of whether beneficiaries achieve the required minimum weight loss performance goal.

Under the proposal, the commenters concluded that MDPP suppliers would be faced with covering their initial DPP expenses without timely payment, which could preclude some entities from becoming MDPP suppliers.

Several commenters urged CMS to pay MDPP suppliers based on attendance alone for the full 12-month core services period, with higher amounts in the first 6 months because they claimed that the majority of the costs associated with professional staff labor are incurred in this time period due to the DPP curriculum being delivered in weekly sessions. Other commenters recommended that the large majority of payment for MDPP services, up to 70 percent for those beneficiaries achieving 5 percent weight loss, be paid during the first 12 months of a beneficiary's MDPP services period. Some commenters stated that the performance payment should be based on completion of the 12-month core services period, rather than on the achievement of weight loss goals that may be affected by factors outside the MDPP beneficiary's or MDPP supplier's control.

A number of commenters estimated the MDPP supplier cost of furnishing MDPP services for the core services period as greater than $500 per beneficiary. One commenter claimed that payment to DPP organizations in the DPP model test, in the NIH Randomized Control Trial, and the private sector were all substantially higher than the average proposed first year per beneficiary payment of $255 that a high-performing DPP organization would anticipate under the MDPP expanded model (to calculate the $255 average payment, the commenter assumed 50 percent of beneficiaries achieve 5 percent weight loss, and all beneficiaries attend 16 sessions in months 1 to 6 and 6 sessions in months 7 to 12). Another commenter further observed that the DPP model test did not include the significant administrative, operational, and reporting requirements necessary to become a Medicare supplier and adhere to the MDPP expanded model

requirements that CMS proposed. The commenters concluded that the significant disparity between the proposed payment for MDPP services and actual needed MDPP supplier investment would impact the MDPP expanded model outcomes, including the MDPP beneficiary's achievement of performance goals and the MDPP supplier's fidelity to the quality of its DPP, in addition to reducing the cost-effectiveness and efficiency of MDPP services.

Moreover, several commenters claimed that the significant MDPP supplier infrastructure that would be required by CMS' proposals and the associated administrative costs to sustain a 12- to 36-month MDPP services period for each MDPP beneficiary would create a burden for most community-based DPP organizations, resulting in barriers to participation in the MDPP expanded model for small or new DPP organizations. Therefore, they reasoned that the proposed distribution of performance payments may be inadequate to support MDPP suppliers in general and may be biased towards organizations with greater resources. The commenters concluded that this bias could further restrict an already limited in-person network of DPP organizations and reduce the opportunity for competition among DPP organizations.

Other commenters reported that a typical performance bonus is 10 to 20 percent of a person's salary for achieving exemplary results, whereas CMS proposed that 85 percent of the maximum total performance payment amount for MDPP services would be based on the achievement of the required minimum weight loss. Several commenters stated that the goal of securing CDC's DPRP full recognition should be a sufficient incentive for MDPP supplier engagement in beneficiary weight loss efforts, because ultimately without this recognition, the DPP organization would not be eligible to be an MDPP supplier that can furnish and bill for MDPP services.

Response: We refer readers to sections III.K.2.d.iii.(3) through (6) of this final rule for discussion of our final policies and payment amounts for the specific types of performance payments under the MDPP expanded model. We also refer readers to section III.K.2.b.i. of this final rule for discussion of our final policy that establishes a maximum 12-month ongoing services period, rather than the 24-month timeframe we proposed. In addition, in a previous response to public comments in this section, we provided our rationale for adopting a performance-based payment methodology for MDPP services in general, where payment will be based on the achievement of attendance and weight loss performance goals.

We appreciate the information provided by the commenters about the amount of payment made by other payers for DPP services, as well as their estimates of MDPP supplier costs for furnishing MDPP services. However, we note that unlike FFS Medicare payment methodologies, we are not providing payments for MDPP services based on the relative resources used by MDPP suppliers but rather using a performance-based payment methodology that is based on the individual MDPP beneficiary's achievement of performance goals. We also do not believe that it would be appropriate to set payment for MDPP services based primarily on historical payments received by DPP organizations under clinical trials or other models where the beneficiary population and other program requirements and activities were not the same as those under the MDPP expanded model. For example, the design features of the NIH Randomized Control Trial differ from the MDPP expanded model, including the personnel teaching the curriculum and the settings where DPP services were furnished. Moreover, we are aware of similar payment structures being used by commercial insurers and accepted by DPP organizations; however, the specific payment amounts vary substantially, and we continue to

believe the performance payment amounts for MDPP services are appropriate under the MDPP expanded model.

However, we agree with commenters that the distribution of the maximum total performance payment amount over the set of MDPP services should be revised to shift a higher percentage to the core services period, especially the first 6 months of the MDPP services period. We believe this shift is appropriate in view of the frequent sessions that must be offered to MDPP beneficiaries by MDPP suppliers during months 1 to 6 for beneficiary achievement of attendance performance goals and the aggressive pursuit of performance goals that we expect to occur during the first 12 months of the MDPP services period, where coverage for MDPP services ends altogether if the beneficiary does not achieve the required minimum weight loss within that 12-month time period. Based on the information provided by the commenters, we believe this revised distribution better accounts for the weight loss trajectory of the typical MDPP beneficiary, where weight loss occurs slowly over many months, while ensuring ongoing financial support for the MDPP supplier that must provide access to MDPP services and teach the DPP curriculum to beneficiaries while the beneficiaries are working to lose weight.

We are specifically increasing the performance payments for attendance at 4 and 9 core sessions and the core maintenance session interval performance payments for those beneficiaries who do not achieve or maintain the required minimum weight loss, consistent with the requests of some commenters as discussed in detail in sections III.K.2.d.iii.(3) and (4) of this final rule, respectively. In comparison with the approximately 50 percent that we proposed, these changes result in about 70 percent of the maximum total performance payment amount for the MDPP services period being available during the first 12 months of the MDPP services period for

beneficiaries who achieve the required minimum weight loss within the first 6 months, as some commenters also requested.

We considered making the distributional changes to shift a higher percentage of the maximum total performance payment amount for the set of MDPP services to the core services period by redistributing only those performance payments that would have been made during months 1 to 24 of the MDPP services period, in order to shift a higher percentage of those payments to the first 6 months of the core services period. However, such a redistribution would have required reducing the performance payments for core maintenance and ongoing maintenance session intervals from the amounts we proposed, while commenters supported the proposed amounts or recommended higher payment amounts, as discussed in sections III.K.2.d.iii.(4) and (5) of this final rule. It would also have reduced the maximum total performance payment amount to $610 from the $810 that we proposed, due to the elimination of ongoing maintenance session interval performance payments of $50 per interval for the 4 intervals that would have occurred during months 25 to 36 of the MDPP services period.

Instead, we are shifting a higher percentage of the maximum total performance payment amount to the core services period by partially redistributing the performance payments that would have been made during months 25 to 36 of the MDPP services period to the core services period because the ongoing services period has been reduced from 24 to 12 months. This approach allows us to finalize performance payments for core maintenance and ongoing maintenance session intervals that are no lower than the amounts we proposed and results in a smaller reduction to $670 for the maximum total performance payment amount.

In considering opportunities to revise the performance payment amounts in response to the perspectives provided by the commenters, we intend for our redistribution to have a minimal

impact on the estimated Medicare expenditures for MDPP services; therefore, we are not redistributing the full amount of $200 that would have been the maximum performance payment amount for months 25 to 36 of the MDPP services period. Rather, we are only partially redistributing payments from the full amount of $200 because our expectation (based on the results of the DPP model test and information from the commenters) is that a higher number of beneficiaries will attend the sessions during the core services period than the number who would have attended the sessions during months 25 to 36 of the ongoing services period, due both to beneficiary attrition over the long duration of the MDPP services period and the coverage requirements for beneficiaries during the ongoing services period. Thus, we believe that redistributing the full amount of $200 to the core services period would result in significantly higher expenditures for the MDPP expanded model than a partial redistribution that more closely reflects performance payments we would have made if the ongoing services period continued through month 36. Therefore, in order to maintain a similar estimate of aggregate Medicare expenditures for MDPP services under our final distribution of performance payments, the final maximum total performance payment amount is necessarily lower than the $810 we proposed.

The partial redistribution of $60 to the performance payments for attendance at 4 and 9 core sessions and $10 to the core maintenance session interval performance payments for beneficiaries who do not achieve or maintain the required minimum weight loss means that the final maximum total performance payment amount for a beneficiary is $670 under the MDPP expanded model. As was also true for our proposals, in the context of estimates of future Medicare savings from the MDPP expanded model, the redistribution of dollars across the set of MDPP services under our final policies takes into account estimates of total Medicare expenditures under the MDPP expanded model for MDPP beneficiaries and estimates of future

reductions in spending for those beneficiaries that would occur from their reduced incidence of type 2 diabetes.

Based on the final performance payments displayed in Table 29, and assuming 50 percent of an MDPP supplier's MDPP beneficiaries achieve the required minimum weight loss within the first 6 months of the core services period (the assumption made by one commenter for ease of estimation, which we also use because it is close to the 44.7 percent of participants in the DPP model test who achieved 5 percent weight loss and [24]) and maintain this weight loss through months 7 to 12, the average MDPP supplier total performance payment amount per beneficiary for the first 12 months of the MDPP services period is $320 under our final policies, compared with $255 under our proposed policies. In the MDPP expanded model performance-based payment methodology, this increase in the estimated average MDPP supplier total performance payment amount per beneficiary for the core services period more substantially recognizes beneficiary achievement of the attendance and weight loss performance goals during this 12-month timeframe that result in a reduced incidence of type 2 diabetes. In addition, we note that these payment changes also result in the opportunity for MDPP suppliers, including those suppliers that are small or new DPP organizations, to receive a larger amount of performance payments in the first 12 months of a beneficiary's MDPP services period that may help reduce DPP organizations' financial barriers to enrollment in Medicare and, therefore, increase access to MDPP services for Medicare beneficiaries. We believe the revised distribution of performance payments shortens the time MDPP suppliers must bear the resource costs of enrolling in Medicare and furnishing MDPP services without receiving significant payments from Medicare,

[24]National Council of Young Men's Christian Associations, Measurement and Monitoring Report. CMS Health Care Innovation Awards, Round One, Sixteenth Quarterly Reporting Period (16QR), April, May, and June 2016.

thereby increasing the likelihood that additional organizations with fewer resources will be able to enroll in Medicare and furnish MDPP services.

As explained previously, we are not redistributing to the other performance payments amounts the full amount of $200 that would have been the maximum total per-beneficiary performance payment for months 25 to 36 of the MDPP services period. This means that the final maximum total performance amount for a beneficiary is $670 under the MDPP expanded model, lower than the $810 we proposed. The final lower maximum total performance payment amount results from our expectation that the ongoing maintenance session interval performance payments for months 25 to 36 of the MDPP services period would have been made for fewer beneficiaries than the increased performance payments that will be made in the first 12 months of the MDPP services period under our final policies, due both to beneficiary attrition over the long duration of the MDPP services period and the policy that performance payments for ongoing maintenance session intervals require the beneficiary to meet both attendance and weight loss performance goals during each interval. As was also true for our proposals, in the context of estimates of future Medicare savings from the MDPP expanded model, the redistribution of dollars across the set of MDPP services under our final policies takes into account estimates of total Medicare expenditures under the MDPP expanded model for MDPP beneficiaries and estimates of future reductions in spending for those beneficiaries that would occur from their reduced incidence of type 2 diabetes.

After considering the public comments received, we are finalizing the proposals for the maximum total performance payment amount and the distribution of performance payments for MDPP services across the set of MDPP services, with modifications. Based on our discussions in sections III.K.2.d.iii.(3) through (6) of this final rule regarding weight loss performance

payments and changes to the performance payments for core sessions, core maintenance session intervals for beneficiaries who do not achieve or maintain the required minimum weight loss, and ongoing maintenance session intervals to reflect the final 12-month ongoing services period policy (discussed in section III.K.2.b.i of this final rule), the final maximum total performance payment amount for the set of MDPP services is $670. The changes to the specific types of performance payments in this final rule that sum to the maximum total performance payment amount for the set of MDPP services result in a substantial increase in the percentage of the maximum total performance payment amount available during the 12-month core services period. The largest absolute percentage increase by type of performance payment is in the first 6 months of the MDPP services period when core sessions are furnished. There is also a significant absolute percentage decrease in the maximum total performance payment amount for ongoing maintenance session intervals, which reflects the shortening of the ongoing services period duration from 24 months to 12 months. The final maximum total performance payment amount and distribution of performance payments for MDPP services are displayed in Table 29.

TABLE 29: Final Maximum Total Amount and Distribution of Performance Payments for MDPP Services

Type of Performance Payment	Maximum Performance Payment for Achieving Attendance and/or Weight Loss Performance Goals	Percentage of Maximum Total Performance Payment Amount
Core sessions	$165	25%
Core maintenance session intervals	$120	18%
Ongoing maintenance session intervals	$200	30%
Weight loss	$185	27%
Total performance payment	**$670**	**100%**

(b) Payment Considerations Related to Coverage of MDPP Services for Beneficiaries with Social Risk Factors

In the CY 2018 PFS proposed rule (82 FR 34141), we discussed our understanding that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support play a major role in health. The Office of the Assistant

Secretary for Planning and Evaluation (ASPE) and the National Academies of Sciences, Engineering, and Medicine recently released reports on the issue of accounting for social risk factors in CMS programs.[25,26] We have previously sought public comment on accounting for social risk factors in CMS programs, primarily on the topics of quality measurement and reporting, such as in the Request for Information Regarding Implementation of the Merit-Based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models published in the October 1, 2015 **Federal Register** (80 FR 59105, 59109, 59110, and 59113).

In the CY 2017 PFS final rule (81 FR 80466), we acknowledged commenters' concerns regarding the potential unintended consequences if the MDPP expanded model were to result in low-income or other disadvantaged populations having less access to ongoing maintenance sessions due to their failure to achieve or maintain the weight loss performance goal required for coverage of these sessions. In addition, through listening sessions, stakeholders provided us with anecdotal information suggesting that racial and ethnic minorities and low socioeconomic status populations lose about 1 percent less weight, on average, than higher socioeconomic groups and non-Hispanic whites.

We proposed an MDPP payment structure for the set of MDPP services that is similar to the structure presented in the CY 2017 PFS proposed rule (81 FR 46416), where performance payments are tied to attendance at MDPP sessions and/or weight loss. Based on information provided to us by stakeholders, we acknowledged that tying performance payment to a specific threshold of weight loss and/or attendance may make achieving the performance goals required

[25] Available at https://aspe.hhs.gov/sites/default/files/pdf/253971/ASPESESRTCfull.pdf.
[26] Available at http://nationalacademies.org/hmd/Reports.aspx?filters=inmeta:activity=Committee+on+Accounting+for+SES+in+Medicare+Payment+Programs.

for the highest performance payments and beneficiary eligibility for coverage of ongoing maintenance sessions more challenging for MDPP suppliers furnishing services to individuals with social risk factors. We noted that our proposal for beneficiary engagement incentives as discussed in section III.K.2.f. of the proposed rule (82 FR 34166 through 34171) would provide MDPP suppliers with the flexibility under certain conditions to furnish in-kind patient engagement incentives, such as transportation, to support beneficiaries in achieving the MDPP expanded model performance goals, including session attendance and weight loss. We expected that these beneficiary engagement incentives may be helpful to MDPP suppliers furnishing services to beneficiaries, including those with social risk factors that could increase their risk of not achieving the MDPP performance goals.

We did not propose to risk-adjust MDPP payments for social risk factors or to adopt additional special payment policies to specifically encourage MDPP suppliers to furnish sessions to beneficiaries with social risk factors because, for the MDPP expanded model, we do not believe that such approaches are necessary to ensure access to MDPP services for all beneficiaries. This is because we believe that the proposed performance goals upon which the performance payments for the set of MDPP services would be based, as well as the payment policies that recognize that weight loss is a gradual process that may occur slowly over the 12 months of the core services period, should allow MDPP suppliers sufficient time to work with all eligible beneficiaries, including beneficiaries with social risk factors, toward achieving the attendance and weight loss performance goals of the MDPP expanded model. However, we noted that we may consider proposing additional payment policies for the MDPP expanded model in the future, as appropriate.

We requested comments about social risk factors in the context of the set of MDPP services that could inform any future considerations of additional payment policies for the MDPP expanded model. We also invited public comments on other types of strategies that we could utilize throughout the testing of the MDPP expanded model to assist MDPP suppliers in providing robust access to MDPP services for beneficiaries with social risk factors, such as learning activities to share best practices among MDPP suppliers in providing the set of MDPP services.

The following is a summary of the public comments received on social risk factors in the context of MDPP services and other types of strategies that we could utilize through the testing of the MDPP expanded model to assist MDPP suppliers in providing access to MDPP services for beneficiaries with social risk factors and our responses:

Comment: Several commenters expressed concern that the proposed performance-based payment methodology did not include risk-stratification of payments for MDPP services. The commenters noted the proposed payment approach could potentially lead MDPP suppliers to cherry-pick beneficiaries and/or service delivery locations based on the probability that the patient population would attend more sessions, be more adherent to the education and counseling they receive, and be more likely to lose weight, while avoiding communities with a high percentage of beneficiaries with social risk factors who might find DPP attendance and adherence more challenging. The commenters noted that such MDPP supplier practices resulting from the proposed MDPP performance-based payment methodology could compromise the advancement of the goals of the MDPP expanded model, and may generate greater inequities and lack of MDPP services access for individuals who already experience a disproportionately higher risk for type 2 diabetes. One commenter expressed concerns about the unknown relation

of the proposed pay-for-performance strategy to health disparities and sought acknowledgement from CMS that the proposal is an experimental approach that has a weak evidence-base. The commenter requested that CMS include references to the data in the final rule regarding the effects on disparities on which the proposals for the MDPP expanded model were based.

The commenters urged CMS to take into account the socioeconomic status of MDPP beneficiaries and how this may impact their achievement of performance goals more generally, and risk-adjust for these factors. One commenter suggested that CMS provide a supplemental payment of 25 percent to MDPP suppliers for furnishing MDPP services in geographies or to groups who, based on the literature, have a higher prevalence of type 2 diabetes in their community, and/or are less likely to complete the set of MDPP services. The commenter recommended that this supplemental payment should be tied to aggregate attendance, rather than weight loss, in order to promote the delivery of MDPP services by community-based organizations that can make ancillary supportive services available to beneficiaries that the commenter stated may lead to greater success in priority communities. As an alternative to this approach, the commenter presented options for tying enhanced payments to individual MDPP suppliers that would pay suppliers different amounts based on the specific population enrolled with a DPP organization.

Other commenters who acknowledged that CMS did not propose to move forward with risk-adjustment for social risk factors in the MDPP expanded model in CY 2018 encouraged CMS to be mindful of how social influences may impact some MDPP beneficiaries and encouraged the Agency to consider risk-adjustment or other methods to appropriately account for social risk factors in future years in the performance-based payment methodology. In contrast, several commenters noted that risk-stratification of payments based on social risk factors is not

necessary for the success of the MDPP expanded model and may lead to discrimination in the model.

Many commenters presented social factors that they state influence health, including income, education, race and ethnicity, employment, disability, and social supports. Other commenters cited research which suggested that addressing socioeconomic factors increases both the sustainability and impact on overall health of efforts to prevent and manage chronic conditions, particularly type 2 diabetes. One commenter identified the following social risk factors as potentially influencing patient outcomes experience by DPP organizations: transportation issues and their impact on consistent participation with face-to-face programs; socioeconomic status and its impact on access to healthy food choices and the ability to participate in safe physical activity; and educational and cognitive level and its impact on understanding key concepts of the DPP and decision-making skills. Another commenter stated that 22 percent of its DPP organization's participants are below the federal poverty guidelines and are achieving, on average, weight loss that is nearly a percentage point lower than participants with household income above the federal poverty line.

Several commenters stressed their commitment to furnishing MDPP services to all individuals who qualify for these services, regardless of their ability to pay or the timeline in which they achieve performance goals, including working hard to address issues like access and affordability that may make it difficult for people to enroll and continue to receive services from the DPP organization. The commenters emphasized that MDPP suppliers must be willing to put time and resources into additional or customized services to meet the needs of communities with social risk factors and drive people to enroll and continue to participate in a lengthy behavior change program like the set of MDPP services. Several commenters encouraged CMS to

continue to align with the CDC's DPRP Standards to encourage and/or incentivize MDPP suppliers, through transparent policies, to furnish MDPP services in low-income areas.

One commenter recommended that CMS develop a list of social risk factors for MDPP suppliers to capture so suppliers can develop a process to query beneficiaries about these issues. Several commenters stated that while the MDPP expanded model proposals regarding beneficiary engagement incentives would provide MDPP suppliers with some flexibility to support different beneficiary needs, it is unclear if this policy will be sufficient to allow MDPP suppliers to appropriately assist low-income or other disadvantaged populations who have less access to programs and resources.

Response: We appreciate the feedback from the commenters on social risk factors in the context of MDPP services, as well as on strategies that we could utilize throughout the testing of the MDPP expanded model to assist MDPP suppliers in providing access to MDPP services for beneficiaries with social risk factors. We also appreciate the support of some of the commenters for our proposals regarding beneficiary engagement incentives to provide MDPP suppliers with additional flexibility to support different beneficiary needs.

In response to the commenter who requested that CMS present references to the data about the effects on disparities on which the proposals for the MDPP expanded model were based, we note that we have adapted model policies to support national expansion and in response to public comments; therefore, we do not currently have existing evidence specific to the effects on disparities of the totality of model design parameters that are being finalized in this final rule. To the extent possible with existing data, sub-group analyses, including beneficiary characteristics such as race and ethnicity, will be conducted at part of the evaluation of the MDPP expanded model.

We will review the information about social risk factors provided by the commenters, as well as our early implementation experience with the MDPP expanded model and other information we receive in the future from stakeholders, as we consider potential proposals for additional payment policies for the MDPP expanded model in the future.

(3) Performance Payments for Core Sessions

The payment structure presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) would have made attendance-based payments of $25 for the first core session, $50 for 4 total core sessions, and $100 for 9 total core sessions. Based on our consideration of information provided in the public comments on CY 2017 PFS proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the attendance-based performance payments for 4 and 9 core sessions differed from these payment amounts.

We proposed that an MDPP supplier would be paid a $25 performance payment the first time it furnishes an MDPP session to an MDPP beneficiary as displayed in Table 30. This performance payment would be available once per beneficiary for the beneficiary's first core session.

We proposed that an MDPP supplier would be paid the performance payment upon furnishing the first core session to a beneficiary who initiates the MDPP services period, regardless of whether the MDPP supplier qualifies for any of the additional performance payments for that beneficiary. Additional performance payments would depend upon the beneficiary's achievement of the performance goals for attendance and/or weight loss. We believed that making the first performance payment based on beneficiary attendance at the first core session would be appropriate because the MDPP supplier would use significant resources to furnish the first session, including collecting administrative information on the beneficiary who

is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP services from that supplier.

On a per-session basis, the performance payment for the first MDPP core session would be the highest performance payment amount for any core session during the core services period. Of note, the first core session performance payment also would provide some payment for MDPP supplier activities to encourage the beneficiary's attendance at additional core sessions following the first session. Such supplier activities could include sending electronic messages or making reminder phone calls about upcoming sessions or providing transportation to the next session under the beneficiary engagement incentives policy proposed in section III.K.2.f. of the proposed rule (82 FR 34166 through 34171). It is only through attendance at the first core session with an MDPP supplier that a beneficiary initiates the MDPP services period and has the potential to achieve weight loss through receiving MDPP services.

Further, we proposed that suppliers would be paid a performance payment for the interval (which we refer to as an "interval performance payment" to distinguish it from other performance payments, such as the performance payment upon an MDPP beneficiary's achievement of the required minimum weight loss, that would not require attendance at multiple sessions) upon a beneficiary's attendance at 4 total core sessions, and again upon a beneficiary's attendance at 9 total core sessions--that is, attendance of 5 more core sessions after having attended his or her first 4. We proposed an interval performance payment of $30 upon a beneficiary attending 4 core sessions and an interval performance payment of $50 upon a beneficiary attending 9 core sessions as displayed in Table 30. Although an MDPP supplier must offer at least 16 core sessions to a beneficiary during the initial 6 months of the MDPP core services period, we did not propose any other interval performance payment for the core sessions

after the performance payment for attendance at 9 core sessions. We noted that while these payment amounts would be somewhat lower than the payment amounts for these milestones presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416), they follow a similar pattern of a higher payment amount associated with attendance at a larger cumulative number of core sessions to provide a significant financial incentive for MDPP suppliers to encourage MDPP beneficiary attendance at core sessions in the first 6 months of the core services period.

On a per-session basis, the payments for attendance at 4 total core sessions and 9 total core sessions would be approximately $10 and $4 to $10, respectively, depending upon the number of sessions attended by the beneficiary beyond the 9 required for the second interval performance payment up to the maximum of 16 core sessions that must be offered to the beneficiary by the MDPP supplier during the initial 6 months of the MDPP core services period. Because the performance payments for core sessions would be based solely on the achievement of attendance performance goals, we believed that these per-session performance payment amounts that would be lower than the proposed performance payment amount for the first core session would still be appropriate because we expected that fewer MDPP supplier resources would be used to furnish sessions to beneficiaries with whom the MDPP supplier has an established relationship. The per-session payment amounts for core sessions were set based on attendance at these sessions, which is associated with ultimate achievement of the required minimum weight loss.

We proposed to make the first interval performance payment for core sessions when the beneficiary has attended 4 core sessions for the following reasons. First, beneficiary attendance at 4 core sessions was a significant attendance milestone in the evaluation of the DPP model test,

which provided evidence that meeting this milestone is tied to weight loss outcomes.[27] According to the second year independent evaluation of the DPP model test, those beneficiaries who attended at least 1 core session lost an average of 7.6 pounds while beneficiaries who attended at least 4 core sessions lost an average of 9 pounds. BMI was reduced from 32.9 to 31.5 among Medicare beneficiaries who attended at least 4 core sessions. Second, in examining CDC's DPRP participant trend data, we found that a higher percentage of participants drop out after 3 core sessions as compared to those who drop out after 4 core sessions, meaning that if a beneficiary completes the 4th core session, he or she is more likely to remain in the DPP for the 12-month program.[28] Therefore, we believed that making the first interval performance payment after beneficiary attendance at 4 core sessions would be appropriate.

We proposed to make the second interval performance payment when the beneficiary has attended 9 core sessions because attending a higher amount of sessions in the initial 6 months of the MDPP core services period, beginning at session 9, has been shown to greatly improve weight loss outcomes. Specifically, according to CDC data, there is a 125 percent increase in weight loss comparing beneficiaries who attend 4 to 8 sessions (1.6 percent weight loss on average) and beneficiaries who attend 9 to 16 sessions (3.6 percent weight loss on average).[29] Therefore, we believed that attendance at 9 sessions reflects clinically meaningful attendance at core sessions and would provide an incentive to MDPP suppliers to encourage beneficiaries to continue into the second 6 months of the MDPP core services period, which is when the 5 percent weight loss from baseline is usually achieved or exceeded. Additionally, 9 is the number

[27]Hinnant L, Razi S, Lewis R, Sun A, Alva M, Hoerger T, Jacobs S, Halpern M. Evaluation of the Health Care Innovation Awards: Community Resource Planning, Prevention, and Monitoring, Annual Report 2015. Awardee-Level Findings: YMCA of the USA; 2016. Table 17. Average/Frequencies Health Outcomes of all Participants through Q11, p. 36. RTI Project Number 0212790.010.001.004, Contract HHSM-500-2010-00021I. Sponsored by the Centers for Medicare & Medicaid Services.
[28]CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.
[29]CDC's Diabetes Prevention Recognition Program dataset as of February 28, 2017.

of core sessions, on average, that a participant must attend in CDC's National DPP in the first 6 months for a CDC-recognized organization to achieve full CDC recognition.

MDPP suppliers would be paid these performance payments when beneficiaries achieve these core session attendance performance goals, regardless of weight loss. Although we proposed to base performance payments during the MDPP services period substantially on weight loss, which is directly associated with a significant decrease in the incidence of type 2 diabetes, we recognized that weight loss is a gradual process and that MDPP suppliers would utilize resources to furnish MDPP services during the period of time when the beneficiary is losing weight. Therefore, we proposed that performance payments for beneficiary attendance at core sessions during the first 6 months of the core services period be based on attendance only.

The proposed maximum total performance payment to MDPP suppliers for furnishing MDPP core sessions would be $105 per beneficiary, as displayed in Table 30.

TABLE 30: Proposed Attendance-Based Performance Payments for MDPP Core Sessions

Performance Goal	Attendance-Based Performance Payment Per Beneficiary
1st core session attended (performance payment)	$25
4 total core sessions attended (interval performance payment)	$30
9 total core sessions attended (interval performance payment)	$50
Maximum total performance payment for core sessions	$105

We considered alternatives to this payment structure for core sessions, such as making higher payments for attendance at the earlier sessions to provide MDPP suppliers with additional funds for the resources necessary for start-up of the MDPP expanded model. We stated that although we understood that there are some up-front supplier costs associated with implementing the MDPP expanded model, we believed that these costs would disproportionately be related to start-up and not generally be ongoing costs borne by the MDPP supplier. In addition, because we expected that many MDPP suppliers are currently offering DPPs through contracts with commercial payers, MDPP suppliers may be able to minimize start-up costs by relying on their

relevant experience with offering other DPPs. Finally, we believed that our proposal for payment of MDPP core sessions already included substantial payment for session attendance early in a beneficiary's participation with the MDPP supplier, considering that MDPP suppliers would be paid an initial $25 performance payment for the first core session attended by the beneficiary and would then be paid performance payments for beneficiary attendance of up to 9 core sessions, regardless of weight loss. We noted that increasing the initial payments for attendance at MDPP sessions would shift the nature of the payment for the set of MDPP services from a performance-based structure based on a balance of attendance and weight loss considerations toward a payment structure that is based on attendance at each session furnished.

The proposed attendance-based performance payments for MDPP core sessions were included at proposed §414.84(b)(1), (2), and (3). We invited public comments on these proposals. We also invited public comments on the alternative considered.

The following is a summary of the public comments received on the proposals for attendance-based performance payments for MDPP core sessions and the alternative considered and our responses:

Comment: Many commenters urged CMS to increase the proposed $25 performance payment for the first core session. They explained that many potential MDPP suppliers are not medical providers in a way similar to most clinicians who commonly work within practices already set up for Medicare, where the practice is fully HIPAA compliant and staff have already been trained in fraud, waste and abuse, false claims, and other policies specific to governmental programs. The commenters claimed that there is a necessary and essential MDPP supplier cost to being Medicare "ready" that is not always similarly incurred in the commercial payer context, especially when in some circumstances the billing of commercial payers is conducted by invoice,

not claim, and those payment arrangements are therefore less costly to the DPP organization than submitting claims for Medicare payment. The commenters stated that each MDPP supplier will have additional set up costs, not only in areas of staffing and training, but in meeting basic requirements of the MDPP expanded model such as the acquisition of medical record systems and Medicare enrollment.

Several commenters requested that CMS review its proposed payment structure for core sessions and, in their view, better balance the amount of money an MDPP supplier would receive for the first session by moving portions of the proposed performance payments for attendance at the fourth session and ninth core session, as well as for core maintenance session intervals, earlier in a beneficiary's MDPP services period to increase payment for the first core session. Another commenter urged CMS to rebalance the attendance-based performance payments for the core sessions to provide 25 percent for the first core session to cover outreach and other start-up costs.

Response: We note that some of the costs identified by the commenters are one-time set up costs, such as the acquisition of medical record systems, that will not be incurred again once the organization is enrolled as an MDPP supplier and furnishing MDPP services on an ongoing basis. We do not believe that increasing the performance payment for the first core session for all MDPP beneficiaries would be appropriate to provide organizations with additional funds for these startup costs in a performance-based payment methodology.

As discussed in section III.K.2.d.ii. of this final rule, we will provide payment for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of

MDPP services. We understand that MDPP suppliers will experience some early set up costs and ongoing costs for activities such as outreach to get Medicare beneficiaries to obtain MDPP services from the supplier and that the MDPP supplier may need to bear these resource costs before receiving significant payment from Medicare for MDPP services. We appreciate that the timing of the performance payments and MDPP suppliers' use of resources for furnishing MDPP services are not fully aligned. Because the MDPP expanded model relies on a performance-based payment methodology that is heavily weighted toward the outcome of the required minimum weight loss that is associated with a reduced incidence of type 2 diabetes, MDPP suppliers will need to bear these resource costs until suppliers begin to receive significant performance payments from CMS. However, we expect that the total performance payment amounts received by MDPP suppliers for the set of MDPP services will provide funds to MDPP suppliers for carrying out these initial and ongoing activities, not just the payment for the first core session furnished to an MDPP beneficiary in the MDPP services period.

We note that the proposed performance payment for the first core session of $25 was the highest performance payment, on a per-session basis, of any of the other proposed core session performance payments. As discussed in the subsequent response to comments, we are finalizing higher performance payments for attendance at 4 and 9 core sessions than we proposed, but $25 is still higher than those final core session performance payments on a per-session basis. Therefore, we believe that the $25 performance payment for beneficiary attendance at the first core session already recognizes some of the startup costs and the more intense resources used by MDPP suppliers early in their participation as MDPP suppliers and in the beneficiary's MDPP services period, respectively.

In addition, given the performance goal of attendance at only one core session for the first core session performance payment, we believe that a performance payment higher than $25 for the first core session could incentivize MDPP suppliers to furnish the first core session to a large number of beneficiaries who are eligible for MDPP services but who may not have a full understanding of the DPP and its expectations or who are not ready to commit to the full DPP. Such an MDPP supplier practice could result in fewer beneficiaries benefiting from MDPP services by achieving the required minimum weight loss that reduces their risk of type 2 diabetes. Thus, we continue to believe that a performance payment of $25 for attendance at the first core session is the most appropriate payment amount for beneficiary achievement of this attendance performance goal.

Comment: Several commenters urged CMS to make significantly higher core session performance payments, noting that the most intense MDPP supplier administrative activities occur during the first 6 months of the core services period, specifically teaching the health behavior change, motivating individuals to lose 5 percent of their weight, and encouraging session attendance. The commenters emphasized that significant MDPP supplier activities are required to furnish the weekly core sessions that must be offered in the first 6 months of the MDPP services period, further noting that these activities lessen beginning in month 7 when sessions must be offered only a minimum of monthly. They claimed that most supplier costs, such as administrative costs, staffing, beneficiary engagement, marketing, materials, and recruitment are incurred up front in the initial 6 months of the MDPP services period and are experienced by the MDPP supplier regardless of beneficiaries' achievement of the required minimum weight loss in that 6-month time period. Under the proposal, the commenters

expressed concern that MDPP suppliers would be faced with covering the initial overhead expenses without the opportunity to receive sufficient, timely performance payments.

Therefore, the commenters recommended that CMS reallocate performance payments from the performance payments for 5 percent weight loss and core maintenance session intervals to the first 16 weeks of the MDPP services period when the majority of costs are incurred by the DPP organization. Some commenters specifically recommended the redistribution of $60 to payment for core sessions from the proposed $160 performance payment for achievement of the required minimum weight loss, which would result in a total performance payment for attendance at core sessions of $165, compared to the $105 that CMS proposed (the sum of the performance payments for attendance at the first, 4, and 9 core sessions).

Some commenters supported making core session performance payments after beneficiary attendance at the fourth and ninth core sessions as CMS proposed, based on the evidence cited by the commenters that if a beneficiary completes his or her fourth core session, he or she is more likely to remain in the DPP for the full 12-month core services period.

Response: We agree with the commenters that the 4 and 9 core session attendance performance goals represent milestones that reflect the increased likelihood that the MDPP beneficiary will complete the 12-month core services period and, therefore, achieve the required minimum weight loss.

We appreciate the detailed information presented by the commenters on the critical need to appropriately engage beneficiaries in the first 6 months of the MDPP services period in order to support beneficiaries in achieving the core session attendance performance goals, as well as the information on the number and intensity of MDPP supplier activities necessary during this period in order to meet these goals. After reviewing these descriptions, we believe that it is

appropriate to increase the final performance payment amounts from the proposed $30 and $50 for attendance at 4 and 9 core sessions, respectively. The increased core session attendance-based payment amounts reflect the importance of these core session attendance milestones to ultimate MDPP beneficiary achievement of the required minimum weight loss, given the association between greater session attendance and achievement of weight loss. In addition, we note that as a result of these performance payment increases during the first 6 months of the MDPP services period, greater payment for beneficiaries who achieve the performance goals will be available to MDPP suppliers in months 1 to 6 of the core services period that may result in more timely and substantial financial support during that time period for the high intensity of supplier activities needed to promote further beneficiary achievement of performance goals. We recognize that MDPP suppliers will be working diligently throughout this 6-month period to engage beneficiaries, encourage attendance, teach the weekly DPP curriculum, and support beneficiary behavior change through beneficiary engagement incentives and other activities.

Therefore, in view of our final policy that shortens the maximum ongoing services period from 24 to 12 months as discussed in section III.K.2.b.i. of this final rule, we will redistribute some of the funds that would have been available for ongoing maintenance session interval performance payments for months 25 to 36 of the MDPP services period to the 4 and 9 core session attendance-based performance payments.

Because we consider both these milestones to be of similar importance in recognizing beneficiary achievement of attendance performance goals that are associated with completion of the 12-month core services period and achievement of the required minimum weight loss, we are increasing both performance payments by 70 to 80 percent from the proposed amounts, resulting in final attendance-based performance payments for 4 and 9 core sessions of $50 and $90,

respectively. While the commenters did not specifically recommend these payment amounts for attendance at 4 and 9 core sessions, several commenters specifically urged us to increase the total payment for core sessions (attendance at the first, 4, and 9 core sessions) from the $105 that we proposed to $165, which would represent a substantial increase in the performance payments for core session attendance. As discussed in the previous response to comments, we are not increasing the performance payment for attendance at the first core session from the $25 payment amount that we proposed. However, we will increase the total attendance-based payment for core sessions from $105 to $165 as recommended by the commenters through proportionately similar increases in the performance payments for attendance at 4 and 9 core sessions.

We believe that increasing the final 4 and 9 session attendance-based performance payments by 70 to 80 percent from the proposed amounts represents a significant increase in the performance payments for attendance at 4 and 9 core sessions that is consistent with the requests of the commenters for increased total payment for attendance at core sessions. Moreover, the final performance payment amounts appropriately recognize the importance of meeting these core session attendance milestones that are linked to the achievement of the required minimum weight loss that leads to a reduction in incidence of type 2 diabetes and reduced Medicare expenditures.

After considering the public comments received, we are finalizing the proposals for the performance payments for core sessions at §414.84(b)(1), (2), and (3), with modifications. We are finalizing the performance payment for the first core session attended at $25 as we proposed. We are increasing the performance payment for 4 core sessions attended to $50 and the performance payment for 9 core sessions attended to $90. These final performance payment

amounts result in a total attendance-based performance payment amount for MDPP services furnished to an MDPP beneficiary in the first 6 months of the core services period of $165, an increase of approximately 60 percent over the proposed total performance payment amount of $105 for the 6-month period of core sessions. The final attendance-based performance payments for MDPP core sessions are displayed in Table 31.

TABLE 31: Final Attendance-Based Performance Payments for MDPP Core Sessions

Performance Goal	Attendance-Based Performance Payment Per Beneficiary
1st core session attended (performance payment)	$25
4 total core sessions attended (interval performance payment)	$50
9 total core sessions attended (interval performance payment)	$90
Maximum total performance payment for core sessions	$165

(4) Performance Payments for Core Maintenance Session Intervals

We proposed that performance payments for core maintenance sessions would be tied to the beneficiary's achievement of attendance and weight loss performance goals during a core maintenance session interval. A core maintenance session interval, as we proposed to define it at §410.79(b), would mean one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers at least 1 core maintenance session per month to an MDPP beneficiary.

The payment structure presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 core maintenance sessions and achieve or maintain a minimum 5 percent weight loss for a $45 payment to be made to an MDPP supplier for the core maintenance session interval. If 5 percent weight loss was not achieved or maintained during the core maintenance session interval, no separate performance payment would be made. MDPP suppliers would still have been required to offer (and furnish if the beneficiary attended) MDPP services during core maintenance intervals to beneficiaries

regardless of weight loss. Based on our consideration of information provided in the public comments on the CY 2017 PFS proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of the required minimum weight loss as the outcome of MDPP services, our proposal for the performance payments for core maintenance sessions differed from the payment amounts included in the CY 2017 PFS proposed rule (81 FR 46415 through 46416).

For the MDPP expanded model, we proposed performance payments amounts for core maintenance session intervals that would value achievement of both session attendance and the required minimum weight loss, with an emphasis on achieving the weight loss performance goal. We proposed that an MDPP supplier would be paid a performance payment for a core maintenance session interval if a beneficiary achieves the performance goal of attending at least 3 core maintenance sessions during the interval. The specific performance payment amount would be determined by whether the beneficiary has also achieved or maintained the required minimum weight loss within the interval. The achievement or maintenance of the required minimum weight loss within the 3-month core maintenance session interval would be determined based on a measurement taken in-person during any 1 session within that 3-month interval. We proposed that MDPP suppliers would be paid a performance payment for no more than 2 core maintenance session intervals for each MDPP beneficiary.

As discussed previously, we recognized that weight loss is a process that may still be ongoing for some beneficiaries during the final months of the core services period. According to an analysis of participant data from CDC's DPRP, the longer a participant remains in the lifestyle change program, the greater his or her average weight loss achieved.[30] Findings indicate

[30]CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

that it takes an average of 17 DPP sessions attended to exceed the required minimum weight loss, and the 9 percent or greater weight loss goal is more likely to be achieved upon attending 19 sessions on average. This average number of sessions exceeds the 16 core sessions that must be offered to the MDPP beneficiary during the first 6 months of the MDPP services period and emphasizes the importance of core maintenance sessions to achievement of meaningful weight loss goals.

Of further note, the National DPP's core maintenance sessions were developed based on results from the original 2002 DPP Randomized Control Trial and CDC's DPRP Standards were developed with this science in mind.[31] Core maintenance sessions are integral for the expected reduction in the incidence of type 2 diabetes to be experienced by MDPP beneficiaries. These findings were recently confirmed in a literature review on combined diet and physical activity programs to prevent type 2 diabetes conducted by the Community Preventive Services Task Force that reiterated the year-long intensity and duration of the National DPP.[32]

Therefore, we believed that providing no performance payment to MDPP suppliers for furnishing core maintenance sessions to beneficiaries who have not achieved the required minimum weight loss prior to or during months 7 to 12 of the core services period could reduce the opportunity for MDPP beneficiaries to achieve the weight loss performance goal. Such a payment methodology could reduce the likelihood that MDPP suppliers would continue to work to engage beneficiaries in the weight loss process if those beneficiaries had not achieved the required minimum weight loss after completion of the initial 6 months of the MDPP core services period. We noted that, as finalized in the CY 2017 PFS final rule (81 FR 80459),

[31] Available at https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf.
[32] Available at http://www.thecommunityguide.org/diabetes/combineddietandpa.html.

suppliers must offer a minimum of 1 core maintenance session per month in months 7 to 12 of the core services period to eligible beneficiaries, regardless of the beneficiary's weight loss. We further believed that it would be possible for some beneficiaries to have achieved the required minimum weight loss performance goal by the time the core sessions have been completed, and we wanted to incentivize MDPP suppliers to work toward the weight loss performance goal in that timeframe. However, we believed that it would also be appropriate to place some value on achieving attendance performance goals alone through performance payments for core maintenance session intervals so that MDPP suppliers continue to work to engage all beneficiaries in striving to achieve the required minimum weight loss performance goal.

As discussed in section III.K.2.d.iii.(2)(a) of the proposed rule (82 FR 34139 through 34141), we proposed that the maximum total performance payment for MDPP core maintenance sessions would be $120 for beneficiaries who achieve both the attendance and weight loss performance goals during months 7 to 12 of the core services period. Specifically, we proposed to pay MDPP suppliers $60 for a core maintenance session interval if a beneficiary attends 3 sessions and achieves or maintains the required minimum weight loss during that interval, and to pay MDPP suppliers $10 for a core maintenance session interval if the beneficiary attends 3 sessions but does not achieve or maintain the required minimum weight loss during that core maintenance session interval.

As compared to the payment amounts with and without achievement or maintenance of the required minimum weight loss that were presented for core maintenance session intervals in the CY 2017 PFS proposed rule (81 FR 46415 through 46416), these proposed payment amounts are both higher. As discussed previously, we believed that it would be appropriate in months 7 to 12 of the core services period to provide some performance payment for achievement of

attendance performance goals even if the required minimum weight loss is not achieved, in order to provide the greatest opportunity for beneficiaries to achieve the required minimum weight loss over the full core services period. In addition, we proposed a higher payment amount for core maintenance session intervals with achievement or maintenance of the required minimum weight loss to recognize that achievement and maintenance of the required minimum weight loss are necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in achieving weight loss and sustaining their weight loss over time.

Proposed performance payments for the core maintenance session intervals are displayed in Table 32. On a per-session basis, these payments would be approximately $20 and $3, respectively. Although both of these payment amounts would provide payment to MDPP suppliers for the resources involved with furnishing core maintenance sessions, we believed that the relatively high per-session performance payment of $20 in comparison to the per-session performance payment amounts for core sessions would be appropriate due to the achievement or maintenance of both the required minimum weight loss and beneficiary attendance at core maintenance sessions, as compared to core sessions where the performance payment would be based solely on attendance. On the other hand, we believed that the relatively low per-session payment amount in our core maintenance session interval performance payment proposal for core maintenance sessions for those beneficiaries who do not achieve the weight loss performance goal, while providing some performance payment for attendance at core maintenance sessions by beneficiaries still working to achieve the required minimum weight loss, would be appropriate because these sessions have not yet resulted in those beneficiaries achieving the weight loss performance goal.

TABLE 32: Proposed Performance Payments for Core Maintenance Session Intervals

Performance Goal	Performance Payment Per Beneficiary (*with* achievement or maintenance of required minimum weight loss)	Performance Payment Per Beneficiary (*without* achievement or maintenance of required minimum weight loss)
3 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)	$60	$10
3 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)	$60	$10
Maximum total performance payment for core maintenance session intervals (two consecutive 3-month intervals over months 7-12 of the MDPP core services period)	$120	$20

The proposed core maintenance session interval performance payments for core maintenance sessions were included at proposed §414.84(b)(4). We invited public comments on these proposals.

The following is a summary of the public comments received on the proposals for core maintenance session interval performance payments for core maintenance sessions and our responses:

Comment: Many commenters disagreed with the proposal that an MDPP beneficiary must attend 3 core maintenance sessions in each 3-month core maintenance session interval for an MDPP supplier to be paid the core maintenance session interval performance payment for that interval. The commenters observed that because MDPP suppliers must offer, at a minimum, monthly sessions to MDPP beneficiaries during months 7 to 12 of the core services period, the payment proposal would require a beneficiary to achieve 100 percent attendance every 3 months in order for the MDPP supplier to be paid the performance payment. The commenters stated that this is a very high attendance goal that is unlikely to be met, which would result in MDPP

suppliers not being paid for MDPP services they are required to offer and some of which the beneficiary attended. One commenter further reasoned that this attendance performance is unnecessary because it was not required in the DPP model test which still realized cost savings for Medicare.

The commenters speculated that in order to promote 100 percent attendance of 3 sessions in a 3-month core maintenance session interval, MDPP suppliers might have to offer more sessions in that interval to accommodate the schedules of the MDPP beneficiaries. They added that offering additional sessions would lead to greater MDPP supplier cost that would not be covered by the proposed performance payments for core maintenance session intervals. Therefore, the commenters urged CMS to change the attendance requirement for core maintenance session intervals from 3 to 2 sessions in order for performance payments to be made, in order to address scenarios where beneficiaries were unable to attend one monthly session in a 3-month period of time during months 7 through 12 of the core services period.

Several commenters recommended that CMS increase the performance payments for core maintenance session intervals, especially for beneficiaries who have not achieved or maintained the required minimum weight loss. The commenters opposed the use of combined weight loss and attendance performance goals to determine the performance payment amount for the interval during months 7 through 12 of the core services period. Most commenters addressing this issue recommended that CMS make the same performance payment, suggesting values that ranged from the proposed $60 to higher amounts such as $72.50, for core maintenance session intervals for beneficiaries who achieved or maintained the requirement minimum weight loss and those who did not meet the weight loss performance goal because MDPP suppliers are required to offer these sessions to all MDPP beneficiaries.

The commenters stated that providing the same payment for core maintenance session intervals, regardless of the achievement of the weight loss performance goal, would better align beneficiary eligibility with payment for core maintenance sessions. Under such an approach, similar to the first 6 months of the core services period, performance payments in months 7 through 12 would be attendance-based in order not to penalize MDPP suppliers financially for the MDPP beneficiary's weight loss performance because weight loss could reasonably occur over the first 12 months of the MDPP core services period, not just the first 6 months. The commenters described significant administrative costs for necessary MDPP supplier activities during months 7 through 12, including the required tracking of Medicare beneficiaries, in-person weigh-ins, and outreach to enrollees to ensure attendance is high. The commenters stated that these administrative activities could actually increase the MDPP supplier's per-session costs in comparison with months 1 through 6 of the core services period where core sessions must be offered weekly to MDPP beneficiaries.

Response: We appreciate the recommendations of the commenters regarding the performance goals for core maintenance session interval performance payments, as well as the performance payment amounts for beneficiaries who have achieved or maintained the required minimum weight loss and those who have not achieved the weight loss performance goal. In terms of promoting alignment between beneficiary eligibility and payment during months 7 to 12 of the core services period, because we are using a performance-based payment methodology for payment of MDPP services and MDPP services are covered for all beneficiaries in months 7 to 12 of their MDPP services period, it is not possible to fully align eligibility and payment. This contrasts with ongoing maintenance session interval performance payments discussed in section III.K.2.d.iii.(5) of this final rule where the performance payment for a given interval and

beneficiary coverage of the subsequent ongoing maintenance session interval are aligned because both depend upon beneficiary maintenance of the required minimum weight loss and attendance at 2 sessions in the ongoing maintenance session interval.

We continue to believe that it is important after making attendance-based performance payments for months 1 to 6 of the MDPP services period to begin to base performance payments in part on the achievement of weight loss beginning in month 7 of the core services period, a time by which we expect some beneficiaries to have achieved the required minimum weight loss outcome goal for MDPP services. Our expectation is supported by findings from the CDC's DPRP that it takes an average of 17 DPP sessions attended to exceed the required minimum weight loss.[33] Given that MDPP suppliers must offer a minimum of 16 sessions during the first 6 months of the MDPP services period, we believe it is reasonable to expect that a number of MDPP beneficiaries will have achieved the required minimum weight loss by month 7 of the core services period. On the other hand, we recognize that weight loss is a process that may still be ongoing for some beneficiaries during the final months of the core services period. Therefore, we believe it is appropriate to maintain performance goals for performance payment for core maintenance session intervals that rely both on attendance and the achievement or maintenance of the required minimum weight loss to encourage high engagement of MDPP suppliers with the MDPP beneficiaries to whom they are offering sessions toward the goal of achieving or maintaining the required minimum weight loss.

Thus, we do not believe it would be appropriate to make a performance payment of $60 for session attendance alone in months 7 to 12 of the core services period at the same payment amount that we are finalizing for beneficiaries who meet both the attendance and weight loss

[33] CDC's Diabetes Prevention Recognition Program dataset as of March 1, 2017.

performance goals. However, we appreciate the interest of the commenters in a substantial increase from the $10 that we proposed as the core maintenance session interval performance payment for beneficiaries who are attending sessions that must be offered by the MDPP supplier and still working to achieve the required minimum weight loss. Given the considerable expected engagement of MDPP suppliers with MDPP beneficiaries who are still working to achieve the required minimum weight loss at the end of the first 6 months of the core services period, we agree with the commenters that it would be appropriate to provide a higher core maintenance session interval performance payment for beneficiaries who meet the attendance performance goal for these intervals but have not yet achieved the required minimum weight loss. However, we also intend for our performance-based payment amounts for months 7 to 12 of the core services period to financially incentivize high engagement of MDPP suppliers with the MDPP beneficiaries to whom they are offering sessions toward the goal of achieving or maintaining the required minimum weight loss.

Therefore, we believe that a performance payment of $15 for core maintenance session interval performance payments for those beneficiaries who do not achieve or maintain the required minimum weight loss during the interval but meet the interval attendance performance goal appropriately balances these objectives. We note that this payment amount reflects a significant increase of 50 percent over our proposed payment amount, yet the sizeable difference between the $60 and $15 performance payments that continues to exist for core maintenance session interval performance payments for beneficiaries who do or do not achieve or maintain the required minimum weight loss, respectively, will strongly incentivize MDPP suppliers to engage with MDPP beneficiaries to work toward achieving or maintaining the required minimum weight loss throughout the 3-month core maintenance session intervals.

Because MDPP suppliers must offer, at a minimum, monthly core maintenance sessions to all MDPP beneficiaries during months 7 to 12, regardless of the beneficiary's attendance or achievement of weight loss, we agree with the commenters that it is appropriate to reduce the attendance requirement for the performance payments during this time period from 3 to 2 sessions per interval. Lowering the required session attendance for the performance payments during this time will provide additional flexibility to beneficiaries to allow them to balance life events and MDPP session attendance, without beneficiary decisions resulting in financial consequences for MDPP suppliers that must offer sessions regardless of actual attendance. We believe that attendance of 2 sessions in a core maintenance session interval still represents substantial beneficiary engagement and, because we also provide payment that differs in relation to achievement of the weight loss performance goal during core maintenance session intervals, this flexibility does not discourage MDPP beneficiaries and MDPP suppliers from a high level of engagement during months 7 to 12 of the core services period.

Comment: Several commenters urged CMS to fully align eligibility and performance payment for core maintenance session intervals, similar to the proposal for eligibility and payment for ongoing maintenance session intervals. For example, if an MDPP beneficiary did not meet the attendance performance goal for the first core maintenance session interval performance payment, the commenters recommended that the beneficiary not be covered for the second core maintenance session interval. Under such an approach, the MDPP supplier would not be required to continue to use its resources to offer additional core maintenance sessions to the beneficiary whose attendance was too low to result in a performance payment being made to the MDPP supplier.

Response: As the commenters observed, eligibility and payment are aligned for ongoing maintenance session intervals where a beneficiary must meet the performance goals for the performance payment for an interval, namely attendance at 2 sessions and maintenance of the required minimum weight loss, to be eligible for the subsequent ongoing maintenance session interval as discussed in section III.K.2.c.iv.(1)(b) of this final rule. However, with respect to core maintenance sessions intervals, in the CY 2017 PFS final rule (81 FR 80465), we finalized the MDPP core benefit for all MDPP beneficiaries as 12 consecutive months consisting of at least 16 weekly core sessions over months 1 to 6 and at least 6 monthly core maintenance sessions over months 6 to 12 that must be offered to each MDPP beneficiary regardless of attendance or weight loss.

We made no proposals to change the coverage policy under circumstances where an MDPP beneficiary's attendance at sessions that must be offered by the MDPP supplier is too low to result in a performance payment to that supplier. We further note that 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. Our final policy at §424.205(b)(1) specifies that to enroll in Medicare as an MDPP supplier, an entity must have and maintain MDPP preliminary recognition or full CDC DPRP recognition. Therefore, we are not requiring the achievement of attendance or weight loss performance goals during the first core maintenance session interval for the MDPP beneficiary to have coverage of the second core maintenance session interval, which is consistent with the CDC DPRP Standards for core maintenance session access. Because the achievement of performance goals is required for performance payments for core maintenance session intervals, eligibility and payment are not aligned during months 7 through 12 of the MDPP services period.

After considering the public comments received, we are finalizing the proposals for core maintenance session interval performance payments for core maintenance sessions at §414.84(b)(4), with modifications. We will pay MDPP suppliers $60 for a core maintenance session 3-month interval if a beneficiary attends at least 2 sessions during the interval and achieves or maintains the required minimum weight loss during that interval, and pay MDPP suppliers $15 for a core maintenance session interval if the beneficiary attends at least 2 sessions but does not achieve or maintain the required minimum weight loss during that core maintenance session interval. The final performance payments for core maintenance session intervals are displayed in Table 33.

TABLE 33: Final Performance Payments for Core Maintenance Session Intervals

Performance Goal	Performance Payment Per Beneficiary (*with* achievement or maintenance of required minimum weight loss)	Performance Payment Per Beneficiary (*without* achievement or maintenance of required minimum weight loss)
2 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)	$60	$15
2 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)	$60	$15
Maximum total performance payment for core maintenance session intervals (two consecutive 3-month intervals over months 7-12 of the MDPP core services period)	$120	$30

(5) Performance Payments for Ongoing Maintenance Session Intervals

Similar to our proposal for the payment of core maintenance session intervals described previously, we proposed to make performance payments to MDPP suppliers for 3-month ongoing maintenance session intervals. This payment would be made when suppliers furnish ongoing maintenance sessions during the 24 months of the ongoing services period after the 12-month MDPP core services period ends. We proposed that an MDPP supplier would be paid

a performance payment for an ongoing maintenance session interval if an MDPP beneficiary achieves the performance goals of attending at least 3 ongoing maintenance sessions and maintaining the required minimum weight loss from baseline measured in-person during a session at least once within that interval. Under this proposal, an MDPP supplier would not be paid a performance payment unless the beneficiary has achieved both of these performance goals within that 3-month interval. An ongoing maintenance session interval, as we proposed to define it at §410.79(b), would mean one of the up to eight consecutive 3-month time periods during the ongoing services period, during which an MDPP supplier offers at least 1 ongoing maintenance session to an MDPP beneficiary per month.

The payment structure presented in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) would have required the MDPP beneficiary to attend 3 ongoing maintenance sessions and maintain the required minimum weight loss for a $45 payment to be made to an MDPP supplier for the ongoing maintenance session interval. Based on our consideration of information provided in the public comments on the CY 2017 PFS proposed rule and our increased emphasis in the performance payments on the achievement and maintenance of weight loss as the outcome of MDPP services, our proposal for the performance payment for ongoing maintenance session intervals differed from that payment amount.

We proposed that MDPP suppliers could be paid up to 8 performance payments of $50 each for ongoing maintenance session intervals. Just like the other proposals for performance payments, we proposed this payment in CY 2018 dollars to ensure consistency in calendar year dollars among performance payments for a given calendar year. However, we noted that no ongoing maintenance session interval payments, available only for intervals in the ongoing services period during months 13 through 36 of an MDPP beneficiary's MDPP services period,

would be made in CY 2018 based on our proposal discussed in section III.K.2.a. of the proposed rule (82 FR 34141) that MDPP services be available on April 1, 2018. Under this proposal, MDPP services would only be available for 9 months of CY 2018 so no MDPP beneficiaries would attend ongoing maintenance sessions in CY 2018. The first ongoing maintenance session interval performance payments would be made in CY 2019 and would equal $50 adjusted by the percent change in the Consumer Price Index for All Urban Consumers (CPI-U) (U.S. city average) for the 12-month period ending June 30th, 2018, as discussed in section III.K.2.d.iii.(9) of the proposed rule (82 FR 34147 through 34148).

This proposed payment amount would be somewhat higher than the potential payment discussed in the CY 2017 PFS proposed rule (81 FR 46415 through 46416) to recognize that maintenance of the required minimum weight loss is necessary for the reduced incidence of type 2 diabetes and to encourage MDPP suppliers to work to engage beneficiaries in sustaining their weight loss over time. The maximum total performance payment for MDPP ongoing maintenance sessions would be $400, as displayed in Table 34. On a per-session basis, this payment would be approximately $17, which we believed would be appropriate for MDPP suppliers that furnish ongoing maintenance sessions to beneficiaries who maintain the required minimum weight loss during ongoing maintenance session interval. We noted that this per-session payment amount would be somewhat lower than the $20 per-session payment amount included in the core maintenance session interval performance payment for beneficiaries who achieve attendance and weight loss performance goals during the 3-month intervals in months 7 to 12 of the MDPP core services period. Like the proposed performance payment for core maintenance session intervals, the proposed performance payment for ongoing maintenance session intervals would value both attendance and weight loss. However, we believed it is likely

that the required minimum weight loss would be first achieved during core maintenance session intervals, and we also believed that a somewhat higher per-session payment amount would be appropriate under these circumstances. In contrast, we believed that a somewhat lower per-session payment amount for ongoing maintenance sessions during intervals where the required minimum weight loss is maintained, rather than achieved, would be appropriate.

We considered an alternative policy in which an MDPP supplier would receive a payment for an ongoing maintenance session interval so long as the beneficiary attended at least 1 ongoing maintenance session during the interval and maintained the required minimum loss. In this scenario, we considered that the MDPP supplier would still be required to offer at least 2 additional ongoing maintenance sessions (at least one per month) to the beneficiary over the 3-month interval. However, we believed that the goal of ongoing maintenance sessions is to promote both sustained beneficiary engagement and weight loss and, therefore, we believed that ongoing maintenance session interval performance payments should be tied to achieving both attendance and weight loss performance goals.

The proposed payment policy also would align with the coverage limitations for ongoing maintenance sessions at §410.79(c)(1)(iii) in that beneficiaries also would be required to attend all 3 sessions within a given ongoing maintenance session 3-month interval to be covered for the subsequent 3-month interval. We noted that the proposed coverage and payment policies would be aligned for ongoing maintenance session intervals, where attendance at 3 sessions within an interval would be required for a performance payment as well as for coverage of ongoing maintenance sessions in the next interval. In contrast, MDPP suppliers would be required to offer core maintenance sessions in both core maintenance session intervals for all beneficiaries,

regardless of a beneficiary's attendance at core maintenance sessions, although attendance would be required for a performance payment to be made for the core maintenance session interval.

TABLE 34: Proposed Performance Payments for Ongoing Maintenance Session Intervals

Performance Goal	Performance Payment Per Beneficiary (*with* maintenance of the required minimum weight loss)	Performance Payment Per Beneficiary (*without* maintenance of the required minimum weight loss)
3 sessions attended in 1 ongoing maintenance session interval	$50	$0
Maximum total performance payment for ongoing maintenance session intervals (8 consecutive 3-month intervals over months 13-36 of the MDPP ongoing services period)	$400	*$0 to $350

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 7 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

The proposed ongoing maintenance session interval performance payments for ongoing maintenance sessions were included at proposed §414.84(b)(5). We invited public comments on these proposals. We also invited public comments on the alternative considered.

The following is a summary of the public comments received on the proposals for ongoing maintenance session interval performance payments for ongoing maintenance sessions and the alternative considered and our responses:

Comment: Some commenters supported the proposed $50 ongoing maintenance session interval performance payment, which they believe is appropriate given the MDPP supplier resources that would be used to furnish sessions during those intervals. One commenter, who also advocated for an increase in the performance payments for core sessions in order to increase the maximum total performance payment amount available in the first 12 months of the MDPP services period to meet the MDPP supplier financial need for sustaining its DPP, further urged CMS to reduce the ongoing maintenance session interval performance payment from $50 to $45.

Several commenters expressed concern that if an MDPP beneficiary in an ongoing maintenance session 3-month interval does not achieve the 3 session attendance goal and/or does

not maintain the required minimum weight loss, the MDPP supplier would not receive the performance payment for that interval. The commenters stated that MDPP suppliers would expend resources to furnish MDPP services to the MDPP beneficiary during the 3-month interval but bear the financial risk under the proposal of not getting paid if the beneficiary fails to attend at least 3 sessions and maintain the required minimum weight loss. They further noted that to achieve beneficiary attendance of 3 sessions during the 3-month interval, MDPP suppliers would likely have to offer more than 3 ongoing maintenance sessions to MDPP beneficiaries during that time period. The commenters urged CMS to change the attendance requirement for performance payment for ongoing maintenance session intervals to 2 of the 3 sessions that must be offered, in order to help more beneficiaries stay in the DPP and reduce the financial risk to the MDPP supplier. Particularly over the 24-month long ongoing services period that CMS proposed, the commenters stated that monthly beneficiary attendance could be hard to sustain and in actuality not be important, especially if the MDPP beneficiary maintains the required minimum weight loss throughout that time period.

Response: As discussed in section III.K.2.b.i. of this final rule, we are finalizing the ongoing services period as 12 months, rather than the 24-month duration that we proposed. In addition, as discussed in section III.K.2.c.iv., we are finalizing the policy that the eligibility for coverage of a subsequent ongoing maintenance session 3-month interval during months 16 to 24 of the MDPP services period depends both on beneficiary attendance at 2 ongoing maintenance sessions in the prior ongoing maintenance session interval and maintenance of the required minimum weight loss.

In the proposed rule (82 FR 34145), we considered an alternative policy in which an MDPP supplier would receive a performance payment for an ongoing maintenance session

interval so long as the beneficiary attended at least 1 ongoing maintenance session during the interval and maintained the required minimum weight loss, which is similar to the requests of some of the commenters that the performance payment require attendance at 2 ongoing maintenance sessions, rather than 3. However, we note that we continue to believe that the goal of ongoing maintenance sessions is to promote both sustained beneficiary engagement and weight loss and, therefore, we believe that ongoing maintenance session interval performance payments should be tied to achieving both weight loss and significant attendance performance goals. However, because MDPP suppliers must offer, at a minimum, monthly ongoing maintenance sessions to all MDPP beneficiaries with coverage of each 3-month ongoing maintenance session interval during months 13 to 24 of the MDPP services period, regardless of the beneficiary's attendance or maintenance of weight loss, we believe it is appropriate to reduce the attendance requirement for the performance payments during this time period from 3 to 2 sessions per interval.

Our reasoning for this decision is similar to our rationale for finalizing a core maintenance session interval attendance performance goal of 2 sessions for the core maintenance session interval performance payments as discussed in section III.K.2.d.iii.(4) of this final rule. Lowering the required session attendance for the performance payments during the ongoing services period will provide additional flexibility to beneficiaries to allow them to balance life events and DPP session attendance, without the decisions of beneficiaries who maintain the required minimum weight loss resulting in financial consequences for MDPP suppliers that must offer sessions regardless of actual attendance. We believe that attendance of 2 sessions in an ongoing maintenance session 3-month interval still represents substantial beneficiary

engagement that promotes the integration of behavior change longer-term into a beneficiary's lifestyle in order for him or her to maintain the required minimum weight loss.

We also believe that the final shorter ongoing services period makes beneficiary attendance at 2 sessions in each 3-month interval feasible. We acknowledge that the MDPP supplier bears some risk that an MDPP beneficiary who must be offered a minimum of 3 sessions during an ongoing maintenance session interval will not attend 2 sessions and/or will not maintain the required minimum weight loss during that interval so the MDPP supplier would not receive an ongoing maintenance session interval performance payment for that interval for that beneficiary. However, we pay for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers during the MDPP services period, and the aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services.

Moreover, we continue to believe that maintaining the required minimum weight loss is an appropriate performance goal that must be met for an ongoing services interval performance payment to be made, given that the first ongoing maintenance session interval begins 12 months after the beginning of the MDPP services period. At that point at least half way through the maximum length of the beneficiary's MDPP services period, providing a performance payment for attendance alone would not be consistent with our emphasis in the MDPP expanded model on the achievement of the outcome of weight loss.

We note that the final attendance and weight loss performance goals for ongoing maintenance session interval performance payments are aligned with beneficiary eligibility for the subsequent ongoing maintenance session interval, a consistency that will incentivize MDPP suppliers to sustain their efforts regarding beneficiary engagement and minimize MDPP supplier

and beneficiary confusion about MDPP services during the ongoing services period. Due to this alignment, the MDPP supplier financial risk during the ongoing services period is limited to a maximum of 3 sessions in a single ongoing maintenance service interval, because eligibility and performance payment are aligned during this period. If a beneficiary does not meet the attendance and weight loss performance goals for an interval performance payment, the beneficiary is not eligible for coverage of ongoing maintenance sessions in the next interval, so the MDPP supplier is not required to offer additional sessions to the beneficiary.

We appreciate the support of the commenters for the proposed ongoing maintenance session interval performance payment amount of $50. Given our emphasis in the MDPP expanded model on the achievement of the required minimum weight loss that results in a reduced incidence of type 2 diabetes, we believe it is appropriate to adopt this payment amount under the performance-based payment methodology because the performance payment is only made if the beneficiary maintains the required minimum weight loss. Reducing the payment amount would lessen our emphasis on maintaining weight loss, which would be contrary to our interest in improving the health of beneficiaries through MDPP services that ultimately lead to lower Medicare expenditures.

After considering the public comments received, we are finalizing the proposals for ongoing maintenance session interval performance payments for ongoing maintenance sessions at §414.84(b)(5), with modifications. We will pay MDPP suppliers $50 for an ongoing maintenance session 3-month interval if a beneficiary attends at least 2 sessions during the interval and maintains the required minimum weight loss during that interval. The final performance payments for ongoing maintenance session intervals are displayed in Table 35.

TABLE 35: Final Performance Payments for Ongoing Maintenance Session Intervals

Performance Goal	Performance Payment Per Beneficiary (*with* maintenance of the required minimum weight loss)	Performance Payment Per Beneficiary (*without* maintenance of the required minimum weight loss)
2 sessions attended in 1 ongoing maintenance session interval and required minimum weight loss maintained	$50	$0
Maximum total performance payment for ongoing maintenance session intervals (4 consecutive 3-month intervals over months 13-24 of the MDPP ongoing services period)	$200	*$0 to $150

* = The specific payment amount depends on whether the beneficiary has coverage of 1 to 4 ongoing maintenance session intervals, as well as whether the beneficiary meets the performance goals for the performance payment for that ongoing maintenance session interval.

(6) Weight Loss Performance Payments

We proposed that if a beneficiary achieves the required minimum weight loss measured at any session attended during the core services period, an MDPP supplier would be paid the weight loss performance payment of $160 displayed in Table 36. As discussed in section III.K.2.d.iii.(2)(a) of the proposed rule (82 FR 34139 through 34141), we proposed that 23 percent of the maximum total performance payment amount for the set of MDPP services would be paid for the achievement of weight loss, regardless of session attendance, because weight loss is the most important outcome for the MDPP expanded model. The proposed performance payment of $160 for the required minimum weight loss, which constitutes approximately 90 percent of the maximum total weight loss performance payment, was proposed to be the large majority of the available weight loss performance payment based on the strong evidence for the association of the required minimum weight loss with a reduction in the incidence of type 2 diabetes.

We noted that this association is evidenced by the CDC's National DPP, which is based on the 2002 DPP Randomized Control Trial and follow-up efficacy trials.[34] All of the trials found that the greater the intensity and duration of the diabetes prevention program—with 1 year being the most effective program "dose"—the greater the reduction in the incidence of type 2 diabetes. Specially, persons at high-risk for type 2 diabetes who participated in a year-long lifestyle change program, focused on modest weight loss (5-7 percent), experienced a 58 percent lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention. The DPP Randomized Control Trial, as well as the DPP model test, involved the provision of 16 weekly core sessions and 6 monthly core maintenance sessions (all approximately 1 hour in length), similar to the set of core services in the MDPP expanded model. We recognized that not all beneficiaries would be able to achieve the required minimum weight loss within the first 6 months, which is the period when core sessions are furnished. Therefore, we believed that our proposed policy for payment of the performance payment upon achievement of the required minimum weight loss any time during the 12 months of the MDPP core services period would allow MDPP suppliers the greatest flexibility to work throughout the full MDPP core services period with beneficiaries who face difficulty in achieving this weight loss performance goal.

We also proposed that, in addition to the weight loss performance payment for the required minimum weight loss, an MDPP supplier would be paid an additional weight loss performance payment of $25 if the beneficiary achieves at least 9 percent weight loss from his or her baseline weight at any time during the MDPP services period as displayed in Table 36. We proposed this additional weight loss performance payment based on information from stakeholders that commercial payers paying for DPPs frequently include an incentive payment

[34] Available at https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf.

for 9 percent weight loss as an incentive to try to encourage greater and/or continued weight loss and behavior change. We believed that making an additional weight loss performance payment for 9 percent weight loss at any time during the MDPP services period would provide an additional incentive for MDPP suppliers to continue weight loss efforts with beneficiaries, especially during the ongoing services period, which may extend for a period of up to 24 months.

We proposed that MDPP suppliers may submit claims for these weight loss performance payments on the date when the beneficiary first reaches the required minimum or 9 percent weight loss, as measured in-person during a session, respectively, and each weight loss performance payment would be paid to only one supplier and only once per beneficiary. In the unusual circumstance where the beneficiary achieved 9 percent weight loss as the first weight loss change measured from baseline, the MDPP supplier could bill and be paid both the 5 percent and 9 percent weight loss performance payments.

TABLE 36: Proposed Weight Loss Performance Payments

Performance Goal	Performance Payment Per Beneficiary
5 percent weight loss (required minimum weight loss)	$160
9 percent weight loss	$25
Maximum total performance payment for weight loss	$185

The proposed weight loss performance payments were included at proposed §414.84(b)(6) and (7). We invited public comments on these proposals.

The following is a summary of the public comments received on the proposals for weight loss performance payments and our responses:

Comment: While generally supportive of weight loss performance payments for the achievement of weight loss during the MDPP services period, several commenters recommended that CMS make performance payments for a lower percentage of weight loss than the 5 percent weight loss that CMS proposed, either as additional incremental weight loss performance

payments or in place of the proposed performance payment for 5 percent weight loss. Those commenters advocating for additional incremental weight loss performance payments for lower percentages of weight loss believe this approach would allow MDPP suppliers to be paid for continued DPP support when a beneficiary achieves 3 percent and 4 percent weight loss. Under such a methodology, the commenters claimed that MDPP suppliers and MDPP beneficiaries would be able to work toward a more achievable early weight loss performance goal that would also sustain the MDPP suppliers' operations. The MDPP supplier would receive a performance payment when the early weight loss performance goal is achieved, thereby enabling the MDPP supplier to help beneficiaries reach even greater weight loss from baseline. A few commenters further urged CMS to make an additional performance payment for any MDPP beneficiary who achieves the required minimum weight loss and then maintains that level of weight loss at the end of the core services period.

Several commenters recommended that CMS gradually phase-in the percentage of weight loss required for the first weight loss performance payment during implementation of the MDPP expanded model, to allow MDPP suppliers to follow a learning curve in starting up their DPP. One scenario described by the commenters would provide a performance payment for 3 percent weight loss in the DPP organization's first year in the MDPP expanded model, 4 percent in the second year, and 5 percent in the third year and thereafter.

A few commenters requested that CMS eliminate the weight loss performance payment entirely to help avoid putting MDPP suppliers serving low-resources communities at immediate risk. Alternatively, the commenters suggested that CMS could guarantee the amount of weight loss performance payment for MDPP suppliers below a certain volume of beneficiaries, while making the payment for weight loss based on actual performance for MDPP suppliers of a larger

size or to MDPP suppliers in a pooled group so that random variation in beneficiary weight loss could be overcome. Another commenter noted that a beneficiary's weight can fluctuate during the MDPP services period and, as such, a general downward trend in weight may be a more valid measure of progress than a percentage weight loss over a prescribed interval.

One commenter pointed out that professional care guidelines about weight loss do not translate population health averages to individual treatment targets, and in using 5 percent weight loss as the performance goal to determine payment for an individual Medicare beneficiary, the commenters observed that CMS did not value the significant health benefit for individual beneficiaries of lower levels of weight loss. The commenter further noted that the 5 percent weight loss performance payment per MDPP beneficiary did not align with the CDC's DPRP Standards, which are DPP-wide achievement of an average of 5 percent weight loss across those patients who attend 4 or more sessions.

Several commenters urged CMS to reduce the proposed amount of the 5 percent weight loss performance payment to approximately 10 percent of the maximum available total performance payment per beneficiary from the 20 percent CMS proposed and redistribute the dollars to attendance-based payments for sessions during the core services period.

Response: With regard to the potential for lowering the weight loss performance payment goal to 3 percent or 4 percent or, alternatively, making incremental weight loss performances for 3 percent, 4 percent, and 5 percent weight loss, we note that the MDPP expanded model was determined to meet the statutory requirements for expansion, where certification of the DPP model test was based on findings that demonstrated that 5 percent weight loss was associated with reductions in Medicare expenditures. Therefore, the goal of the MDPP expanded model is at least 5 percent weight loss for each beneficiary, which is expected

to lead to a reduction in the incidence of type 2 diabetes. We do not have data to support an expanded model that does not require the achievement and maintenance of the required minimum weight loss, so we do not believe it would be appropriate to make a weight loss performance payment for achievement of weight loss that is less than 5 percent, to guarantee the weight loss performance payment for all beneficiaries served by small MDPP suppliers, or to eliminate the weight loss performance payment entirely in favor of solely attendance-based performance payments. In addition, we expect there to be some natural, small downward or upward fluctuations in a beneficiary's weight as measured over time, in relation to fluid intake, the composition of recent meals, hormonal changes, or other factors. We believe that making a weight loss performance payment based on a one-time in-person weight measurement at a session for less than a 5 percent weight loss would risk Medicare making a weight loss performance payment when a beneficiary has experienced a natural downward weight fluctuation rather than true weight loss that has the potential to be sustained.

Furthermore, because there is no specific number of beneficiaries per MDPP supplier, we do not believe it would be appropriate to make weight loss performance payments based on program-wide achievement of 5 percent weight loss, rather than individual beneficiary weight loss, because this would reduce an MDPP supplier's incentive to actively help each beneficiary to meet the required minimum weight loss, particular if a few beneficiaries lost a large percentage of their weight. While we aim to maintain consistency to the extent possible with CDC's DPRP Standards, we note that standards for full recognition status, which require meeting weight loss and attendance standards that are measured at the aggregate rather than individual level, are set to ensure the quality and integrity of the services furnished by the DPP organization. In contrast, the performance-based payment methodology for the MDPP expanded

model establishes performance goals for beneficiaries so Medicare can make performance payments based on claims submitted by MDPP suppliers for MDPP services furnished to individual beneficiaries who achieve those performance goals. We believe that these differences between the DPP organization-wide rationale for the DPRP Standards and the performance goals for payment for MDPP services furnished to individual MDPP beneficiaries under the MDPP expanded model lead to reasonable differences in the measurement of 5 percent weight loss for these two purposes.

In response to the commenters who urged us to reduce the proposed 5 percent weight loss performance payment from 20 percent to 10 percent of the maximum total performance payment amount per beneficiary and redistribute the dollars to attendance-based payments in the core services period, we continue to emphasize that the achievement and maintenance of the required minimum weight loss is the outcome of MDPP services that is associated with a reduction in the incidence of type 2 diabetes. Therefore, we do not believe it would be appropriate to reduce the amount of the performance payment for 5 percent weight loss to less than the $160 we proposed, because that would reduce the emphasis on the weight loss outcome in the performance payments.

However, as discussed in section III.K.2.d.iii.(5) of this final rule, the maximum total performance payment for ongoing maintenance session intervals has been reduced due to the shortening of the ongoing services period from the 24 months that we proposed to 12 months in this final rule. Dollars for performance payments that would have been made for ongoing maintenance session intervals in months 25 to 36 of the MDPP services period have been partially redistributed to attendance-based performance payments for core sessions during the first 6 months of the MDPP services period, as discussed in section III.K.2.d.iii.(3) of this final

rule. This is consistent with the interests of the commenters who requested a redistribution of a portion of the 5 percent weight loss performance payment in order to increase attendance-based payments for sessions in the core services period. Finally, we note that because the maximum total performance payment amount per beneficiary is $670 as discussed in section III.K.2.d.iii.(2)(a) of this final rule, which is lower than the $810 that we proposed, the final $160 5 percent weight loss performance payment is actually a higher percentage (24 percent) than the proposed 20 percent of the maximum total performance payment amount.

Comment: While several commenters supported the proposal to make a weight loss performance payment for 9 percent weight loss at any point in time during the MDPP services period, a number of commenters opposed this additional weight loss performance payment that is in addition to the proposed performance payment for the required minimum weight loss. The commenters noted that the CDC DPRP target is 5 percent weight loss and, while they acknowledge the potential value to beneficiary health of greater weight loss beyond the 5 percent, they believe that making a performance payment for a weight loss of 9 percent under the MDPP expanded model goes beyond the core DPRP framework and initial research and may not be realistic or appropriate for many MDPP beneficiaries. One commenter who urged CMS not to finalize the 9 percent weight loss performance payment further suggested that the $25 represented in this performance payment be distributed to higher core maintenance session payments for beneficiaries who did not achieve or maintain the required minimum weight loss in the 3-month core maintenance session intervals.

Response: While we acknowledge the concerns of some commenters that the proposed $25 performance payment for 9 percent weight loss is not included as a standard in the CDC's DPRP, we continue to agree with other commenters that making an additional weight loss

performance payment for 9 percent weight loss at any time during the MDPP services period will provide an additional incentive for MDPP suppliers to continue weight loss efforts with MDPP beneficiaries, especially during the ongoing services period which may extend for a period of up to 12 months after the end of the core services period. We also understand that commercial payers paying for DPPs frequently include an incentive payment for 9 percent weight loss as an incentive to try to encourage greater and/or continued weight loss and behavior change.

We recognize that 9 percent weight loss may not be realistic or appropriate for every MDPP beneficiary. However, by finalizing the performance payment for 9 percent weight loss as $25, which is less than 4 percent of the maximum total performance payment amount available for an MDPP beneficiary, we will not provide such a high incentive to MDPP suppliers that we risk MDPP suppliers encouraging continued weight loss for those beneficiaries who are unlikely to benefit from weight loss beyond the required minimum.

After considering the public comments received, we are finalizing our proposals, without modification, for the weight loss performance payments at §414.84(b)(6) and (7). The final weight loss performance payments are displayed in Table 37.

TABLE 37: Final Weight Loss Performance Payments

Performance Goal	Performance Payment Per Beneficiary
5 percent weight loss (required minimum weight loss)	$160
9 percent weight loss	$25
Maximum total performance payment for weight loss	$185

(7) Summary Table of Performance Payments for the Set of MDPP Services

In summary, for furnishing MDPP services during the MDPP services period, we proposed that MDPP suppliers could be paid a minimum of $25 per beneficiary (if the beneficiary attends the first core session) and a maximum total of $810 per beneficiary (if the beneficiary achieves all performance goals, maintains eligibility for 36 months, and does not

change MDPP suppliers). Table 38 summarizes all of the proposed performance payments for the set of MDPP services that were discussed in sections III.K.2.d.iii.(3) through (6) of the proposed rule (82 FR 34141 through 34146).

TABLE 38: Proposed Performance Payments for the Set of MDPP Services

Performance Goal	Performance Payment Per Beneficiary (*with* the required minimum weight loss)	Performance Payment Per Beneficiary (*without* the required minimum weight loss)
1st core session attended	$25	
4 total core sessions attended	$30	
9 total core sessions attended	$50	
3 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)	*$60	$10
3 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)	*$60	$10
5 percent weight loss achieved	$160	$0
9 percent weight loss achieved	$25	$0
3 sessions attended in ongoing maintenance session interval (8 consecutive 3-month intervals over months 13-36 of the MDPP ongoing services period)	*$50	**$0
Total performance payment	**$810**	**$125**

* = The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.
** = A beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least once during the final core maintenance session 3-month interval to have coverage of the first ongoing maintenance session interval. Then, a beneficiary must attend at least 3 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval to have coverage of the next ongoing maintenance session interval.

Comment: One commenter requested that MDPP services be paid at a higher payment amount when medical professionals, who currently already furnish other services to Medicare beneficiaries, furnish MDPP sessions than when unlicensed coaches teach the sessions, due to the additional training medical professionals have received.

Response: As finalized in the CY 2017 PFS final rule (81 FR 80479), MDPP services must be furnished by trained coaches, including trained community health workers and health

professionals, who teach beneficiaries with prediabetes how to lower their risk of progressing to type 2 diabetes with methods that do not include medication or other interventions for beneficiaries diagnosed with diabetes. While any individual may be eligible to become a DPP coach, provided that they meet requirements and trainings as dictated by the CDC's DPRP Standards, an individual can only become an eligible coach for purposes of furnishing MDPP services after having their required identifying information submitted on an MDPP supplier's enrollment application, being screened by CMS or its contractors, and as a result, being determined to be eligible to furnish MDPP services on behalf of an MDPP supplier as discussed in section III.K.3.e.iv.(2) of this final rule. Thus, all DPP coaches, whether or not they are licensed health professionals who also furnish other services to Medicare beneficiaries, must meet the same DPRP Standards and the other requirements established in this final rule to be eligible coaches who can furnished MDPP services.

We proposed that the payment methodology for MDPP services be performance-based in relation to the achievement of the performance goals of session attendance and weight loss. While we acknowledge that licensed health professionals have training and a scope of practice that extends beyond community health workers who are trained DPP coaches, for purposes of the performance payments for MDPP services we see no reason to value in the payment methodology the MDPP beneficiary's achievement of the same performance goals differently based on additional credentials of the coach who furnished the session that resulted in the performance goal being met. The literature does not demonstrate that DPP sessions furnished by coaches with additional credentials result in greater achievement of patient outcomes than sessions furnished by coaches without additional credentials, where all coaches meet the CDC's

DPRP Standards.[35,36,37,38] Therefore, we expect that each MDPP supplier will consider the characteristics of the most effective coaches furnishing MDPP services to its MDPP beneficiaries, including whether or not specific coaches have additional credentials, in relation to the resources used by the MDPP supplier to pay those coaches, and the MDPP supplier will make decisions about the specific coaches to include on the supplier's roster accordingly.

Comment: Several commenters recommended that MA plans be given flexibility in making MDPP services available to their eligible plan enrollees, including, but not limited to, contracting directly with a vendor who in turn contracts with approved entities that furnish the CDC-approved DPP curriculum with payment arrangements that may or may not be the same as the payment methodology CMS proposed. With respect to payment for MDPP services furnished to MA plan enrollees, the commenters requested that MA plans be permitted to utilize the payment framework proposed by CMS, use a value-based performance contracting arrangement, or put in place any other alternative payment arrangement that meets the needs of the MA plan and their eligible plan enrollees in the communities in which they operate. The commenters urged CMS to clarify that the detailed proposed payment framework applies only to MDPP services furnished to Medicare fee-for-service beneficiaries.

Response: We appreciate the recommendations from the commenters about MA plan flexibilities that may be used in making MDPP services available to their eligible plan enrollees, including their requests for clarification about the relationship between the proposed

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[35]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.
[36]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.
[37]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.
[38]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

performance-based payment methodology for MDPP services and payment for MDPP services furnished to MA plan enrollees. Under section 1854(a)(6)(B)(iii) of the Act, CMS is prohibited from requiring an MAO to contract with specific providers and from requiring specific price or payment structures under the contracts with network providers; these provisions are reflected in the regulation at §422.256(a)(2)(ii). However, the Act, at sections 1852(a)(2) and (k)(1) and 1866(a)(1)(O) of the Act, also imposes requirements that MAOs pay out-of-network providers (that is, providers that do not contract with the MAO) and that such providers accept as payment in full the amount that would have been paid under original (fee-for-service) Medicare when the out-of-network provider furnishes covered services to an MA plan enrollee.

Therefore, we are not adopting any requirements to govern how an MAO pays its network providers -- either in amount or structure -- for MDPP services and believe that existing law adequately addresses when an out-of-network provider furnishes covered MDPP services. We note that as it appears unlikely that any MDPP services would be furnished as emergency or urgently needed services, we anticipate that the out-of-network payment requirements would be applicable only for MA private fee-for-service plans, MA point-of-service (POS) plans, or MA preferred provider organization (PPO) plans that regularly cover out-of-network services. Under these existing authorities, MA plans currently have flexibility in their payment methodologies for Part B services furnished to MA plan enrollees through network providers. Because MDPP services are covered under Part B, MA plans will have this same payment flexibility for MDPP services furnished by network providers to MA plan enrollees.

Table 39 summarizes all of the final performance payments for the set of MDPP services that were individually finalized in sections III.K.2.d.iii.(3) through (6) of this final rule.

TABLE 39: Final Performance Payments for the Set of MDPP Services

Performance Goal	Performance Payment Per Beneficiary (*with* the required	Performance Payment Per Beneficiary

	minimum weight loss)	**(*without* the required minimum weight loss)**
1st core session attended	$25	
4 total core sessions attended	$50	
9 total core sessions attended	$90	
2 sessions attended in first core maintenance session interval (months 7-9 of the MDPP core services period)	*$60	$15
2 sessions attended in second core maintenance session interval (months 10-12 of the MDPP core services period)	*$60	$15
5 percent weight loss achieved	$160	$0
9 percent weight loss achieved	$25	$0
2 sessions attended in ongoing maintenance session interval (4 consecutive 3-month intervals over months 13-24 of the MDPP ongoing services period)	*$50	**$0
Total performance payment	**$670**	**$195**

* = The required minimum weight loss from baseline must be achieved or maintained during the core maintenance session 3-month interval or maintained during the ongoing maintenance session 3-month interval.
** = A beneficiary attends at least 1 core session during the core services period to initiate the MDPP services period; must attend at least 1 session during the final core maintenance session 3-month interval; and must achieve or maintain the required minimum weight loss at least once during the final core maintenance session 3-month interval to have coverage of the first ongoing maintenance session interval. Then, a beneficiary must attend at least 2 sessions and maintain the required minimum weight loss at least once during an ongoing maintenance session 3-month interval to have coverage of the next ongoing maintenance session interval.

(8) Considerations Related to Potential Future Geographic Adjustment of MDPP Payments

Although Medicare is a national program, it frequently adjusts fee-for-service payments to hospitals, physicians, and other providers and suppliers according to the geographic locations in which they furnish services. These adjustments generally account for differences in the relative costs of doing business in different geographic areas compared to the national average. For example, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary must adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. This adjustment factor for hospitals is the wage index, and we currently define hospital geographic areas (labor market areas) based on the definitions of

Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget. Similarly, a geographic adjustment is also made for services paid under the PFS, and a geographic practice cost index (GPCI) has been established for every Medicare PFS payment locality, many of which are statewide, for each of the three components of a service's relative value units (that is, the relative value units for work, practice expense, and malpractice).

We proposed to make performance-based payments to MDPP suppliers in intervals based on achievement of performance goals, rather than fee-for-service payments for individual services furnished. Although we intended for those performance payments to make payment to MDPP suppliers for MDPP services that involve the use of supplier resources, we stated that we were unsure if there is notable variation in the relative costs of furnishing MDPP services among geographic areas. Because the DPP model test was carried out in only eight states, we did not have the data to determine whether there are geographic differences nationwide. In addition, because a substantial portion of the proposed MDPP performance payments would be based on the beneficiary's achievement of weight loss performance goals, we were uncertain about the appropriateness of geographically adjusting such performance-based payments.

Therefore, we did not propose geographic adjustment of performance payments for MDPP services. However, we invited public comments on issues related to geographic adjustment of payment for MDPP services in the context of the MDPP performance-based payment methodology, including appropriate sources of information for determining any geographic cost differences. We noted that we may consider proposing additional payment policies for the MDPP expanded model in the future. We requested that commenters submitting information on these issues provide justification, including any relevant analysis, to support any

suggestions regarding potential future geographic adjustment of performance-based payments for MDPP services.

The following is a summary of the public comments received on issues related to geographic adjustment of payment for MDPP services in the context of the proposed MDPP performance-based payment methodology, including appropriate sources of information for determining any geographic cost differences, and our responses:

Comment: Several commenters recommended that CMS consider varying the payment structure for MDPP suppliers in differing geographic markets in which MDPP suppliers operate, given the potential effects the region may have on operating costs. One commenter explained that any business, including an MDPP supplier, relies on varying market analyses based on region, such as urban versus rural, and on factors such as environment, legislation and competition, in establishing the parameters of the business. The commenter stated that business processes result in differing administrative and operational costs based on region and organizational structure that the commenter noted, if not addressed through the MDPP payment structure, would impact MDPP supplier sustainability and network adequacy, including the delivery of MDPP services to populations of greatest need. Another commenter noted that the major cost drivers of DPPs are salaries, which are highly variable across the U.S. A commenter acknowledged the DPP model test was conducted in limited geographic areas but believes CMS has enough experience with geographic payment adjustments in performance- based payment structures to apply such adjustments to payments for these services. The commenters urged CMS to consider geographic adjustment of payment for MDPP services now or in the future, emphasizing that the geographic adjustment of payment for MDPP services would be consistent with methodologies used for other services paid under the Medicare program.

Response: We note that the commenters recommending geographic adjustment of payment for MDPP services did not provide specific sources of information for determining geographic cost differences for MDPP services. Moreover, they did not suggest any specific geographic adjustment methodology in the context of the MDPP performance-based methodology that fundamentally differs from the resource-based payment methodologies that apply to most other services paid under the Medicare fee-for-service program.

We will review the suggestions provided by the commenters, as well as our early implementation experience with the MDPP expanded model and other information we receive in the future from stakeholders, as we consider proposing additional payment policies for the MDPP expanded model in the future, as appropriate

Comment: While not specifically related to geographic adjustment, one commenter requested that CMS consider using authority provided in section 1853(c)(7) of the Act to make adjustments in payment rates to MA plans for benefit changes directed through national coverage determinations or legislative action to recognize the uncertainty in which MA plans operated when developing their CY 2018 bids.

Response: We decline to make an adjustment in payment rates for benefit changes related to MDPP services and believe that we lack authority to do so in this specific circumstance in this final rule. Under section 1853(c)(7) of the Act, adjustments in payment rates to MA plans are available only where a change in benefits or services results from a national coverage determination or a legislative change and the service or benefit required to be provided is projected by the Secretary to result in a significant increase in the costs to Medicare+Choice of providing benefits under contracts entered into under section 1857 of the Act. MDPP services meet neither of these requirements.

First, MDPP services are available under the MDPP expanded model, which has been expanded in duration and scope under section 1115A(c) of the Act. Therefore, while a new service, coverage of MDPP services does not result from a legislative change or a national coverage determination. Second, we recognize that MA plans may negotiate contracts with MDPP suppliers that require the MA plan to pay more than the payments finalized in this final rule (that would pay MDPP suppliers a maximum total performance payment amount of $670 in CY 2018, as described in section III.K.2.d.iii.(2)(a) of this final rule, for furnishing MDPP services to fee-for-service beneficiaries). However, even where an MA plan enters into a contract that pays MDPP suppliers an amount that is substantially higher than the amount that would result from the policies finalized in this final rule, the costs associated with MDPP services objectively fail to rise to the level of a "significant increase" in the costs of providing benefits under contracts entered into under section 1857 of the Act. Further, the CY 2017 PFS final rule adopting the set of MDPP services as an additional preventive benefit under Part B (published in the November 15, 2016 **Federal Register**) and guidance to MAOs were both issued prior to the June 5, 2017 bid deadline date for CY 2018, so MAOs had adequate notice to incorporate these costs into bids for CY 2018 coverage.

(9) Updating MDPP Payment Amounts

To account for inflation, we proposed to update MDPP payment amounts annually based on the CPI-U. The CPI-U is a measure of the average change over time in prices paid for a market basket of consumer goods and services, and is a measure of economy-wide inflation. There are no statutory requirements for the update factor for payments for MDPP services so there is no requirement that a productivity adjustment be applied to the MDPP services update factor as there are for certain other Medicare-covered items and services where prices are

updated by the CPI-U, such as the Clinical Laboratory Fee Schedule; Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule; Ambulance Fee Schedule; and Ambulatory Surgical Center payment system.

We considered using other indices such as the Medicare Economic Index (MEI) to update the MDPP payment amounts. The MEI measures price changes in the inputs required to operate a self-employed physician practice. We did not believe that the MEI would be appropriate to update MDPP payment amounts because MDPP suppliers are not similar to self-employed physician practices. We noted that the CPI-U by definition is an economy-wide measure of inflation and, therefore, in the absence of an appropriate specific index for MDPP services, we believed the CPI-U to be the most technically appropriate index available to update payments for MDPP services. We further noted that the CPI-U is used to update Medicare payments for other Medicare-covered items and services, such as ambulance, clinical laboratory, and ambulatory surgical center services.

We proposed to update MDPP performance payments and the bridge payment (a proposed one-time payment to an MDPP supplier for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier as discussed in detail in section III.K.2.d.v. of the proposed rule (82 FR 34153 through 34155)) that may be paid to MDPP suppliers in the following manner:

- Beginning in CY 2019 and each year forward, the performance payment and bridge payment amounts would be adjusted by the 12-month percent change in the CPI-U (U.S. city average) for the period ending June 30th of the year preceding the update year. The percent change update would be calculated based on the level of precision of the index as published by

the Bureau of Labor Statistics and applied based on one decimal place of precision. The annual MDPP services payment update would be published by CMS transmittal.

The proposed methodology to update MDPP performance payments and the bridge payment was included at proposed §414.84(d). We invited public comments on this proposal.

The following is a summary of the public comments received on the proposal for the methodology to update MDPP performance payments and the bridge payment and our responses:

Comment: Several commenters supported the proposal to update MDPP performance payment and bridge payment amounts annually using the CPI-U.

Response: We appreciate the support of the commenters for the proposed methodology to update MDPP performance payments and the bridge payment annually using the CPI-U.

After considering the public comments received, we are finalizing the proposal, without modification, to update MDPP performance payments and the bridge payment at §414.84(d).

(10) MDPP Supplier Billing and Payment for MDPP Services

(a) Payment for MDPP Services on an Assignment-Related Basis

We proposed that performance payments and bridge payments to MDPP suppliers for MDPP services would be made only on an assignment-related basis in accordance with §424.55. As described in Chapter 1, Section 30.3 of the Medicare Claims Processing Manual,[39] CMS identifies a number of supplier and practitioner types who furnish services under the Medicare program and who are required to accept assignment for all Medicare claims for their services. This means that they must accept the Medicare allowed amount as payment in full for their services, regardless of whether the supplier is a participating or non-participating provider in the Medicare program. In these circumstances, the beneficiary's liability is limited to any applicable

[39] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf.

deductible plus the 20 percent coinsurance if coinsurance applies to the service. CMS currently mandates assignment for claims from multiple types of suppliers and practitioners, including clinical diagnostic laboratory services and physician lab services; physician services to individuals dually entitled to Medicare and Medicaid; and services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians/nutritionists, anesthesiologist assistants, and mass immunization roster billers. The beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective, and when these claims are inadvertently submitted as unassigned, Medicare Administrative Contractors (MACs) process them as assigned.

Consistent with our established requirements for these other types of suppliers, some of whom are similar to MDPP suppliers in that they furnish a limited breadth of Medicare-covered services, we believed that it would be appropriate to require all MDPP suppliers, whether they are participating or not participating in Medicare, to accept assignment. We also believed that making performance payments for MDPP services solely on an assignment-related basis would be the most appropriate methodology, given the proposed performance-based MDPP payment methodology which would be based on the achievement of weight loss and/or attendance performance goals and not based on the MDPP supplier resource expended to furnish individual MDPP services. We further noted that as finalized in the CY 2017 PFS final rule (81 FR 80464), 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. Under our proposal, Medicare would pay 100 percent of the Medicare allowed charge for MDPP services furnished to MDPP beneficiaries, and a beneficiary

would have no liability for covered MDPP services. MDPP suppliers would be required to accept the Medicare allowed charge as payment in full and would not be able to bill or collect from the beneficiary any amount.

Finally, to minimize the potential administrative burden on beneficiaries related to payment for MDPP services on an assignment-related basis, we proposed that for purposes of claims for services submitted by an MDPP supplier, Medicare would deem such claims to have been assigned by the beneficiary (or the person authorized to request payment on the beneficiary's behalf) and the assignment accepted by the MDPP supplier. This proposed treatment of claims from MDPP suppliers in new §424.55(d) would be consistent with the current exception in §424.55(c) regarding payment to a supplier, which specifies that when payment under the Act can only be made on an assignment-related basis or when payment is for services furnished by a participating physician or supplier, the beneficiary (or the person authorized to request payment on the beneficiary's behalf) is not required to assign the claim to the supplier in order for an assignment to be effective.

The proposed assignment-related basis for performance payments and bridge payments made to MDPP suppliers was included at proposed §414.84(b) and (c). The proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective was included at proposed §424.55(d). We invited comments on these proposals.

The following is a summary of the public comments received on the proposals for the assignment-related basis for performance payments and bridge payments made to MDPP suppliers and the proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective and our responses:

Comment: Several commenters supported the proposal to make performance payments and bridge payments to MDPP suppliers on an assignment-related basis. One commenter specifically supported the proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for the supplier to be paid directly by Medicare, claiming that this approach would reduce unnecessary paperwork and administrative burden for both the MDPP beneficiary and the MDPP supplier.

Response: We appreciate the commenters' support for our proposals for the assignment-related basis for performance payments and bridge payments made to MDPP suppliers and the proposal not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective.

After considering the public comments received, we are finalizing the proposals, without modification, to make performance payments and bridge payments to MDPP suppliers on an assignment-related basis at §414.84(b) and (c). In additional, we are finalizing the proposal, without modification, not to require the beneficiary to assign the claim for MDPP services to the MDPP supplier in order for assignment to be effective at §424.55(d).

(b) Requirements for Payment of Bridge Payments and Performance Payments

We proposed that MDPP suppliers may only submit claims for a performance payment or bridge payment for MDPP services when all of the requirements for the payment are met. Claims for services that do not meet these requirements will not be paid. In accordance with §424.80, we reminded MDPP suppliers that there are exceptions to the prohibition of reassignment of claims by suppliers for certain arrangements provided the applicable requirements are met. We noted that Medicare may pay an agent who furnishes billing and collection services to the supplier if the conditions of §424.80(b)(5) are met.

Proposed requirements for performance payments and the bridge payment included that the MDPP services were furnished to a beneficiary eligible for MDPP services as specified at §410.79(c) and that the MDPP supplier complies with all applicable enrollment and program requirements. In addition, we proposed that the MDPP services must be furnished by an eligible coach on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date, and the MDPP supplier must submit the National Provider Identifier (NPI) of the coach on MDPP claims. We described additional details on how eligible coach information would be processed in section III.K.2.d.iii.(10)(d) of the proposed rule (82 FR 34151 through 34152). All specific additional proposed requirements for the performance payment or bridge payment, as discussed in sections III.K.2.d.iii.(3) through (6) and III.K.2.d.v. of the proposed rule (34141 through 34146 and 34153 through 34155), would also need to be met.

In order to submit a claim for a performance payment under the MDPP expanded model, the billing supplier is required to have documentation in the beneficiary's MDPP record, as specified in proposed §424.205(g), that all requirements for the payment, including the achievement of the performance goal(s) applicable to the performance payment, have been met. We noted that the billing supplier's MDPP record for the beneficiary may include a copy of the beneficiary's MDPP record from a previous MDPP supplier that has been provided to the billing supplier at the request of the MDPP beneficiary. If an MDPP supplier is submitting a claim for an interval performance payment based on attendance at more than one session, this copy of the MDPP record from the previous MDPP supplier may be used as part of the billing supplier's documentation demonstrating that the attendance or weight loss performance goal for the performance payment was achieved. We noted that as we finalized at §424.59(b) in the CY 2017 PFS final rule (proposed to be redesignated and amended at §424.205(g)), MDPP suppliers are

required to maintain and handle any personally identifiable information (PII) and protected health information (PHI) in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards. Therefore, MDPP suppliers must follow these rules, as applicable, when providing any copies of information from a beneficiary's MDPP records to another MDPP supplier.

We proposed that any weight loss measurement taken and recorded by an MDPP supplier for the purposes of performance payments must be taken in-person during an MDPP core session, core maintenance session, or ongoing maintenance session by the MDPP supplier during the MDPP services period. We believed that in-person measurements would be the most feasible method for weight ascertainment at this time for services because the beneficiary would attend regular in-person sessions with the MDPP supplier. Moreover, we believed that self-reported weight loss would not be reliable for the purposes of performance payment in the MDPP expanded model. This proposal also would apply to our proposed policy regarding virtual make-up sessions, described in detail in section III.K.2.c.iv.(3) of the proposed rule (82 FR 34136 through 34137), meaning that weight loss could not be measured or reported during a virtual make-up session for the purpose of the MDPP supplier submitting a claim for a performance payment. We also proposed to require that weight loss be measured in-person at an MDPP session to align with CDC's DPRP standards, which require for in-person sessions that weight be measured in-person at the session.

In addition, we noted that the achievement or maintenance of the required minimum weight loss that determines the performance payment amount for a core maintenance session interval and the maintenance of the required minimum weight loss that determines whether a performance payment for an ongoing maintenance session interval would be made must be

determined by an in-person weight measurement at a session furnished during the applicable interval. Thus, for these interval performance payments, achievement of the performance goal for minimum weight loss would not need to be determined based on attendance at a session furnished by the MDPP supplier billing for that performance payment. However, as discussed previously, if achievement of the performance goal for minimum weight loss was measured at a session furnished by a previous MDPP supplier in the interval, the subsequent supplier must have documentation through a copy of the beneficiary's MDPP record from that previous supplier that the weight loss performance goal was met in the interval to bill for the interval performance payment. Finally, the performance payments for the required minimum and 9 percent weight loss would only be billed by the MDPP supplier furnishing the session at which the weight loss performance goal is met during an in-person session.

Furthermore, we proposed that the beneficiary must achieve the applicable attendance performance goal for core session, core maintenance session interval, or ongoing maintenance session interval performance payments upon attendance at a session furnished by the MDPP supplier billing for that specific performance payment. An MDPP supplier could only bill for a performance payment on the date the beneficiary has achieved all performance goals associated with that performance payment. We noted that in order to bill for an interval performance payment that is based on attendance, the MDPP supplier that furnished the session where the attendance goal is met would bill for the performance payment, even if that supplier did not itself furnish all sessions attended by the MDPP beneficiary during that interval. In these circumstances, as discussed previously, if attendance at a session furnished by a previous MDPP supplier occurred in the interval, the subsequent supplier must have documentation through a copy of the beneficiary's MDPP record from that previous supplier of the session attendance in

order to bill for the interval performance payment based on attendance at that session. An MDPP supplier may not bill for an interval performance payment when the MDPP supplier does not furnish the session where the attendance goal is met.

For all interval performance payments, we proposed that the performance payment would be based on the date the MDPP supplier furnished the session where the interval attendance performance goal is met. Thus, for those intervals where the performance payment would be based on MDPP beneficiary session attendance that spans 2 calendar years, the interval performance payment would be the amount applicable to the later calendar year, reflecting the annual update from the prior year as discussed in section III.K.2.d.iii.(9) of the proposed rule (82 FR 34147 through 34148) .

The proposed conditions for payment by CMS of performance payments and bridge payments to MDPP suppliers were included at proposed §414.84(b) and (c). We invited public comments on these proposals.

We received no public comments specific to the proposed conditions for payment of performance payments and bridge payments to MDPP suppliers.

We are finalizing the proposals, without modification, for the conditions for payment of performance payments and bridge payments to MDPP suppliers at §414.84(b) and (c).

(c) Reporting HCPCS G-Codes on Claims for MDPP Services

We proposed to establish 19 unique Healthcare Common Procedure Coding System (HCPCS) G-codes so that MDPP suppliers may submit claims for payment when all the requirements for billing the codes have been met. Our proposal for the HCPCS G-codes is displayed in Table 40.

We noted that each MDPP supplier would be able to bill one of the 18 payable HCPCS G-codes on the date when all the requirements for billing the code have been met, including the session attendance for specific core and ongoing maintenance session intervals and achievement and/or maintenance of weight loss, as applicable to the specific HCPCS G-code. One of the proposed HCPCS G-codes would be nonpayable and assigned a payment amount of $0 because it would only be reported on a claim that also includes a payable HCPCS G-code for MDPP services as described subsequently.

HCPCS G-codes GXXX1 through GXXX3 and GXXX8 through GXX17 may each be paid only once in a beneficiary's lifetime, and the Medicare claims processing system would ensure that no more than one of each specific performance payment per beneficiary reported with these HCPCS G-codes is made. In addition, because only one performance payment may be made for each core maintenance session interval per beneficiary, the claims processing system would also ensure that no more than one unit of HCPCS code GXXX4 or GXXX6 and no more than one unit of HCPCS code GXXX5 or GXXX7 was paid in a beneficiary's lifetime.

Due to these lifetime limitations on payment for certain HCPCS codes for each beneficiary, in the circumstances where two MDPP suppliers furnished sessions during the MDPP services period and both MDPP suppliers met all requirements for billing the same HCPCS G-code, based on our operational processes, we would pay the first valid claim received and deny the second claim. The first valid claim received for a beneficiary for a given HCPCS G-code with a lifetime limitation would be determined through the CMS' Common Working File (CWF), which processes claims for all MACs.

Based on information from the CDC's national DPP, we expected that circumstances where a beneficiary changes MDPP suppliers during the MDPP services period would be

uncommon. In addition, in view of the typical structure of DPPs where core sessions are offered weekly for the first 6 months of the core services period, and then offered monthly, we believed it would be rare for more than one MDPP supplier to meet the requirements for billing for the same once-per-lifetime performance payment. However, as an example an MDPP beneficiary could maintain the required minimum weight loss throughout the first core maintenance session interval and attend 3 sessions furnished by one MDPP supplier in the first 1 ½ months of the first core maintenance interval, and then change to another supplier and attend 3 more core maintenance sessions furnished by a subsequent MDPP supplier before the end of that interval. While both MDPP suppliers would meet the requirements for billing HCPCS code GXXX6, we would only pay the first claim for the HCPCS G-code that was submitted. The second claim for HCPCS code GXXX6 received by us would be denied. We expected that our operational processes would result in MDPP suppliers submitting claims for HCPCS G-codes as soon as the sessions are furnished that meet all of the requirements for billing for the particular performance payment, and that this practice would generally result in the performance payment being made to the MDPP supplier that furnished the first session where the performance goals were met.

Finally, as discussed in section III.K.2.d.v. of the proposed rule (82 FR 34153 through 34155), we did not propose to limit the number of bridge payments, which would be reported with HCPCS code GXX18, that may be paid for an MDPP beneficiary who changes MDPP suppliers during the MDPP services period.

TABLE 40: Proposed HCPCS G-Codes for MDPP Services

Proposed HCPCS G-Code for MDPP Services*	Proposed Payment Amount	Description of MDPP Service
GXXX1	$25	1st core session attended
GXXX2	$30	4 total core sessions attended
GXXX3	$50	9 total core sessions attended
GXXX4	$10	3 core maintenance sessions attended in months 7-9 (weight- loss goal not achieved or maintained)
GXXX5	$10	3 core maintenance sessions attended in months 10-12 (weight loss goal not achieved or maintained)
GXXX6	$60	3 core maintenance sessions attended in months 7-9 and weight loss goal achieved or maintained
GXXX7	$60	3 core maintenance sessions attended in months 10-12 and weight loss goal achieved or maintained
GXXX8	$160	5 percent weight loss from baseline achieved
GXXX9	$25	9 percent weight loss from baseline achieved
GXX10	$50	3 ongoing maintenance sessions attended in months 13-15 and weight loss goal maintained
GXX11	$50	3 ongoing maintenance sessions attended in months 16-18 and weight loss goal maintained
GXX12	$50	3 ongoing maintenance sessions attended in months 19-21 and weight loss goal maintained
GXX13	$50	3 ongoing maintenance sessions attended in months 22-24 and weight loss goal maintained
GXX14	$50	3 ongoing maintenance sessions attended in months 25-27 and weight loss goal maintained
GXX15	$50	3 ongoing maintenance sessions attended in months 28-30 and weight loss goal maintained
GXX16	$50	3 ongoing maintenance sessions attended in months 31-33 and weight loss goal maintained
GXX17	$50	3 ongoing maintenance sessions attended in months 34-36 and weight loss goal maintained
GXX18	$25	Bridge payment – first session furnished by MDPP supplier to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier
GXX19	$0	MDPP session reported as a line-item on a claim for a payable MDPP services HCPCS G-code for a session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable MDPP services HCPCS G-code

* = Illustrative HCPCS G-code numbers were placeholders to allow for comment on the CY 2018 PFS proposed rule. Final HCPCS codes for MDPP services under the MDPP expanded model are included in Table 41 of this final rule.

We also stated that we plan to issue specific billing instructions to MDPP suppliers for those 14 proposed HCPCS G-codes (excluding GXXX1, GXXX8, GXXX9, GXX18, and GXX19) that represent an interval performance payment where attendance at more than 1 session is required for the performance payment to be made. Suppliers would report the

applicable HCPCS G-code as a line-item on the claim on the date the session was furnished where the interval attendance goal was met. On the same claim, suppliers would also report 1 line-item of HCPCS code GXXX19 for each other session furnished by the supplier during the interval that was not previously reported on a claim but that counts toward achievement of the attendance performance goal for the applicable HCPCS G-code.

When billing for a HCPCS G-code that represents a cumulative number of MDPP sessions where some sessions already have been reported on a previous claim, only the sessions not previously reported on a claim would be reported by the MDPP supplier. For example, HCPCS code GXXX3 (9 total core sessions attended) would be used to bill for 9 core sessions attended, and the line-item of HCPCS code GXXX3 would represent the 9th core session furnished. Separate line-items of HCPCS code GXX19 would be reported on the same claim only for the 5th through 8th core sessions furnished by the MDPP supplier. Claims for HCPCS codes GXXX1 (1st core session attended) and GXXX2 (4 core sessions attended) would already have been submitted, and those claims would have included line-items for the 1st core session, and for the 2nd, 3rd, and 4th core sessions.

We believed that instructing MDPP suppliers to report a line-item for each session on a single claim submitted for an interval performance payment would simplify the tracking and administrative activities of MDPP suppliers and the reporting of the coach NPI on claims for MDPP services furnished to beneficiaries as discussed in section III.K.2.d.iii.(10)(d) of the proposed rule (82 FR 34151 through 34152). We further believed that there should be no significant administrative burden for MDPP suppliers to include information on all sessions they furnished on interval performance payment claims for two reasons. First, the documentation requirements for MDPP sessions at §424.205(g), including the beneficiary's eligibility, specific

session topics attended, the NPI of the coach who furnished the session attended, the date and place of service of sessions attended, and weight, would require the MDPP supplier to document and retain this information. Therefore, MDPP suppliers would have documentation of the date of each session and the NPI of the furnishing coach for reporting on each line-item on the claim for the interval performance payment. Second, MDPP suppliers would be instructed not to submit separate claims for each session represented in an interval performance payment. All sessions would be reported on the single claim that would be submitted for the interval performance payment.

In the case of an MDPP supplier submitting a claim for an interval performance payment where the billing supplier did not furnish all the sessions attributable to the interval because another supplier had furnished some of the first sessions in the interval, the billing supplier would report on the claim only the sessions it furnished. However, the supplier would need to maintain MDPP records documenting that all requirements, including session attendance and achievement or maintenance of weight loss, if applicable, for billing the HCPCS G-code for the interval for the beneficiary were met. Any sessions covered by the interval performance payment HCPCS G-code but not furnished by the supplier submitting the claim for that interval would not be reported as separate line-items on the claim. However, the billing supplier would need to maintain in the beneficiary's MDPP record a copy of his or her MDPP record from the previous supplier in order to consider sessions furnished by the previous supplier in determining that the performance goal(s) for the interval performance payment were met.

Although the NPIs of the coaches who furnished such sessions that would not be reported as separate line-items would also not be recorded on the claim, the billing supplier would still be required to maintain documentation in the beneficiary's MDPP record of the NPI of each coach

who furnished each session through a copy of the beneficiary's MDPP record about those sessions from the previous supplier. Therefore, upon medical review, CMS and its contractors would be able to review and assess the remaining coaches who furnished sessions to Medicare beneficiaries associated with a claim submitted for a given interval performance payment HCPCS G-code, but who do not have an NPI reported on the claim. Because we expected it to be uncommon for suppliers not to furnish all sessions attributable to an interval and due to the administrative burden that could result from a requirement that an MDPP supplier report specific information on sessions on a claim that the particular supplier did not itself furnish, we believed that the program integrity risk associated with the limitation in the completeness of information from administrative claims data under this scenario would be low. However, we would monitor the completeness of reporting line-items on claims for interval performance payments and may consider revising our billing instructions in the future if we determine that we lack information from administrative claims on a significant number of sessions furnished to MDPP beneficiaries.

We invited public comments on the proposals to create 19 HCPCS G-codes for billing for the performance payments and bridge payment.

The following is a summary of the public comments received on the proposals to create 19 HCPCS G-codes for billing for the performance payments and bridge payment and our responses:

Comment: Several commenters observed that the general proposed billing process appeared to be simple based on the use of the CMS-1500 claim form and the proposed 19 unique HCPCS G-codes specific to the MDPP expanded model. However, many commenters expressed concern about the complexity of the proposed coding and billing procedures, as well as the accompanying administrative burden on MDPP suppliers to generate and submit correct claims

for MDPP services. Several commenters stated that the proposal would require the entity billing for MDPP services to know whether or not the MDPP beneficiary has achieved his or her performance goals and how far along the beneficiary is in the MDPP services period in order to accurately bill for MDPP services. The commenters claimed that the complexity of the proposals would be unlikely to drive value in the MDPP expanded model and concluded that the extensive billing processes could discourage organizations from participating in the model because those processes would require more time and effort than DPPs have capacity to provide under their current business model. One commenter further added that the administrative requirements of the claims submission processes for submitting 19 HCPCS G-codes for a single beneficiary for MDPP services furnished over time would especially not be cost-effective for small, community-based nonprofit organizations in the context of the proposed performance payment amounts for MDPP services.

A number of commenters recommended that CMS reduce the number of HCPCS G-codes for MDPP services from the 19 new codes proposed. Several commenters urged CMS to provide payment for each MDPP session furnished by streamlining coding to only establish a separate HCPCS G-code for each type of session (core, core maintenance, and ongoing maintenance), coupled with a performance payment when the required minimum weight loss is achieved, in order to substantially simplify coding and billing. One commenter requested that CMS align the MDPP expanded model HCPCS codes and billing requirements with established Medicare diabetes self-management education and training services codes and billing policies. Another commenter reasoned that the more CMS can simplify the coding requirements for the MDPP expanded model and work to align the billing and coding processes with private health plans, the better the chance of broader, more meaningful access to and participation in MDPP

services for patients. In contrast, a commenter reported that the claims submission and payment processes have been difficult to date for DPP organizations to implement under current private health plan processes and, therefore, encouraged CMS to streamline its proposed processes.

Several commenters urged CMS to pay separately for the MDPP supplier administrative resources necessary to deliver MDPP services, including the preparation and submission of claims. One commenter noted that community-based organizations may be unfamiliar with Medicare billing requirements and recommended that CMS provide separate payment for an entity that serves as an Integrator between MDPP suppliers, CMS, and other payers.

Response: We acknowledge the large number of new HCPCS G-codes that we proposed to require to provide payment for the multiple types of performance payments and the bridge payment that we are finalizing for the MDPP expanded model. While this is a significant number of codes specific to the MDPP expanded model to be reported by an MDPP supplier on the CMS-1500 claim form when the performance goal(s) for the performance payments or the requirements for the bridge payment are met for MDPP services furnished to an MDPP beneficiary, we agree with those commenters who stated generally that the reporting of HCPCS G-codes for MDPP services on the CMS-1500 claim form should be straightforward. Many types of suppliers paid under the PFS for services currently report CPT and alpha-numeric HCPCS codes that describe those services on the CMS-1500 claim form without substantial problems.

We also understand that entities that enroll in Medicare as MDPP suppliers and have not previously billed Medicare for services will have a learning curve in preparing claims. However, we view this learning as unavoidable with the enrollment as MDPP suppliers of different types of organizations that do not already furnish other types of services to Medicare beneficiaries.

We are committed to providing clear guidance to MDPP suppliers on coding and billing for MDPP services to support suppliers' implementation of the most efficient and accurate processes for their respective organizations.

Claim preparation and submission is the responsibility of the MDPP supplier or their billing agent, and Medicare may pay the MDPP supplier or an agent who furnishes billing and collection services to the supplier if the conditions of §424.80(b)(5) are met. We will not make separate payments to MDPP suppliers for the administrative activities related to claims preparation and submission, nor will we provide separate payments to an entity that serves as an Integrator between CMS, MDPP suppliers, and other payers. MDPP suppliers will bear the cost of these activities.

As several commenters recognized, one of the more significant challenges for MDPP suppliers in billing correctly will be identifying and tracking where the beneficiary is in the MDPP services period, which defines what MDPP services must be offered to the beneficiary, as well as the HCPCS G-codes that can be reported for performance payments during that timeframe. This may be especially difficult when the MDPP beneficiary switches suppliers during the MDPP services period and the subsequent supplier does not yet have the beneficiary's MDPP records from the previous supplier. Another challenge for MDPP suppliers will be identifying when MDPP beneficiaries have met all the performance goals for the performance payment such that the MDPP supplier may submit a claim for the relevant HCPCS G-code that may be paid. These particular tasks result from the once-per-lifetime limitation on MDPP services and the performance-based payment methodology under the MDPP expanded model. In contrast, under the Medicare fee-for-service payment methodologies, most services are billed individually as they are furnished, without regard to the achievement of performance goals, and

most services do not have a once-per-lifetime limitation, especially a limitation that applies to services that may be furnished over many months.

In terms of the alignment of the MDPP expanded model HCPCS G-codes and billing requirements with those currently used for diabetes self-management education and training services, we note that diabetes self-management education and training services are subject to different requirements than MDPP services that are paid based on a performance-based payment methodology specifically established for this expanded model. Therefore, the codes and billing requirements for these different services are not aligned. In terms of alignment with processes used by private payers, the commenters did not provide specific information regarding these processes that we understand, in some cases, are based on invoices and not based on claims. While we appreciate the interest of the commenters in using similar claims processes for all patients in a DPP, regardless of payer, to reduce confusion and administrative burden on the MDPP supplier, this is not feasible given the specific requirements that apply to MDPP services furnished under the MDPP expanded model and the standard CMS claims processing systems upon which the MACs rely to process and pay Medicare claims.

Regarding the requests of some commenters that we reduce the number of HCPCS G-codes to have only a single code for each type of session, we note that our operational processes will edit in the claims processing system to ensure that we make only a maximum of one of each type of performance payment per beneficiary due to the lifetime limitation on MDPP services. Moreover, only the MDPP supplier submitting the claim for a performance payment will know whether or not the beneficiary has achieved or maintained the required minimum weight loss, as the beneficiary's weight is not submitted on administrative claims. Because the majority of the performance payments are in some way related to the achievement or maintenance of the

required minimum weight loss, either through identifying whether or not any performance payment should be made or determining the specific performance payment amount to be paid, and the MDPP supplier has documentation of the beneficiary's weight for each session furnished in-person, we believe the MDPP supplier is in the best position to prepare an accurate claim that identifies the specific performance payment that applies to the MDPP services furnished to the beneficiary.

Therefore, each performance payment and the bridge payment require separate payable HCPCS G-codes to be reported on claims to allow editing in the claims processing system for the once-per-lifetime limitation on the performance payment and to apply the policies for the bridge payment. Additionally, a nonpayable HCPCS G-code must be reported as a separate line-item on a claim for a payable HCPCS G-code for each additional session furnished by the billing supplier that counts toward achievement of the attendance performance goal for the payable HCPCS G-code so that we are able to monitor for compliance with the attendance requirement for the performance payment. While we proposed 19 new HCPCS G-codes for the MDPP expanded model, because we are finalizing an ongoing services period maximum duration of 12 months, rather than the 24 months that we proposed, 4 of the proposed HCPCS G-codes for reporting MDPP services in months 25 to 36 of the ongoing services period are not needed. Therefore, we are establishing 15 new HCPCS G-codes, effective April 1, 2018, for the MDPP expanded model. The final HCPCS G-codes and their long descriptors are displayed in Table 41.

Comment: One commenter requested that CMS clarify whether another HCPCS G-code or a specific HCPCS modifier will be established as a way to indicate on claims whether one of

the sessions reported was a virtual make-up session in view of the proposal to limit the number of virtual make-up sessions.

Response: We are finalizing limitations on the number of virtual make-up sessions as discussed in section III.K.2.c.iv.(3)(b) of this final rule. So that we can monitor for compliance with these limitations, we are also establishing new HCPCS code modifier VM (Medicare Diabetes Prevention Program (MDPP) Virtual Make-up Session.) to be appended to the HCPCS G-code on each claim line-item that represents a virtual make-up session. Because the HCPCS G-codes for the first core session and weight loss performance payments require that a weight be measured in-person at the session that is reported on the line-item for those HCPCS codes, only 12 of the 15 final HCPCS G-codes for the MDPP expanded model may be reported with HCPCS modifier VM as indicated in Table 41.

Comment: One commenter disagreed with the operational plan that if two MDPP suppliers both meet the requirements for billing a single HCPCS G-code with a one unit lifetime limitation, CMS would only pay the first claim for the HCPCS G-code that was submitted. The commenter stated this is not a viable solution for reconciling the submission of two claims from different MDPP suppliers for the same HPCPCS G-code and may result in confusion and discord among MDPP suppliers.

Response: While we appreciate the commenter's concern about our paying the first claim received for a HCPCS G-code when a different MDPP supplier later submits a claim for the same code, we do not have the straightforward operational capacity to further adjudicate timely the decision about which MDPP supplier should receive the payment for the once-per-lifetime HCPCS G-code if two MDPP suppliers submit a claim for the same HCPCS G-code. Conceptually, we believe it is appropriate that payment be made to the MDPP supplier that

furnished the first session that meets all of the requirements for billing for the performance payment reported with that HCPCS code. Our planned operational practice of paying the first claim received would generally result in the performance payment being made to the MDPP supplier that furnished the first session where the performance goals were met because MDPP suppliers would be incentivized to submit claims for HCPCS G-codes as soon as the sessions are furnished that meet all of the requirements for billing for the particular performance payment. Therefore, in general we believe that the appropriate supplier would be paid the performance payment reported with the HCPCS G-code.

We will monitor the frequency of circumstances where we receive two claims from different MDPP suppliers for the same performance payment for the same MDPP beneficiary and, if indicated, compare the date of the session reported on each paid and unpaid claim where the performance goals for the payment were met. If we see frequent circumstances where the payment was not made to the MDPP supplier that furnished the first session where the performance goals were met, we may consider revisions to this policy so that we are able to specifically reconcile claims for the same performance payment from different MDPP suppliers. However, we remain concerned that any adjudication of these circumstances could require us to hold claims for MDPP services without payment for a period of time and generally delay performance payments to MDPP suppliers, which could result in greater MDPP supplier confusion and burden.

Comment: One commenter requested that CMS confirm that an MDPP supplier can submit a claim for the 5 percent weight loss performance payment on the date that the beneficiary achieves the weight loss goal any time during the 12-month core services period. The commenter explained that one section of the proposed rule suggested that only attendance-

based performance payments would be made in the first 6 months of the MDPP services period, whereas another section stated that the 5 percent weight loss performance payment could be made upon achievement of the required minimum weight loss any time during the 12 months of the core services period.

Response: We appreciate the commenter's request for clarification about the time period during the MDPP services period when the 5 percent weight loss performance payment can be billed and paid. The 5 percent weight loss performance payment may be billed by the MDPP supplier on the date it furnishes any session during the 12 months of the core services period when 5 percent weight loss is achieved by the MDPP beneficiary. We note that other than the weight loss performance payments, during the first 6 months of the core services period the core session performance payments are the only other type of performance payments that can be made and they are solely based on the achievement of attendance performance goals.

Comment: One commenter encouraged CMS to develop billing templates for MDPP coaches because coaches are not billing specialists, yet the coaches teach the DPP curriculum.

Response: We define a coach in the MDPP expanded model as an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer. While we understand that coaches teach the DPP curriculum to MDPP beneficiaries during sessions, we only make performance payments for the beneficiary's achievement of attendance and/or weight loss performance goals or the bridge payment to MDPP suppliers. Thus, MDPP suppliers or their billing agents must prepare and submit claims for Medicare for payments under the MDPP expanded model. Coaches will not submit claims to Medicare and, therefore, will not need to have billing templates.

Comment: One commenter requested that CMS clarify whether, under the circumstances when an MDPP beneficiary completes the full 12-month core services period without achieving or maintaining the required minimum weight loss but requests to continue with ongoing maintenance sessions furnished by the MDPP supplier, the MDPP supplier is permitted to bill the beneficiary for those ongoing maintenance sessions. Similarly, the commenter requested that CMS clarify whether the MDPP supplier can bill the beneficiary for sessions after the beneficiary completes the 36 months of eligibility for MDPP services but remains eligible for the DPP.

Response: We recognize that beneficiaries who are no longer eligible for MDPP services as specified at §410.79(c)(1) and (2) may still wish to continue participating in DPP sessions. In these cases, MDPP suppliers may decide whether to continue offering such services and whether to bill the individual for such services. In cases where the claim is assigned, section 1879(b) of the Act establishes certain requirements for suppliers that wish to charge beneficiaries for the cost of a non-covered service. This section, however, only addresses the Medicare denial reasons specified in sections 1862(a)(1), 1862(a)(9), and 1879(g) of the Act. Because MDPP services fall under section 1861(ddd) and thus section 1879(b) of the Act does not address the denial reason in the commenter's question, the requirements in section 1879 are not applicable. Therefore, MDPP suppliers that opt to offer services beyond the set of MDPP services for which the beneficiary is eligible may charge the beneficiary for those services, and may do so without requiring the beneficiary to sign an Advanced Beneficiary Notice of Noncoverage (ABN). Although the MDPP supplier standard at §424.205(d)(11) requires MDPP suppliers to disclose MDPP-related information to beneficiaries at the onset of services, including what is covered and MDPP eligibility criteria, we highly encourage MDPP suppliers to provide notification to a

beneficiary when his or her eligibility for MDPP services ends and when continued receipt of DPP services would result in a beneficiary's out-of-pocket expense.

Given the commenter's questions about the circumstances when an MDPP supplier may charge a beneficiary for DPP services furnished when the beneficiary is not eligible for MDPP services, we want to further clarify which DPP services are considered covered as a part of the set of MDPP services and, therefore, charging beneficiaries for these services furnished during the MDPP services period would not be permitted. As defined at §410.79(a) and (c)(2), the core services period consists of, a*t least* 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period (emphasis added)" and two core maintenance session intervals, which mean two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary *at least* one core maintenance session per month (emphasis added). Similar, as defined at §410.79(a) and (c)(2), during the ongoing services period an MDPP supplier offers *at least* 1 ongoing maintenance session to an MDPP beneficiary per month (emphasis added).

These provisions establish the minimum number of sessions an MDPP supplier must offer during these months as a part of the set of MDPP services, as required at §424.205(d)(10), but do not establish an upper limit on the number of MDPP sessions that can be offered under these time periods. An MDPP supplier may offer sessions beyond what are required under the MDPP expanded model. However, any additional MDPP services offered beyond the minimum required during the core and ongoing services periods would still be subject to the requirements at §410.79(a) and (c)(2) and, as an additional preventive service, no cost-sharing can be applied to MDPP services. Thus, an MDPP supplier may not charge an MDPP beneficiary for any additional MDPP services furnished beyond the minimum that must be offered during the core

services period or during the ongoing services period, provided that the beneficiary is eligible for MDPP services and is in his or her MDPP services period.

After considering the public comments received, we are finalizing the proposals to establish new HCPCS G-codes for reporting MDPP services under the MDPP expanded model, with modifications. Because we are finalizing the ongoing services period duration of 12 months, rather than the 24 months that we proposed, 4 of the proposed HCPCS G-codes for reporting MDPP services in months 25 to 36 of the ongoing services period are not needed. Therefore, we are adopting 15 new HCPCS G-codes, effective April 1, 2018, for the MDPP expanded model. In addition, the descriptions of the HCPCS G-codes for core maintenance and ongoing maintenance session interval performance payments have been modified to reflect the final attendance performance goal of 2 sessions for each interval, as discussed further in sections III.K.2.d.iii.(4) and (5) of this final rule. The final HCPCS G-codes, long descriptors, indication of whether or not each code may be reported with modifier VM as a virtual make-up session, and their payment amounts are displayed in Table 41.

TABLE 41: Final MDPP Expanded Model HCPCS G-Codes

HCPCS G-Code	Long Descriptor	May be Reported with Modifier VM (Virtual Make-Up Session)	Final Payment Amount
G9873	First Medicare Diabetes Prevention Program (MDPP) core session was attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	No	$25
G9874	Four total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	Yes	$50
G9875	Nine total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the	Yes	$90

HCPCS G-Code	Long Descriptor	May be Reported with Modifier VM (Virtual Make-Up Session)	Final Payment Amount
	MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.		
G9876	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.	Yes	$15
G9877	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12.	Yes	$15
G9878	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.	Yes	$60
G9879	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP	Yes	$60

HCPCS G-Code	Long Descriptor	May be Reported with Modifier VM (Virtual Make-Up Session)	Final Payment Amount
	curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12.		
G9880	The MDPP beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight in months 1-12 of the MDPP services period under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 5% weight loss from baseline as measured by an in-person weight measurement at a core session or core maintenance session.	No	$160
G9881	The MDPP beneficiary achieved at least 9% weight loss (WL) from his/her baseline weight in months 1-24 under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 9% weight loss from baseline as measured by an in-person weight measurement at a core session, core maintenance session, or ongoing maintenance session.	No	$25
G9882	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 13-15 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 13-15.	Yes	$50
G9883	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 16-18 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 16-18.	Yes	$50
G9884	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 19-21 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during	Yes	$50

HCPCS G-Code	Long Descriptor	May be Reported with Modifier VM (Virtual Make-Up Session)	Final Payment Amount
	months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 19-21.		
G9885	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 22-24 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 22-24.	Yes	$50
G9890	Bridge Payment: A one-time payment for the first Medicare Diabetes Prevention Program (MDPP) core session, core maintenance session, or ongoing maintenance session furnished by an MDPP supplier to an MDPP beneficiary during months 1-24 of the MDPP Expanded Model (EM) who has previously received MDPP services from a different MDPP supplier under the MDPP Expanded Model. A supplier may only receive one bridge payment per MDPP beneficiary.	Yes	$25
G9891	MDPP session reported as a line-item on a claim for a payable MDPP Expanded Model (EM) HCPCS code for a session furnished by the billing supplier under the MDPP Expanded Model and counting toward achievement of the attendance performance goal for the payable MDPP Expanded Model HCPCS code.(This code is for reporting purposes only).	Yes	$0

In the CY 2018 PFS proposed rule (82 FR 34151), we also invited public comment on matters related to billing instructions for MDPP suppliers that we plan to issue to require the reporting of additional session line-items on claims for MDPP services so that information on the date and coach NPI for each session furnished by the billing supplier would be submitted on claims. However, we noted that we intend to provide additional claims submission instructions in guidance.

The following is a summary of the public comments received on matters related to billing instructions for MDPP suppliers that we plan to issue to require reporting additional session line-items on claims for MDPP services so that information on the date and coach NPI for each session furnished by the billing supplier would be submitted on claims and our responses:

Comment: Several commenters emphasized the need for CMS to provide additional detailed instructions on billing requirements for coding, charting, and charges so that MDPP suppliers are prepared for an audit. One commenter provided specific recommendations for items CMS should include in future billing instructions, regardless of the final HCPCS G-codes established for the MDPP expanded model. These items included: a table with the HCPCS G-codes and their payment amounts; groupings of HCPCS G-codes most likely to be billed together; a sample completed CMS-1500 claim form for various scenarios; and ICD-10-CM diagnosis codes to be reported on claims for MDPP services.

Response: We appreciate the interest of the commenters in ensuring that MDPP suppliers, many of whom may not have previously billed Medicare for services, have sufficient information to accurately and correctly prepare all elements of claims for submission to Medicare in accordance with the final policies of the MDPP expanded model. We share the interest of the commenters and recognize the importance of comprehensive, clear billing instructions to streamline the work of MDPP suppliers that will submit claims and MACs who will process those claims for payment of MDPP services. We will be issuing specific billing instructions for MDPP services in advance of the April 1, 2018 start date of the MDPP expanded model. We will consider the suggestions of the commenter regarding the contents, as well as information and requests provided to us by other stakeholders, as we develop and refine comprehensive billing instructions for MDPP suppliers. Finally, we note that we expect a learning curve for MDPP

suppliers and MACs with respect to claims for MDPP services, and we are prepared to provide further billing instructions or clarify the instructions already provided as the MDPP expanded model begins to be implemented and claims are prepared, submitted, and processed for the first time.

(d) Reporting the Coach National Provider Identifier (NPI) on Claims

In the CY 2017 PFS final rule, we established the policy that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they will be required to obtain NPIs. Further details on these policies are described in section III.K.2.e.iii. of the proposed rule (82 FR 34158 through 34166).

As stated in Chapter 26, Section 10.4 of the Medicare Claims Processing Manual,[40] the NPI of the rendering provider is to be reported as Item 24J on the line-item for each service reported on the CMS-1500 claim form. Our proposal in section III.K.2.d.iii.(10)(c) of the proposed rule (82 FR 34149 through 34151) would require that, in the circumstances of a claim for an interval performance payment for MDPP services, each session furnished by the billing supplier be reported as a separate line-item on the claim. In addition, we proposed to require MDPP suppliers to report the NPI of the coach who furnished the session as Item 24J on the line-item for each session reported on claims for performance payments for MDPP services. Under our proposal, the coach who furnished the session would be the rendering provider for purposes of reporting on the CMS-1500 claim form.

Although only MDPP suppliers, not coaches, would be subject to potential Medicare administrative actions related to payments the suppliers may receive, we believed that our proposal to require the NPI of the coach who furnished the session to be reported as the

[40] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf.

rendering provider for each line-item HCPCS G-code on a claim for MDPP services would provide us with a number of program integrity protections, including the ability to monitor MDPP coach activity to identify suspected fraud or other improper payments and to determine the need for medical review or investigation as appropriate. We would only process claims for payment of MDPP services when all of the coach NPIs reported on the claim are associated with eligible coaches who have been submitted on the coach roster in the MDPP supplier's enrollment application, and when all of the coaches have successfully completed Medicare's screening processes. We would also only process claims for payment of MDPP services furnished by a coach on or after his or her coach eligibility start date, and, if applicable, prior to his or her coach eligibility end date, as the definitions of these terms were included in proposed §424.205(a).

Without such program integrity protections, we would lack a sufficient method to verify that payment is being made for services furnished by a coach who has met the requirements outlined in section III.K.2.e.iii. of the proposed rule (82 FR 34158 through 34166). This verification would help protect both Medicare beneficiaries and the Medicare Trust Funds. Including coach NPIs on claims could also encourage accuracy in reporting on the achievement of beneficiary attendance and/or weight loss performance goals because both CMS and MDPP suppliers would be able to identify on the claim in question which coaches furnished the sessions attributable to the performance payment. In addition, because the accuracy of information reported on the claim would ultimately be the MDPP supplier's responsibility and the MDPP supplier would attest to the accuracy of each claim submitted, including the relevant coach NPIs on the claim could assist the MDPP supplier when conducting internal monitoring of claim accuracy.

These proposed requirements for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers were included at proposed §414.84(b) and (c). We invited public comments on these proposals.

The following is a summary of the public comments received on the proposals for the requirements for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers and our responses:

Comment: Several commenters supported the proposal to require MDPP suppliers to report the NPI of the coach who furnishes an MDPP session on the claim line-item for that session. One commenter noted that because coaches will not have to individually enroll in Medicare but will be required to obtain an individual NPI, the coach NPI information for each session will be available, making the proposed reporting approach feasible for MDPP suppliers.

Response: We appreciate the commenters' support for our proposed requirements for reporting the coach NPI as the rendering provider on session line-items included on claims submitted by MDPP suppliers for performance payments and bridge payments.

After considering the comments received, we are finalizing the proposal, without modification, for reporting the coach NPI as the rendering provider on session line-items included on claims for performance payments and bridge payments to MDPP suppliers at §414.84(b) and (c).

iv. Comparison of Final Supplier Requirements for Furnishing the Set of MDPP Services and Supplier Payment

As in the DPP model test under section 1115A(b) of the Act, MDPP services are based on a CDC-approved DPP curriculum and, therefore, MDPP suppliers must offer sessions in accordance with that curriculum. We are finalizing a performance-based payment methodology for MDPP services, which ties most payments to outcomes – in this case, weight loss and session attendance - to help incentivize suppliers to be engaged in their beneficiaries' weight loss efforts. Given this methodology, we recognize that there will be an inherent amount of supplier financial risk, and that coverage of sessions and supplier requirements and payment will not always align under the MDPP expanded model final polices. This section clarifies how these elements fit together in the MDPP expanded model under its final policies, as displayed in Table 42.

TABLE 42: Final Set of MDPP Services and Payment

MDPP Services	MDPP Beneficiary Eligibility for Coverage	MDPP Supplier Must Offer	MDPP Supplier Payment
Core sessions (months 1 to 6 of the MDPP services period)	An eligible beneficiary has Medicare coverage of core sessions in the first 6 months of the MDPP core services period, regardless of attendance or weight loss. *NOTE: To start the MDPP services period, the beneficiary attends his or her first core session, which begins the beneficiary's MDPP services period timeline of a maximum of 24 months.	At least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the beneficiary's MDPP services period.	• $25 performance payment for beneficiary attendance at the first core session. • $50 interval performance payment after the beneficiary has attended a total of 4 core sessions. • $90 interval performance payment after the beneficiary has attended a total of 9 core sessions. *NOTE: All payments for core sessions are independent of beneficiary weight loss.
Core maintenance sessions (months 7 to 12 of the MDPP services period)	Beneficiary has coverage of core maintenance sessions in months 7 to 12 of the MDPP services period, regardless of attendance or weight loss.	At least 1 core maintenance session per month in months 7 to 12 of the MDPP services period.	• $15 payment if a beneficiary attends 2 sessions within a 3-month core maintenance session interval but does not achieve or maintain the required minimum weight loss at least once within that 3-month core maintenance session interval; *or* • $60 if a beneficiary attends 2 sessions *and* achieves or maintains the required minimum weight loss at least once within that 3-month core maintenance session interval. *NOTE: There are 2 consecutive core maintenance session intervals.

MDPP Services	MDPP Beneficiary Eligibility for Coverage	MDPP Supplier Must Offer	MDPP Supplier Payment
Ongoing maintenance sessions (months 13 to 24 of the MDPP services period)	Beneficiary has coverage of ongoing maintenance sessions in the first ongoing maintenance session interval (months 13 to 15 of the MDPP services period) if: • He or she attended at least 1 session during the final core maintenance session interval (months 9 to 12 of the MDPP services period) and had weight measured. • He or she achieved or maintained the required minimum weight loss at least once during the final core maintenance session interval (months 10 to 12 of the MDPP services period). A beneficiary has coverage of a subsequent ongoing maintenance session interval (for up to 9 months after the end of the first ongoing maintenance session interval) if: • He or she attended at least 2 sessions and maintained the required minimum weight loss from baseline at least once during the previous ongoing maintenance session interval.	At least 1 ongoing maintenance session per month for up to 12 months, if the beneficiary maintains eligibility to have coverage of ongoing maintenance sessions.	• $50 payment if a beneficiary attends 2 sessions and maintains the required minimum weight loss from baseline at least once within a 3-month ongoing maintenance session interval. *NOTE: There are up to four consecutive ongoing maintenance session intervals.

Once an MDPP supplier enrolls in Medicare to furnish MDPP services, it must offer the set of MDPP services in accordance with the MDPP supplier standards (noted in section III.K.2.e.iv.(4) of this final rule and at §424.205(d)), including that it must offer at least 16 core sessions, furnished no more frequently than once per week, over the first 6 months of the MDPP core services period; at least 1 core maintenance session per month over months 7 to 12 of the MDPP core services period; and at least 1 ongoing maintenance session per month for up to 12 additional months (months 13 through 24 of the MDPP services period), if the beneficiary maintains eligibility for coverage of ongoing maintenance sessions. We recognize that beneficiaries might not attend these sessions. However, they must be made available, in accordance with CDC's DPRP Standards, to beneficiaries as long as they are eligible for

coverage of MDPP services. We further note that the set of MDPP services must be furnished in compliance with all applicable federal laws and regulations.

Although a beneficiary is not required to use MDPP services at all, the MDPP services period is initiated by the beneficiary attending his or her first core session, which begins the MDPP services period timeline. To qualify for coverage of ongoing maintenance sessions, a beneficiary also needs to attend at least 1 session during the final core maintenance session interval where in-person weight measurement is performed that demonstrates the achievement or maintenance of the required minimum weight loss.

All of the final performance payments except for the weight loss performance payments require the achievement of an attendance performance goal, and if a beneficiary does not achieve attendance performance goals, an MDPP supplier will not be paid a performance payment that relies on achieving those goals. For example, if a beneficiary does not attend 2 sessions in the first core maintenance session interval, a supplier will not be paid a performance payment for the interval that spans months 7 to 9 of the MDPP core services period. However, a supplier must offer at least 1 core maintenance session per month to the beneficiary to ensure that the beneficiary has the opportunity to attend. Furthermore, although the weight loss performance payments are based solely on the achievement of the required minimum or 9 percent weight loss, we note that all weight loss measurements must be obtained in-person at a session so that if a beneficiary does not attend a session where weight loss can be measured and compared to baseline, the MDPP supplier will not be paid a performance payment that relies on achieving a weight loss performance goal.

v. Payment Policies When a Beneficiary Changes MDPP Suppliers

In the CY 2017 PFS final rule (81 FR 80470), we confirmed that a beneficiary may change MDPP suppliers at any time. However, we deferred specific policies regarding attribution of beneficiaries who change MDPP suppliers as related to payment to future rulemaking. We subsequently made proposals for payment policies when a beneficiary changes MDPP suppliers during the MDPP services period in the proposed rule (82 FR 34153 through 34155).

At proposed §414.84(a), we proposed to define "bridge payment" as a one-time payment to an MDPP supplier for furnishing its first MDPP services session to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier. We used this definition in the proposed MDPP payment policies for the circumstances when a beneficiary changes MDPP suppliers for any reason during the MDPP services period after the beneficiary has attended at least the first core session.

In cases where the beneficiary changes MDPP suppliers, there would be a shift in accountability for offering the set of MDPP services for which the beneficiary is eligible for coverage from one MDPP supplier to a subsequent MDPP supplier. Similar to our proposal for a performance payment to an MDPP supplier that furnishes the first core session to an MDPP beneficiary who initiates the MDPP services period as discussed in section III.K.2.d.iii.(3) of the proposed rule (82 FR 34141 through 34143) , we proposed that an MDPP supplier would be paid a bridge payment of $25 for furnishing its first session to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier, regardless of whether the MDPP supplier is paid any performance payments for that beneficiary. A subsequent MDPP supplier would be paid this bridge payment after furnishing the first session to a beneficiary and

billing the appropriate HCPCS G-code only if the supplier did not furnish the first core session to the MDPP beneficiary.

We believed that making a bridge payment that would be the same amount as the performance payment for the first core session discussed in section III.K.2.d.iii.(3) of the proposed rule (82 FR 34141 through 34143) would be appropriate because we expected the MDPP supplier's resources used to be similar under both of these circumstances. The subsequent supplier would expend resources for furnishing a first session to a beneficiary, including collecting administrative information on the beneficiary who is not already known to the supplier, regardless of whether the beneficiary goes on to receive further MDPP sessions from that supplier.

We proposed that the bridge payment would be paid to the subsequent MDPP supplier any time a beneficiary changes suppliers during the MDPP services period, regardless of when during the core services period or ongoing services period the beneficiary changes MDPP suppliers. The bridge payment was not intended to be a performance payment, which could be paid to the subsequent MDPP supplier in addition to the bridge payment if a beneficiary achieves a performance goal while receiving MDPP services from that the subsequent supplier. Rather, the bridge payment would account for the financial risk a subsequent MDPP supplier takes on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period. We believed that when suppliers furnish MDPP services to MDPP beneficiaries in these circumstances, they generally would not have the same opportunity for performance payments that they would have if the beneficiary had been receiving MDPP services from the supplier from the beginning of the MDPP services period because certain performance goals, such as the required minimum weight loss, might already have been achieved by the beneficiary. The

proposed bridge payment policy would play an important role in ensuring access to MDPP services and freedom of choice of MDPP suppliers for those beneficiaries who either choose to or must change suppliers during the MDPP services period.

If we were to only make performance payments for MDPP services as proposed in sections III.K.2.d.iii.(3) through (6) of the proposed rule (82 FR 34141 through 34146) and not make a bridge payment to a subsequent supplier when an MDPP beneficiary changes suppliers during the MDPP services period, access problems could result due to the number of scenarios where subsequent MDPP suppliers offering and furnishing MDPP services would be paid no performance payment for the sessions furnished. We provided the following examples to illustrate such scenarios.

- A beneficiary changes from MDPP supplier A to MDPP supplier B after attending core session 4; attends core sessions 5 to 8 with supplier B; and then decides not to attend any more MDPP sessions. Supplier B does not meet the requirements for billing for the performance payment for the 9th core session because only 8 core sessions were attended, despite supplier B offering and furnishing core sessions 5 to 8.

- A beneficiary who has not met the required minimum weight loss performance goal changes from MDPP supplier A to MDPP supplier B after completing the first 3-month core maintenance session interval; attends 2 core maintenance sessions in months 9 through 12 with supplier B; and then fails to attend the 3rd core maintenance session in this interval. Supplier B does not meet the requirements for billing for the performance payment for the second core maintenance session interval despite offering and furnishing core maintenance sessions and the beneficiary eligibility for coverage of MDPP services then ends after month 12, the end of the core services period.

We believed that circumstances like these examples where subsequent MDPP suppliers would receive no payment for sessions furnished to MDPP beneficiaries who change suppliers during the MDPP services period in the absence of the bridge payment policy could lead to those MDPP suppliers preferentially seeking to furnish the remaining MDPP services during the MDPP services period to beneficiaries who have either already achieved the required minimum weight loss, or whom they believe will attend sessions and achieve weight loss, because the required minimum weight loss is tied to eligibility for ongoing maintenance sessions and higher performance payment for core maintenance session intervals.

We noted that we proposed in section III.K.2.e.iv.(4) of the proposed rule (82 FR 34163 through 34164) that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier's own capacity limits to furnish MDPP services to additional beneficiaries and on a discretionary basis if a beneficiary significantly disrupts the session for other participants or becomes abusive. However, MDPP suppliers could comply with this access requirement, while still preferentially seeking to furnish the remaining MDPP services in the MDPP services period to MDPP beneficiaries they believe are most likely to achieve the performance goals. To ensure beneficiary freedom of choice of MDPP supplier, including the choice to change suppliers, we believed that our proposal to make a bridge payment would help mitigate the likelihood of MDPP suppliers acting on such preferences. The subsequent supplier would be paid a bridge payment for a beneficiary who changes suppliers, even if the beneficiary does not achieve performance goals that result in a performance payment being made to the subsequent supplier.

We considered an alternative policy in which the bridge payment would only be made in circumstances where the subsequent supplier would not be paid a performance payment that is

based on attendance at the first session furnished by that supplier. For example, under this alternative if a beneficiary attends the first session during the ongoing maintenance session interval for months 13 through 15 at one MDPP supplier and then changes to a subsequent MDPP supplier that furnishes 2 additional ongoing maintenance sessions within that same interval and the beneficiary maintains the required minimum weight loss, the subsequent supplier would not be paid the $25 bridge payment but would be paid the ongoing maintenance session interval performance payment for months 13 through 15. The subsequent supplier would only be paid the $25 bridge payment if the beneficiary did not maintain the required minimum weight loss for the performance payment for that ongoing maintenance session interval. We did not propose this alternative because we believed it would be appropriate to make a bridge payment for the first session furnished by the subsequent supplier that expends resources for furnishing a session to a beneficiary not previously known to that supplier, unrelated to whether or not the beneficiary achieves a performance goal that results in a performance payment being paid to the subsequent supplier.

We proposed that an MDPP supplier could be paid either one performance payment for furnishing the first core session or one bridge payment per beneficiary, but not both. We proposed this policy because we believed that the potential to be paid both a performance payment for the first core session and a bridge payment, or multiple bridge payments, for the same beneficiary, could increase the risk of MDPP suppliers encouraging discontinuous care patterns. Such patterns could hinder the achievement of the required minimum weight loss that leads to a reduction in the incidence of type 2 diabetes and could lead to increased Medicare expenditures for MDPP services. Financial incentives resulting from the potential for multiple bridge payments to a single supplier for one beneficiary could lead MDPP suppliers to encourage

beneficiaries to repeatedly change among them between sessions during the MDPP services period so that the suppliers may repeatedly bill for bridge payments. We believed that limiting the bridge payment to one per beneficiary per supplier and making it available for payment only if the performance payment for the first core session was not paid to that same supplier helps mitigate this risk. However, we did not propose to limit the number of MDPP suppliers that may be paid a bridge payment for a particular beneficiary because we are not proposing to limit beneficiary freedom of choice for MDPP suppliers. We proposed only to limit the bridge payments that a particular MDPP supplier may be paid for each MDPP beneficiary to one.

Although this proposed limit was intended to provide some protection against MDPP suppliers encouraging certain care patterns for the purposes of their financial gain alone, we understood there may be organizations enrolled in Medicare as the same supplier type but under separate MDPP supplier enrollment records that are part of a larger franchise or umbrella organization with shared financial interests. We noted that there is some program integrity risk that these organizations could coordinate to bill multiple bridge payments that would ultimately increase total MDPP payments to separately enrolled MDPP suppliers to serve the financial interests of the umbrella organization. This scenario could occur if MDPP suppliers systematically encourage beneficiaries to change suppliers for the purpose of being paid the bridge payment.

Although we believed that organizations under a larger umbrella organization may have a greater financial incentive and opportunity to engage in this behavior, we understood that any two or more MDPP suppliers could coordinate in this way, potentially affecting large numbers of MDPP beneficiaries. To mitigate this risk, we proposed to prohibit MDPP suppliers and other individuals or entities performing functions or services related to MDPP services on an MDPP

supplier's behalf from unduly coercing an MDPP beneficiary's decision to change or not to change to a different MDPP supplier, including through the use of pressure, intimidation, or bribery as described further in section III.K.2.e.iv.(4) of the proposed rule (82 FR 34163 through 34164). We would monitor MDPP supplier billing patterns to detect how frequently bridge payments are paid and to determine whether patterns exists that may suggest fraudulent activity regarding bridge payment claim submissions across suppliers, conducting audits, medical reviews, and investigations as appropriate.

In the CY 2017 PFS final rule, we finalized at §410.79(b) that a beneficiary's baseline weight refers to the MDPP beneficiary's body weight recorded during that beneficiary's first core session. This definition applies to determine weight loss throughout the MDPP services period. Additionally, the once-per-lifetime policy finalized at §410.79(d)(1) applies if a beneficiary changes MDPP suppliers, and the services furnished by the subsequent supplier would begin where the beneficiary left off with the previous supplier. We recognized that these policies could require the beneficiary to request that a copy of his or her MDPP record be provided by the previous supplier to the subsequent supplier so that the subsequent supplier could determine whether the beneficiary achieves or maintains the required minimum weight loss and has information about the MDPP services already furnished. We also finalized at §424.59(b) (proposed to be redesignated and amended as §424.205(g)) that an MDPP supplier shall maintain documentation that includes services furnished and body weight measurements. Finally, we finalized at §424.59(b) (proposed to be redesignated and amended as §424.205(g)) that MDPP suppliers are required to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable privacy laws and CMS standards. Any sharing of

information from a beneficiary's MDPP record between MDPP suppliers must follow these rules, as applicable.

The proposed bridge payment was included at proposed §414.84(c). We invited public comments on this proposal and the alternative considered. The following is a summary of the public comments received on the proposals for the bridge payment, and the alternative considered and our responses:

Comment: Many commenters supported the proposal to make a bridge payment to the subsequent MDPP supplier when a beneficiary switches suppliers after receiving MDPP services from a previous supplier. The commenters stated that beneficiaries should be permitted to change MDPP suppliers during the course of the MDPP services period and, therefore, the bridge payment both supports beneficiary freedom choice to access his or her chosen DPP organization and provides some payment to the subsequent MDPP supplier enrolling the beneficiary in its DPP. The commenters claimed that the bridge payment would make a payment for some of the additional resources used by the MDPP supplier to establish the beneficiary within its DPP, as well as incentivize MDPP suppliers to take on beneficiaries midway through their MDPP services period. In contrast to this perspective, one commenter noted that bridge payments would not support continuity in the MDPP services period and have the potential to encourage fraud or "cherry-picking" of beneficiaries because beneficiaries could change MDPP suppliers at will. The commenter expressed concern that providing bridge payments would interfere with the ability of MDPP suppliers to have accurate tracking of progress through the DPP and across MA plans.

One commenter stated that although CMS proposed that only one bridge payment per MDPP supplier per beneficiary would be made, they believe that a performance payment for the

first core session and a bridge payment to the same MDPP supplier may be needed under some circumstances, as well as two bridge payments to an MDPP supplier for an MDPP beneficiary under other circumstances. The commenter described the example of a beneficiary who enrolls with an MDPP supplier in Colorado, moves to Florida for the winter where the beneficiary continues MDPP services with another MDPP supplier in that state, and then returns to Colorado and wants to complete the DPP with the first MDPP supplier. The commenter pointed out the under the proposal, the Florida MDPP supplier would receive a bridge payment while the Colorado MDPP supplier would not, despite the need for the Colorado supplier to reengage the beneficiary when the beneficiary returned to Colorado after spending the winter in Florida. Therefore, the commenter urged CMS to allow a performance payment for the first core session and a bridge payment to be made for a single MDPP beneficiary to an MDPP supplier, as well as to allow two bridge payments per beneficiary per supplier to be made.

One commenter who expressed concern about the amount of switching between MDPP suppliers that could occur during a beneficiary's 36-month long MDPP services period urged CMS to limit changing suppliers to no more than two switches per beneficiary during any 1 year of the MDPP services period. Another commenter requested that CMS clarify how it will track how many times beneficiaries switch MDPP suppliers and whether there would be any limit on the number of times a beneficiary could switch MDPP suppliers.

Response: We appreciate the support of many of the commenters for our proposal to make one bridge payment per beneficiary per MDPP supplier during the MDPP services period. As we clarified in the CY 2017 PFS final rule (81 FR 80470), beneficiaries will be able to change MDPP suppliers at any time in order to ensure beneficiary freedom of choice of supplier under the MDPP expanded model.

Given this established policy which allows beneficiaries to change MDPP suppliers at any time during the MDPP services period, our bridge payment proposal was intended to partially account for the financial risk a subsequent MDPP supplier takes on by furnishing services to a beneficiary changing MDPP suppliers during the MDPP services period. We appreciate the concerns of the commenter about the potential for beneficiaries to change MDPP suppliers at will, thereby reducing continuity of care and the ability of MDPP suppliers to track the progress of MDPP beneficiaries in their DPPs. However, we understand from many commenters that beneficiaries switching MDPP suppliers during the MDPP services period may occur for a variety of reasons, including the relatively frequent circumstances where beneficiaries reside seasonally in different areas of the country. Therefore, we continue to believe that providing one bridge payment per beneficiary per MDPP supplier of $25 does not financially incentivize MDPP suppliers to encourage unnecessary switching but, instead, responds to the needs of beneficiaries and MDPP suppliers by reducing potential barriers to switching.

Furthermore, we expect that our different payment policies for core sessions, core maintenance session intervals, and ongoing maintenance session intervals that rely upon attendance at several sessions within a period of time and for weight loss performance payments will encourage the transfer of MDPP beneficiary records from a previous supplier to the subsequent supplier, which should facilitate continuity of care throughout the beneficiary's MDPP services period. For example, in order for a subsequent MDPP supplier to bill for a weight loss performance payment, to bill correctly for a core maintenance session interval performance payment, or to determine a beneficiary's eligibility for coverage and payment of an ongoing maintenance session interval, the subsequent MDPP supplier will need to acquire the

MDPP beneficiary record from the previous supplier to have documentation of the beneficiary's baseline weight. In addition, in order to bill for an interval performance payment that requires attendance at multiple sessions and fully reflects the beneficiary's session attendance, the subsequent MDPP supplier will need to acquire the MDPP beneficiary record from the previous supplier to have documentation of sessions furnished by that supplier that count towards achievement of the attendance performance goal for the interval performance payment that will be billed by the subsequent MDPP supplier.

In response to the commenter who presented a scenario where one supplier furnished MDPP services to a beneficiary, the beneficiary then switched to a subsequent supplier that furnished sessions and was paid a bridge payment, and the beneficiary then switched back to the first MDPP supplier, we do not believe it would be appropriate to make a bridge payment to the first supplier in this scenario. We do not believe the financial risk or the supplier resources required for the first supplier to resume accountability for a beneficiary's MDPP services when that supplier already has a relationship with the beneficiary are so substantial that making a bridge payment to the first supplier would be appropriate, given that the first supplier would already have been paid the performance payment for the beneficiary's first core session. In addition, financial incentives resulting from the potential for two (or more) bridge payments to a single supplier for one beneficiary could lead MDPP suppliers to encourage beneficiaries to unnecessarily change among them between sessions during the MDPP services period so that the suppliers may bill for bridge payments. We believe that limiting the bridge payment to one per beneficiary per supplier and making it available for payment only if the performance payment for the first core session was not paid to that same supplier helps mitigate this risk.

We also do not believe it would be appropriate to limit the number of times a beneficiary can switch MDPP suppliers during the MDPP services period in order to preserve beneficiary access to care and freedom of choice. We further believe that our final methodologies for performance payments and bridge payments do not incentivize beneficiaries to change MDPP suppliers nor MDPP suppliers to encourage beneficiaries to switch suppliers. While beneficiaries have full freedom of choice of MDPP suppliers during the MDPP services period, MDPP beneficiaries have no incentive under the policies of the MDPP expanded model itself to change MDPP suppliers during the MDPP services period. Furthermore, because we are limiting our bridge payment to only one per MDPP beneficiary per MDPP supplier that has not already received a performance payment for the first core session, MDPP suppliers do not have a financial incentive to encourage beneficiaries to unnecessarily change among them between sessions during the MDPP services period so that the suppliers may bill for bridge payments. Finally, as discussed in section III.K.2.d.iii.(10)(c) of this final rule, we are finalizing a HCPCS G-code for the bridge payment that will be submitted on a claim to CMS for the first session furnished by the subsequent supplier to an MDPP beneficiary who has previously received one or more MDPP services from a different MDPP supplier. Therefore, we will be able to obtain information about the number and pattern of beneficiaries switching MDPP suppliers during the MDPP services period from our analysis of administrative claims data.

Comment: Several commenters urged CMS to increase the proposed bridge payment amount of $25 because they believe it underestimates the amount of time and resources an MDPP supplier would need to spend to onboard a beneficiary to a subsequent MDPP supplier. One commenter claimed that successful transition of an individual from one MDPP supplier to another would require individual communication and research on the beneficiary's participation

to date, production of new materials, and more administrative time than would be covered by the proposed bridge payment amount. The commenters requested that the bridge payment amount be increased to accurately reflect the time and effort of the subsequent MDPP supplier required for transitioning an MDPP beneficiary to that supplier.

Response: We appreciate the information provided by the commenters about the subsequent MDPP supplier resources that would be required for a successful transition of an MDPP beneficiary from one MDPP supplier to a subsequent MDPP supplier. We understand that the subsequent MDPP supplier will need to gather information about the beneficiary's participation to date in MDPP services, including obtaining the beneficiary's MDPP records from the previous supplier, in order to furnish the appropriate sessions and curriculum to the beneficiary.

However, we continue to believe a bridge payment in the amount of $25 is appropriate for the MDPP expanded model. While we acknowledge based on the commenters' description that the activities and resources required for a subsequent MDPP supplier to enroll an MDPP beneficiary in its DPP are somewhat different from those of the previous MDPP supplier that furnished the MDPP beneficiary's first core session, we continue to believe there is sufficient similarity between furnishing the first core session in the MDPP services period and furnishing the first session to an MDPP beneficiary who has previously received MDPP services from another supplier that the payment amounts should be the same.

We note that as discussed in section III.K.2.d.iii.(3) of this final rule, we are finalizing $25 as the performance payment for the first core session. In addition, as discussed in section III.K.2.d.ii. of this final rule, we are paying for the set of MDPP services through a performance-based payment methodology that makes periodic performance payments to MDPP suppliers

during the MDPP services period. The aggregate of all performance payments constitutes the total performance-based payment amount for the set of MDPP services. The subsequent MDPP supplier, like the previous MDPP supplier, will have the opportunity to be paid performance payments based on where the beneficiary is in the MDPP services period when the beneficiary enrolls with the subsequent MDPP supplier and on the performance goals achieved by the beneficiary which receiving MDPP services from the subsequent supplier. The aggregate of the bridge payment and performance payments to the subsequent supplier will constitute the total performance-based payment amount for the MDPP services furnished to the MDPP beneficiary by the subsequent MDPP supplier.

Comment: Several commenters requested that CMS clarify how the performance payments would be made when a beneficiary switches MDPP suppliers during the MDPP services period, expressing concern about the adequacy of payment depending on the timing of the switch. A number of commenters provided the example of a beneficiary switching from supplier A to supplier B during the ongoing services period, after the beneficiary has already met the required minimum weight loss and many of the available performance payments have already been made to supplier A. The commenters noted that supplier B would then be responsible for offering ongoing maintenance sessions throughout the ongoing services period, which would require the use of supplier B's capital for which the remaining performance payments that may be made for MDPP services furnished to the beneficiary by supplier B may not be sufficient.

One commenter requested clarification about a specific scenario where the commenter was concerned that supplier B's payment could be penalized when a beneficiary switches suppliers. In the example presented by the commenter, the beneficiary attends 16 core sessions

(months 1 to 6) with supplier A and achieves and maintains the required minimum weight loss. The beneficiary transfers to supplier B closer to her home and, in transferring, misses the first monthly (month 7) core maintenance session, but then attends 3 sessions (months 8 to 10) in a row. The commenter requested that CMS clarify if supplier B would still receive a bridge payment, since the month 7 session was not attended. The commenter further requested that CMS provide information about whether supplier B would be paid for the full second core maintenance session interval if the beneficiary completes 3 sessions in months 11 to 13; whether supplier B should bill only for months 10 to 12; or whether performance payments for core maintenance sessions intervals would not be made to supplier B because the beneficiary did not attend the month 7 session.

Response: With respect to the commenters concerned about MDPP suppliers having sufficient capital to offer ongoing maintenance sessions to beneficiaries who switch suppliers during the ongoing services period after most performance payments have been made, we believe the bridge payment provides appropriate payment for the first ongoing maintenance session furnished to the beneficiary by the subsequent supplier. The subsequent supplier then must offer ongoing maintenance sessions in accordance with the beneficiary's coverage of ongoing maintenance session intervals and will be paid ongoing maintenance session interval performance payments if the beneficiary achieves the performance goals of attendance and maintenance of the required minimum weight loss for the interval.

Because the beneficiary has already achieved the required minimum weight loss and ongoing maintenance sessions must only be offered monthly to the beneficiary, we do not believe that the resources used by the subsequent supplier are so substantial that subsequent suppliers will be unable to offer these sessions to beneficiaries. An MDPP beneficiary who has

achieved the required minimum weight loss will already be knowledgeable about the health behavior changes taught in MDPP sessions and will have experienced success incorporating these changes in a meaningful way in his or her own life such that weight loss results. Thus, we expect that subsequent MDPP suppliers offering monthly sessions to these beneficiaries during the ongoing services period will not have to work particularly hard to engage these beneficiaries. In addition, the subsequent MDPP supplier knows they will be paid a bridge payment for the first session furnished and they may also be paid ongoing maintenance session interval performance payments if the beneficiary meets the performance goals for those payments in the future.

In the specific scenario where the beneficiary transfers to subsequent supplier B and misses the month 7 core maintenance session but resumes attending monthly sessions in month 8, supplier B can bill the bridge payment for its first session furnished to the beneficiary, which would be the month 8 core maintenance session. With respect to the beneficiary's month count that defines the core maintenance session interval in the core services period, that does not change based on when the beneficiary attends core maintenance sessions furnished by any MDPP supplier. Therefore, the beneficiary's core maintenance session intervals would always be months 7 to 9 and months 10 to 12 from the date the first core session was furnished to the beneficiary by supplier A.

As finalized in section III.K.2.d.iii.(4) of this final rule, we are adopting a 2-session attendance performance goal for the core maintenance session interval performance payment. Therefore, in the specific scenario described by the commenter where the beneficiary switches suppliers and does not attend any core maintenance session in month 7, but attends core maintenance sessions in months 8 and 9 furnished by supplier B, in addition to the bridge payment to supplier B, supplier B would also bill and be paid for the appropriate HCPCS G-code

for the first core maintenance session interval (months 7 to 9) based on whether or not the required minimum weight loss was maintained (in the commenter's scenario, the required minimum weight loss was achieved with supplier A prior to month 7, and 2 core maintenance sessions were furnished by supplier B in months 8 and 9). Similarly, and regardless of the beneficiary's attendance at core maintenance sessions in months 7 to 9, supplier B would bill and be paid for the appropriate HCPCS G-code for the second core maintenance session interval (months 10 to12) if the beneficiary attends at least 2 sessions furnished by supplier B in that 3-month period and the interval performance payment amount would be based on whether or not the required minimum weight loss was maintained.

After considering the public comments received, we are finalizing the proposals, without modification, for the bridge payment at §414.84(c).

In the proposed rule (82 FR 34155), we also discussed ways to streamline the sharing of information between suppliers about a beneficiary's progress in the MDPP services period when a beneficiary switches suppliers, such as through the development of a model tracker that logs the contact information of a beneficiary's previous supplier and/or coach, and the beneficiary's attendance and weight loss. Beneficiaries could take the tracker with them if they change suppliers during the MDPP services period. Such a tracker would not supplant the previous supplier's beneficiary MDPP record which the subsequent supplier would need to have a copy of in order to consider sessions furnished by the previous supplier in determining whether the subsequent supplier could bill for a performance payment that was based in part on those prior sessions as discussed in section III.K.2.d.iii.(10)(b) of the proposed rule (82 FR 34148 through 34149). If the subsequent supplier did not have the beneficiary's MDPP record from the previous supplier, the subsequent supplier could not use information from the sessions furnished

by the previous supplier, such as weight or session attendance, to determine that the performance goals for a performance payment were met so that the subsequent supplier could bill for the performance payment. However, it might help facilitate the process for subsequent suppliers to enroll beneficiaries partway through the MDPP services period while the subsequent supplier is coordinating with the previous supplier to obtain a copy of the beneficiary's MDPP record from that supplier. We invited public comments on additional ways this data sharing could be streamlined between suppliers.

The following is a summary of the public comments received on additional ways information sharing could be streamlined between suppliers regarding beneficiaries switching MDPP suppliers during the MDPP services period and our responses:

Comment: Several commenters claimed that switching among MDPP suppliers may be more common than CMS appeared to have anticipated in the proposed rule discussion about bridge payments. They expressed concern about the operational implications of managing the MDPP services period for Medicare beneficiaries across hundreds of MDPP suppliers when MDPP beneficiaries change suppliers, circumstances that the commenters speculated may lead to disruptions for the beneficiary and added cost for the MDPP supplier.

The commenters requested that CMS provide greater detail on how the handoff between an MDPP beneficiary's current MDPP supplier to a subsequent MDPP supplier should occur when a beneficiary changes suppliers. Specifically, they sought additional written guidance on the required information to be transmitted and the format and method of transmission in order for a proper transition of a beneficiary from one MDPP supplier to the subsequent MDPP supplier to occur, especially given their expectation that transitions may be common for Medicare beneficiaries who live in different locations in the summer and winter months. The commenters

urged CMS to provide this guidance to avert potential HIPAA issues when transferring protected health information among MDPP suppliers, especially when many MDPP suppliers will be new to the healthcare environment and lack prior experience with performing HIPAA compliant transfers.

While several commenters described a number of challenges related to the transfer of beneficiary information between MDPP suppliers and requested additional guidance from CMS, one commenter presented an approach to facilitating the transfer of information that would be based on encouraging beneficiaries to switch among MDPP suppliers within a supplier network that uses a shared data-management solution. The commenter reported that there are several DPP organizations all around the country that use a single data platform. They suggested that DPP organizations within a single supplier network could develop a simple process within their current platform that would allow the MDPP services information to be transferred from one supplier to another within the supplier network. The commenter claimed that this approach would be more secure and less costly than CMS developing a comprehensive database or having individual MDPP suppliers transfer beneficiaries' MDPP records to other MDPP suppliers via fax or mail. However, they acknowledged that this approach could result in other concerns, such as favoring supplier networks, and further noted that there are areas of the country that even these larger supplier networks do not reach, which would result in the need for a backup solution for information transfer.

Response: We appreciate the commenters raising issues related to information transfer when MDPP beneficiaries switch suppliers during the MDPP services period, and in particular for suggesting potential solutions to mitigate the challenges in this regard under the policies of the MDPP expanded model. We recognize that given the maximum 24-month long duration of

the MDPP services period, MDPP suppliers should anticipate and prepare for beneficiaries switching between suppliers.

We appreciate that certain networks have independently worked towards use of a single data platform by all DPP organizations in the network that could facilitate the transfer of MDPP services information for beneficiaries who may switch among suppliers in a single network.

While we are not adopting any specific MDPP beneficiary information transfer policies or data systems at this time, we acknowledge the concerns raised by the commenters about subsequent MDPP suppliers having correct and timely information about MDPP beneficiaries enrolling in the subsequent supplier's DPP in the middle of the MDPP services period, given our policy that allows full beneficiary freedom of choice of MDPP supplier. As discussed in more detail in section III.K.2.c.iii of this final rule, we are exploring using existing CMS systems for MDPP suppliers to verify beneficiaries' use of prior MDPP services and plan to provide additional information on this mechanism in future guidance, as appropriate. However, this eligibility check will not supplant the need for MDPP suppliers to maintain documentation as described at §424.205(g). We note that health care providers often exchange clinical data when their patients seek care from different providers, and we do not view the need for subsequent MDPP suppliers to obtain beneficiary-level MDPP services data from a previous MDPP supplier as a unique circumstance.

We remind subsequent MDPP suppliers that in order to submit a claim for a performance payment under the MDPP expanded model, the billing supplier must have documentation in the beneficiary's MDPP record that all requirements, including the achievement of the performance goal(s) applicable to the performance payment, have been met. The billing supplier's MDPP record for the beneficiary may include a copy of the beneficiary's MDPP record from a previous

MDPP supplier that has been provided to the billing supplier at the request of the MDPP beneficiary. If an MDPP supplier is submitting a claim for a performance payment based on the achievement or maintenance of the required minimum weight loss or an interval performance payment based on attendance at more than one session, the copy of the MDPP record from the previous MDPP supplier may be used as part of the billing supplier's documentation demonstrating that the attendance or weight loss performance goal for the performance payment was achieved.

In terms of how MDPP suppliers transfer beneficiary data in a HIPAA-compliant manner, we recommend that MDPP suppliers consult with counsel to determine whether they qualify as a HIPAA-covered entity, and, if so, how to manage and transfer data appropriately based on applicability of HIPAA, other applicable state and federal privacy laws, and CMS standards as required. Resources already exist to help provide guidance on these issues and are available at https://www.hhs.gov/hipaa/for-professionals/index.html and https://www.healthit.gov/providers-professionals/ehr-privacy-security.

e. Supplier Enrollment and Compliance

i. Preliminary Recognition

The current CDC 2015 Diabetes Prevention Recognition Program (DPRP) Standards do not have standards for preliminary recognition. In the CY 2017 PFS final rule, we indicated that we would align the CDC's DPRP Standards and the set of MDPP services, to the extent possible. It will not be possible for CMS to permit DPP organizations to enroll as MDPP suppliers based on achievement of any new CDC standard through this rulemaking because any updates to the CDC Standards are not expected to go into effect until 2018.

However, our intent is to allow organizations that do not yet have full recognition, but have demonstrated a capacity to furnish DPP services, to enroll in Medicare as of the effective date of the enrollment policies in this rule. We believe this will increase access to MDPP services. For this reason, we proposed, at §424.205(c), to establish an MDPP interim preliminary recognition standard to permit DPP organizations who meet this standard to enroll in Medicare even if they do not have full CDC recognition. This MDPP interim preliminary recognition standard will be hereafter referred to as "interim preliminary recognition." As we stated in CY 2017 PFS final rule, our intent with this policy is to bridge the gap until such time as any CDC preliminary recognition standards are established following publication of the their DPRP Standards in 2018. Once we have established the transition process with CDC, we would expect DPP organizations that seek to enroll into Medicare to obtain CDC preliminary recognition, but MDPP suppliers who have enrolled in Medicare with interim preliminary recognition would maintain their enrollment eligibility as an MDPP supplier.

(1) MDPP Interim Preliminary Recognition Standard

We proposed, at §424.205(c)(1)(ii)(B), that DPP organizations with pending CDC recognition that meet the following additional criteria would meet the interim preliminary recognition standard:

- The organization must continue to follow the current 2015 CDC DPRP Standards for data submission and submit a full 12 months of performance data to CDC on at least one completed cohort (see Appendix D, 2015 CDC DPRP Standards, https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf). For this purpose, a completed cohort is a set of participants that entered into a lifestyle change program that has a fixed first

and last session and runs for 12 months. An organization can have multiple cohorts running at the same time:

- The 12-month data submission to CDC includes at least 5 participants who attended at least 3 sessions in the first 6 months, and whose time from first session attended to last session of the lifestyle change program was at least 9 months; and
- Of the participants eligible for evaluation in the first criterion, at least 60 percent attended at least 9 sessions in months 1 through 6 and at least 60 percent attended at least 3 sessions in months 7 through 12.

All data requirements reflect current reporting requirements to progress from pending recognition to full recognition through CDC's DPRP; no new data collection would be required.

To implement the interim preliminary recognition standard, DPP organizations with pending recognition would submit data following CDC's typical recognition process. For the current standards, this includes data submission every 12 months, during the month of the anniversary of the effective date. The organization's data submission should include: (1) data for all sessions attended by participants from the approval date to the day before the first anniversary of the effective date, (if the organization has a 2016 effective date; this should include at least 6 months of participant data) *or* data for all sessions attended by participants from the last anniversary of the effective date to the day before the next anniversary of the effective date (if an organization's effective date is before 2016); and (2) one record for each session attended by each participant during the preceding year. CDC would perform a new assessment, interim preliminary recognition, on our behalf. Our interim preliminary recognition will be evaluated by CDC based on those data submissions that use the timetables and submission deadlines that currently apply for CDC recognition. For interim preliminary recognition governed under this

regulation, CDC would provide us with its recommendation as to which organizations have met the recognition standards for interim preliminary recognition, but we, using our authority, would make the final decision. CMS would not make any determination for recognition status governed under current or future CDC DPRP recognition processes. We believe that such an approach would minimize burden for DPP organizations, promote consistency in the application of the standards, and allow for a smooth transition if and when CDC adopts preliminary recognition standards. We intend to release additional guidance on the details of this process once the CDC 2018 Standards are released.

(2) MDPP Supplier Enrollment under the MDPP Interim Preliminary Recognition Standard

Our regulations at §424.59 (redesignated and amended at §424.205 in this final rule) specify that a DPP organization with full CDC recognition is eligible for enrollment as an MDPP supplier if it also meets all of the other conditions for enrollment in §424.59(a) (redesignated and amended at §424.205(b) in this final rule). We proposed that organizations that meet the MDPP interim preliminary recognition standard, in section III.K.2.e.i.(1) of this final rule, and meet all other enrollment conditions would also be eligible to enroll as an MDPP supplier.

We also proposed that DPP organizations would be eligible to enroll as an MDPP supplier if they meet CDC DPRP Standards for preliminary recognition, once any such standards go into effect (§424.205(c)(2)(i)). We anticipate that CDC's preliminary recognition standards will be established on or after January 1, 2018. After the effective date of any updated CDC standards, we proposed that MDPP suppliers who have enrolled in Medicare with MDPP interim preliminary recognition would continue to be eligible for MDPP enrollment (assuming they continue to meet all other requirements for enrollment, described in §424.205(b)). We intend to ensure that any transition an MDPP supplier may make from interim preliminary recognition to

CDC preliminary recognition does not disrupt its status as an MDPP supplier. We will address possible transition issues in future rulemaking or guidance, as appropriate.

We considered an alternative to wait until new CDC DPRP Standards are effective to allow organizations other than those with full recognition to enroll as MDPP suppliers. However, as indicated in the CY 2017 PFS final rule, based on CDC data we believe that waiting until the new DPRP Standards are effective would limit the number of organizations with demonstrated capacity to furnish the set of MDPP services from enrolling in Medicare when enrollment starts and offering MDPP services once they become effective. We invited public comments on this MDPP interim preliminary recognition standard, including performance standards, and the use of this standard as a condition for enrollment in Medicare, and the alternative considered.

The following is a summary of the public comments received on the MDPP interim preliminary recognition standard, including performance standards, and the use of this standard as a condition for enrollment in Medicare proposal and the alternative considered and our responses:

Comment: The majority of commenters supported requiring MDPP organizations to obtain CDC DPRP Recognition, including any preliminary recognition standard CDC finalizes and interim preliminary recognition. Commenters appreciated the provision of more information on the proposed interim preliminary recognition standard and noted the importance of having the interim preliminary recognition process in place to increase the capacity of MDPP.

A commenter requested that a master database of those organizations that meet this new standard be made publicly available well in advance of the effective date of when MDPP services can be delivered and payments made to give suppliers more time to appropriately arrange for the MDPP on behalf of its members.

Response: We appreciate and acknowledge the need for both beneficiaries and clinicians to have access to information on MDPP enrolled suppliers. We note that the CDC currently publishes a registry of recognized DPP organizations online (https://nccd.cdc.gov/ddt_dprp/registry.aspx). We intend to make information on MDPP suppliers enrolled for the purposes of the MDPP expanded model publicly available through a website and intend to release guidance, as appropriate, on where this information will be located.

Comment: There was agreement among some commenters that DPP organizations that have applied for CDC recognition and have delivered the program for at least 12 months are more likely to demonstrate commitment and results to offer MDPP services. However, several commenters expressed concern about the interim preliminary recognition requirement to submit 12 months of data to CDC because their communities do not collect the data when there is no support or funding for this type of program. They also commented that a majority of partnering programs lack awareness of the process, the criteria, and the period of time it takes programs to become CDC-recognized. Another commenter requested that individuals included in the data set should attend four sessions, and not three, in months 1-6 to better align with scientific literature about CDC's threshold of four or more sessions attended as well as previous and current DPRP standards. For an example, the commenter noted, there is a body of knowledge within organizations and in the scientific literature about CDC's threshold of four or more sessions attended and that it does not make sense to change this threshold, especially when there is lack of data (none was provided by CMS or CDC's DPRP in their proposed 2018 standards) to support the change. Finally, we received a comment recommending that interim preliminary recognition be phased out over time as CDC updates its standards and the program matures.

Response: We acknowledge that it may be difficult for some organizations that need financial support while they are collecting data to obtain CDC DPRP Recognition. We understand from our coordination with CDC that some organizations obtain financial support from grants through various sources and that there are currently over 100 payers and/or employers offering coverage for the National DPP in selected markets. Despite the time and resources it takes to achieve CDC recognition, we continue to believe the MDPP preliminary recognition standard is an appropriate minimum standard for DPP organizations to obtain prior to enrollment as an MDPP supplier.

To increase awareness of the process, the criteria, and the period of time it takes programs to become CDC-recognized and then implement MDPP, we intend to provide MDPP supplier support through webinars and other types of guidance and education tools. We will continue to coordinate with CDC to provide relevant resources regarding both CDC recognition as it relates to the MDPP expanded model for organizations preparing to become MDPP suppliers.

We disagree that there is a lack of data about the inclusion of individuals who attend 3 sessions (versus 4) as part of the DPRP data submission. CDC DPRP data show no difference in average percent weight loss for those who attend 3 sessions compared to 4, and therefore we believe including participants who have attended at least 3 sessions as compared to 4 will provide data to make an appropriate assessment for the purposes of MDPP preliminary recognition. Furthermore, by allowing organizations to submit data on individuals who have attended 3 sessions (versus 4), we are increasing the number of organizations who are potentially eligible to achieve interim preliminary recognition.

In response to the comments about phasing out interim preliminary recognition as CDC updates its Standards, we reiterate our intent to align data requirements with CDC Standards. The proposed CDC 2018 Standards include the same requirements for CDC preliminary recognition as we proposed for interim preliminary recognition[41]. As described in section III.K.2.e.i.2 of this final rule, after the effective date of these updated CDC Standards, MDPP suppliers who have enrolled in Medicare with interim preliminary recognition would continue to be eligible for MDPP enrollment (assuming they continue to meet all other requirements for enrollment, described in §424.205(b)). We intend to phase out interim preliminary recognition and ensure that any transition an MDPP supplier may make from interim preliminary recognition to CDC preliminary recognition does not disrupt its status as an MDPP supplier. We will address possible transition issues in future rulemaking or guidance, as appropriate.

Comment: One commenter raised concerns about what would happen to beneficiaries whose MDPP suppliers lost their MDPP supplier status due to loss of CDC DPRP recognition and recommended allowing organizations who move from "preliminary" to "pending" after 24 months to continue to serve MDPP participants but not be able to enroll any new beneficiaries. If after the 12 months of work to improve outcomes the organization is not successful, then at least the beneficiary would be through the first year of the program and would move to a new supplier for ongoing maintenance.

Response: Last year, we finalized in §424.59(d) that the loss of CDC DPRP recognition will result in revocation of a supplier's MDPP billing authority. An example of when this might happen is when an organization is unable to meet the requirements for full recognition after having been in MDPP preliminary recognition for 24 months. In this rule, we maintained the

[41] https://www.gpo.gov/fdsys/pkg/FR-2017-07-14/pdf/2017-14792.pdf.

policy, but modified the language to take into account the addition of interim preliminary recognition, such that, if an MDPP supplier does not satisfy any of the enrollment requirements (finalized at §424.59(a) and proposed to be redesignated and amended at §424.205(b)), which include having preliminary or full recognition, their enrollment would be revoked (proposed at §424.205(h)(1)(i)(B).

We disagree that allowing MDPP suppliers whose MDPP billing authority has been revoked should still provide MDPP services to beneficiaries. When their supplier's MDPP billing authority has been revoked beneficiaries may switch to a new MDPP supplier so they can complete their program.

Comment: Regarding interim preliminary recognition and CDC preliminary recognition, a commenter recommended that we should allow organizations to submit for preliminary recognition when the first year of data are collected, on a rolling basis. For an example, with the new standards requiring data submissions every 6 months, the commenter noted that organizations starting their program in the first 5 months of the program would be punished by waiting until they were 18 months into the program, which is when their next data reporting submission would occur. Another commenter noted that while the current interim preliminary recognition standard focuses on the attendance of the DPP cohort, there is no performance metric associated with the criteria.

Response. In response to the comment about timing of the 12-month data submission for preliminary recognition, the commenter is correct that it is possible that an organization may not have a full 12 months' worth of data needed for preliminary recognition at the 12-month data submission point. In this case, organizations could submit the 12 months of data needed for preliminary recognition at the next 6-month data submission interval, or 18 months from their

effective date, to achieve preliminary status. The interim preliminary recognition finalized in this rule represents a new category of recognition that does not include a weight loss requirement and provides an intermediate step on the path to full recognition. We believe the time it takes to achieve interim preliminary recognition is reasonable since it has reduced the amount of time it may take an organization initiating the CDC recognition process to enroll as an MDPP supplier from 36 months (full recognition) to 12-18 months (MDPP interim preliminary recognition).

In response to the comment regarding establishing a performance metric for interim preliminary recognition, we proposed standards for interim preliminary recognition (which are the same standards CDC has proposed for preliminary recognition in their 2018 DPRP standards) that rely on attendance based measures, not weight loss. We discussed in the CY 2017 PFS final rule (section III.J.7.b of this final rule) that we believed that full recognitions status, which relies on weight loss measures, would be challenging for many organizations to meet initially and, without broadening the eligibility for an MDPP supplier to enroll, we may limit the number of MDPP suppliers available for beneficiaries to access MDPP services. We continue to believe the standards we are finalizing for interim preliminary recognition will adequately assess DPP organizations' capacity to become MDPP suppliers, and thereby increase the numbers of eligible organizations that beneficiaries can access for MDPP services.

Updates to the CDC Standards are not expected to go into effect until 2018, and we are working closely with CDC on maintaining our alignment between interim preliminary recognition and its proposed standards in the 2018 DPRP Standards.

Comment. Some commenters requested that the Special Diabetes Program for Indians (SDPI) Diabetes Prevention (DP) program be certified as grandfathered in to provide services

and receive reimbursement through the MDPP given that it continues to achieve similar results as the National Institutes of Health DPP lifestyle intervention group.

Response. For the purpose of the MDPP services, CDC-recognition is being used for supplier eligibility because the Secretary's determination to expand the DPP model test was based on the CDC-approved program. Consequently, we are not considering other accrediting bodies or standards at this time, nor are we considering grandfathering in programs so they can receive payments for MDPP services without meeting the standards finalized in this rule or finalized in the CY 2017 PFS final rule.

We acknowledge the major contributions of the Special Diabetes Programs for Indians (SDPI) Diabetes Prevention Program (DPP) Demonstration Projects and the many resources—such as the SDPI Diabetes Prevention Toolkit—insights, and lessons learned these projects have contributed on both a local and national level. However, we decline grandfathering in the SDPI programs and making an exception to the MDPP requirements. We do not believe a separate type of recognition can be created for SDPI programs without compromising our intent to rely on the CDC's DPRP. Through the DPRP, CDC is responsible for carrying out a quality assurance function at the national level. Under the CDC's DPRP, we will enroll CDC-recognized organizations that are standardized in delivering the evidence-based behavior change program with quality and fidelity to the original science and subsequent translation studies achieving the outcomes proven to prevent or delay onset of type 2 diabetes. The nine requirements in the DPRP Standards apply equally to all organizations that apply for CDC recognition, regardless of size, experience, capacity, or populations served. We know from CDC that DPRP data collected to date indicate that all types of organizations are successful in achieving full recognition, and

that CDC could not meet its obligation to ensure quality of recognized organizations enrolling as MDPP suppliers if each organization was allowed to use a different set of measures.

We recommend that tribal organizations work with CDC to help tribal organizations offering the SDPI lifestyle change program, meet the DPRP Standards set by CDC. We welcome continued consultation with tribes and tribal organizations as required by the CMS Tribal Consultation Policy.[42]

Comment: While unrelated to the specific proposed policy on preliminary recognition and supplier enrollment, we received several comments regarding our previously finalized proposal in the CY 2017 PFS final rule to require Medicare-enrolled suppliers to furnish MDPP services. One commenter expressed uncertainty as to whether the Medicare enrollment requirement in the CY 2017 PFS final rule created a new requirement for all Medicare Advantage providers and suppliers to be enrolled in Medicare by January 1, 2019. This commenter further inquired whether this requirement would apply to coaches and other personnel or suppliers who may provide MDPP services, noting that this requirement would be burdensome if applied to MDPP and should be lifted for MDPP services.

Response: While we did not propose any new policies related to the requirement for any organization seeking to furnish and receive payment for MDPP services to enroll as an MDPP supplier, we are responding to comments regarding enrollment and Medicare Advantage to clarify this issue. Regarding commenter's recommendation to lift the requirement that coaches who provide MDPP services be Medicare-enrolled, we clarify the requirements of coaches who provide MDPP services to beneficiaries. In the CY 2017 PFS final rule, we finalized the

[42] 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.

requirements for coaches furnishing MDPP services and established that coaches will not enroll in Medicare for purposes of furnishing MDPP services, but that they would be required to obtain NPIs (81 CFR 80479).

Regarding other commenters' recommendations to lift the requirement that suppliers who provide MDPP services be Medicare-enrolled, we decline to adopt the commenters' proposals to eliminate the Medicare enrollment requirement for MDPP supplier-MAOs or for MDPP suppliers with whom MAOs contract to furnish MDPP services. In the CY 2017 PFS final rule, we also finalized the requirement that CDC-recognized organizations that will bill Medicare for MDPP services must enroll in Medicare as MDPP suppliers. MAOs must comply with 42 CFR part 422, subpart E in their relationships with providers; regulations in that subpart generally prohibit employing or contracting with individuals who are excluded from Medicare and require MA organizations to provide basic benefits (that is, Part A and Part B services) only through health care providers that meet the applicable requirements of Title XVIII. We previously issued guidance following the CY 2017 PFS final rule in a November 23, 2016 HPMS guidance memo that we now reiterate. In that HPMS memo, we established that, in order to provide MDPP services, a Medicare health plan such as an MA plan, may choose to contract with an organization that is Medicare-enrolled as an MDPP supplier, or become Medicare-enrolled as an MDPP supplier itself. MA plans that choose to contract with outside Medicare-enrolled MDPP suppliers should follow their normal protocols in accordance with applicable regulations. Medicare health plans that choose to become Medicare-enrolled MDPP suppliers are subject to the supplier enrollment eligibility requirements finalized in this final rule at §424.205.

Comment: One commenter pointed out that for a Medicare Advantage Organization with an MA plan that is part of an integrated system with pending CDC-recognition, the Medicare-

enrollment requirement would interfere with the MAO's ability to contract with providers with which the MAO has existing risk-based relationship that can be aligned with the MAO's incentives with providers.

Response: As stated previously in this section, we finalized the requirement that CDC-recognized organizations that will bill Medicare for MDPP services must first enroll in Medicare as MDPP suppliers. This policy was followed by an HPMS memo that reiterated that, in order to provide MDPP services, a Medicare health plan such as an MA plan, may choose to contract with an organization that is Medicare-enrolled as an MDPP supplier, or become Medicare-enrolled as an MDPP supplier itself. In response to this commenter's concern related to MAOs that operate MA plans as part of an integrated network, where an MA plan is part of such a network and is either not interested in enrolling in Medicare as an MDPP or supplier or has not yet achieved the CDC-recognition required to enroll in Medicare, there is no Medicare prohibition that would prevent an MA plan from contracting with Medicare-enrolled MDPP suppliers under terms that would integrate these suppliers into the existing network or impose risk-based relationships on the newly contracted supplier.

Comment: We received several comments expressing concern about a given MA plan's ability to meet network adequacy requirements based on the number of organizations that are currently eligible to enroll in Medicare as MDPP suppliers (which requires CDC recognition). Commenters noted that some geographic locations may not have an MDPP supplier with which an MA plan may contract to provide MDPP services to its enrollees by the proposed effective date of April 1, 2018. Under these circumstances, commenters noted that eligible beneficiaries may not find these travel distances feasible or safe and that it is unlikely that coaches will be able to regularly travel hundreds of miles to a class. One commenter noted that, while there are

organizations currently in the process of obtaining CDC recognition, the state of Utah is currently without any CDC-recognized organization that has advanced beyond pending status. This commenter additionally noted that there is currently no way of knowing which organizations will achieve preliminary recognition status in time for an MA plan to establish contracts by the April 1, 2018 start date. We also received comments that specifically recommended that CMS relieve MA plans of the requirement to submit network adequacy information and include MDPP-qualified providers in network adequacy reviews for the same reasons stated above related to the perceived lack of MDPP suppliers to meet these requirements.

Response: In response to concerns expressed by MAOs regarding their ability to meet network adequacy standards for MA plans, we note that when a particular provider-type or facility-type (such as MDPP suppliers) is absent from a service area, an MA plan must provide enrollees with a level of access to Medicare-covered services that is consistent with prevailing community patterns of care under §422.112(a)(10). As part of its evaluation of network adequacy in connection with this standard, CMS looks to several factors, including the number and distribution of health care providers in both commercial plans and in Original Medicare capable of furnishing the covered services. In some instances, delivery of covered services consistent with community patterns of care can mean that in order to receive a Medicare-covered service, an MA plan enrollee might have to travel to a provider/facility that is geographically distant from his or her plan's service area. The MA plan would not be required to cover travel expenses in this case (but may elect to cover such expenses as a supplemental benefit) as long as the MA plan is referring the enrollee to providers in a manner consistent with community patterns of care. We therefore decline to relieve MA plans of any general network adequacy requirements, or the requirement to provide access to MDPP services.

After considering the public comments, we are finalizing our proposals, without modification, for MDPP preliminary recognition under the MDPP expanded model at §424.210(c).

ii. Enrollment and Billing Effective Dates

(1) Date MDPP Suppliers May Begin Enrollment

As described in section III.K.2.a. of the CY 2018 proposed rule (82 FR 34131), we proposed to change the start date of the MDPP expanded model to April 1, 2018. All other policies not related to the furnishing or billing of MDPP services would, if finalized, be effective January 1, 2018. Thus, although MDPP suppliers would not be able to begin furnishing MDPP services on January 1, 2018, MDPP supplier enrollment would begin on January 1, 2018, if these proposals are finalized. In the CY 2017 PFS final rule, we established that any organization wishing to furnish MDPP services must enroll as an MDPP supplier, regardless of any existing enrollment in Medicare. As indicated in section J.4. of the CY 2017 PFS final rule, we believe that including an effective date for enrollment that precedes the implementation date for MDPP services is necessary to allow organizations sufficient time to enroll as MDPP suppliers. Thus, MDPP services would only become available after there is sufficient time to enroll MDPP suppliers that will furnish those services.

The following is a summary of the public comments received on the date MDPP suppliers are able to enroll.

Comment: Of the comments we received on this issue, the majority expressed support for the enrollment start date of January 1, 2018. In their agreement, some commenters stipulated that having a 90-day period between when MDPP supplier enrollment began and when enrolled suppliers could begin furnishing MDPP services would provide both a reasonable and necessary

timeframe for organizations to enroll and ensure compliance. One commenter in support of this policy urged that CMS maintain this timeline. The same commenter specifically requested that, though implied, CMS clarify that the enrollment period for MDPP suppliers does not begin on January 1, 2018 and end of April 1, 2018. Other commenters in support of this policy urged that CMS provide guidance materials and resources to help prospective MDPP supplier applicants prepare for and ultimately enroll into Medicare. Commenters requested that this information be made available as soon as possible, with one commenter specifically requesting that CMS issue a timeline under which prospective MDPP supplier applicants should expect CMS to release such information.

Response: We clarify that though MDPP supplier enrollment begins on January 1, 2018, enrollment in Medicare occurs on a rolling basis with no current or expected end date when MDPP supplier applications would no longer be accepted. Prospective MDPP supplier applicants should submit their enrollment application on or after January 1, 2018 once they are ready to do so. Given the time it takes to successfully process an enrollment application and potential delays in that process, we encourage prospective MDPP supplier applicants to apply as soon as feasible for the organization.

Comment: One commenter did not believe that any delay was necessary given that organizations were already enrolled and prepared to begin furnishing MDPP services.

Response: We believe the commenter may have misunderstood previously finalized policies in the CY 2017 PFS final rule. We clarify that only entities enrolled as MDPP suppliers may furnish MDPP services to beneficiaries. Thus, regardless of any previous enrollment in Medicare, all entities wishing to furnish these services must enroll as an MDPP supplier on or after January 1, 2018.

After consideration of the comments received on the MDPP supplier enrollment start date, we are finalizing this policy as proposed. MDPP supplier enrollment shall begin on January 1, 2018, when the policies in §424.205 that enable MDPP supplier enrollment become effective.

(2) Effective Date of MDPP Suppliers' Billing Privileges

Under §424.502, the definition of enroll/enrollment means "the process that Medicare uses to establish eligibility to submit claims for Medicare-covered items and services, and the process that Medicare uses to establish eligibility to order or certify Medicare-covered items and services." Thus, the purpose of enrollment is to establish billing privileges in Medicare. In accordance with our proposal that MDPP services will be available beginning on April 1, 2018 (82 FR 34131), we proposed that MDPP suppliers may not have an effective date of billing privileges that precedes the date that MDPP services become available (82 FR 34157 through 34158 and proposed at§424.205(e)(2)). Given that it typically takes 45-60 days for an enrollment application days to be processed, if an MDPP supplier submitted its application in January, the application may be approved prior to when MDPP services become available on April 1, 2018. For this reason, we specified that, under no circumstances would an MDPP supplier have an effective date for billing privileges for MDPP services prior to April 1, 2018.

We proposed that for MDPP supplier enrollment applications that are submitted and subsequently approved, the effective date for billing privileges would be the date the application was submitted. However, for applications submitted and subsequently approved prior to April 1, 2018, we proposed that the effective date for billing privileges would be April 1, 2018. This is consistent with other suppliers like physicians, non-physician practitioner organizations, ambulance suppliers, and independent diagnostic testing facilities (IDTFs). However, unlike physicians, non-physician practitioner organizations, and ambulance suppliers who may bill for

services for a limited period of time – generally for about thirty days -- prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries, MDPP suppliers would not be permitted to retrospectively bill for services rendered prior to their effective date for billing privileges. Given that MDPP suppliers do not furnish services with immediate impacts on health like the aforementioned Part B suppliers, we chose to utilize the approach of IDTFs. We proposed that as a condition of enrollment, MDPP suppliers would be required to certify in their enrollment application that they are in compliance and will continue to remain in compliance with all MDPP supplier standards that we described in section III.K.2.e.iv of the proposed rule (82 FR 34159 through 34160). Therefore, an MDPP supplier could begin furnishing services on the date the application was submitted, with the goal of having their application subsequently approved. However, we proposed that payment for those services would depend upon whether the enrollment application is subsequently approved.

We proposed that for any enrollment application that is denied under §424.530(a)(1) for non-compliance, but then subsequently approved due to the submission of a corrective action plan (CAP), the effective date of enrollment would be the date of the CAP submission. This is also consistent with practices for existing suppliers, and institutes an appropriate safeguard for Medicare beneficiaries and the program at-large by prohibiting services from being furnished from suppliers who are non-compliant. We acknowledged, however, that if a supplier began furnishing services the date it submitted its application, but was then denied enrollment, it would not be paid for any services it furnished prior to the date it submitted the CAP, if approved. However, as described in section III.K.2.e.iv of this final rule (§424.205(d)), upon submitting its enrollment application, an MDPP supplier certifies that – to its knowledge – it meets and agrees to continue to meet the following MDPP supplier standards, and all other applicable Medicare

requirements. Thus, at the time the MDPP supplier applicant submits its application, it should believe that its enrollment application will be approved. Examples of actions the MDPP supplier could take to improve its certainty and increase the probability that the application will be approved may include reviewing any MDPP supplier supporting documentation to fully understand MDPP supplier enrollment requirements and accompanying CMS guidance or supplier support materials, confirming compliance with the MDPP supplier standards in this rule (including conducting background checks for those who would be screened by CMS during the enrollment process as required under §424.518(c) and §424.205(d)(3)), and conducting a thorough review of the enrollment application to ensure the submitted application is accurate.

We also proposed that if an MDPP supplier adds a new administrative location (defined and discussed further section III.K.2.e.iii.(2) of this section of the final rule) that resulted in a new enrollment record or Provider Transaction Access Number (PTAN), the effective date for billing privileges would be the date the MDPP supplier began its MDPP operations at that location. We believe that this is appropriate given that it follows a similar approach for an effective date that applies to when physician organizations, non-physician practitioner organizations, ambulance suppliers, and IDTFs add a new practice location to an existing enrollment record. Though the definition of administrative location differs from that of practice location, it provides a similar function. We sought comments on these proposals.

We received no comments on our proposals on the effective date for billing privileges, and are finalizing these policies as proposed under §424.205(f).

iii. Enrollment Application

(1) Enrollment Application Type Applicable to MDPP Suppliers

We proposed to require the use of a new, CMS-approved enrollment application specific to MDPP suppliers. We believe that the creation of a new application will be more easily navigated by and reduce the burden on new, non-traditional suppliers because the new enrollment application will only solicit information relevant to the MDPP supplier type. As this new enrollment application is being created specifically for the MDPP expanded model, we have determined that this new enrollment application is exempt from the Paperwork Reduction Act in accordance with section 1115A(d)(3) of the Act. Further, this enrollment application would be considered an "enrollment application" for purposes of part 424 subpart P, and therefore, all existing regulations and administrative guidance that govern the CMS-855 enrollment applications would apply to this new form, unless otherwise specified. We also considered an alternative option to amend the current CMS-855B Medicare Enrollment Application for Clinics/Group Practices and Certain Other Suppliers (CMS-855B) for MDPP supplier enrollment, but we determined that the existing length and complexity of the CMS-855B enrollment application and its applicability to other non-MDPP suppliers may add burdens or unnecessary confusion to MDPP suppliers given that many sections of the current CMS-855B enrollment application would not apply to MDPP suppliers. In addition, we would need to add new sections to solicit information specific to MDPP suppliers, which would only further increase the length of the CMS-855B enrollment application. We invited public comments on this proposal.

The following is a summary of the public comments received on the proposal to require the use of a new, CMS-approved enrollment application specific to MDPP suppliers and our responses:

Comment: The majority of comments received on creating a new, MDPP specific enrollment form supported this proposal. However, the emphasis of these comments expressed a strong desire for simplicity and that CMS make the form available as soon as possible. Commenters stipulated that given that many prospective MDPP suppliers will lack experience with Medicare enrollment, simplicity and plain language would facilitate their ability to enroll with ease. Similarly, commenters expressed that early access to the form would substantially help prospective MDPP applicants prepare for enrollment. In addition to the early access to the form itself, commenters also urged CMS to provide resources and guidance to prospective MDPP suppliers to facilitate their ability to successfully enroll.

Response: We appreciate all of the comments and support regarding our proposal to create a new, MDPP supplier-specific enrollment application based off of the Form CMS-855-B, as well as other commenters who provided suggestions or other considerations. We reemphasize that we proposed to create an MDPP specific enrollment application rather than amend the current Form CMS-855-B specifically to simplify the application to the extent possible and focus the information collected on MDPP supplier-related information. We continue to believe that this approach strikes the appropriate balance between acquiring necessary information from MDPP supplier applicants and doing so in a manner that is clear and as straightforward as possible.

We understand commenters' requests to have expedited access to the enrollment application. Given that many policies related to or specified on the application are being finalized through this rule, we cannot publish the enrollment application prior to the publication of this final rule. However, we agree that having access to the application prior to the enrollment start date will better assist prospective MDPP suppliers preparing to enroll in Medicare, and will plan to release the application as soon as possible following the publication of this final rule. For

this reason, we specified in our proposal that we intend for the information collected on the MDPP supplier enrollment application to build off of what is collected on the 855-B for all supplier types, and proposed additional information collection requirements specific to MDPP suppliers in this rule. Until we are able to make the new enrollment application available, we believe that reviewing the existing 855B enrollment form should begin assisting prospective MDPP suppliers in their enrollment preparation. In an effort to disclose information on the enrollment application at our earliest opportunity, we can announce that the MDPP enrollment application will be entitled Form CMS-20134, Medicare Enrollment Application, MDPP Suppliers. Additional information on the enrollment application's availability will be announced publicly via the CMS website and other methods as applicable and appropriate.

Comment: Another commenter suggested that once MDPP suppliers successfully enroll, that CMS create a list of all enrolled MDPP suppliers as a method of providing resources to prospective MDPP beneficiaries. The commenter noted that such a resource would be particularly necessary given that not all suppliers with CDC recognition will enroll as an MDPP supplier, and thus, having a separate list of available suppliers would facilitate beneficiary access.

Response: We agree with the commenter's suggestion and will explore the possibility of creating this list and making it available to facilitate access. Further details on these efforts will be released through the CMS website as appropriate and when available.

Comment: In addition to supportive comments and suggestions for ways CMS could facilitate prospective applicant's completion of the enrollment application, certain commenters expressed confusion with our proposals, or commented on proposals outside of the scope of this rule. One commenter noted that CMS was requesting comments on whether existing Medicare

providers and suppliers that wish to bill for MDPP services would have to inform Medicare of the intention and satisfy all other requirements but would not need to enroll a second time. This commenter did not support this policy, and therefore, did not support the creation of a new enrollment application. Similarly, a handful of commenters expressed concern about this previously finalized policy, and urged CMS to reconsider the requirement to reenroll, particularly for FQHCs and enrolled physicians.

We clarify that we are not considering exemptions for MDPP supplier enrollment. We appreciate commenters who expressed a desire for CMS to reconsider the policies previously finalized in the CY 2017 PFS, but these policies are out of scope of the proposed rule, and we are not reconsidering previously finalized policies at this time. For our rationale on this previous policy decision, please reference section III.J.7.a of the CY 2017 PFS final rule where we addressed these comments.

After considering the public comments, we are finalizing the proposal to create an MDPP supplier specific enrollment application, as proposed.

(2) Information on MDPP Enrollment Application

On the new MDPP enrollment application, we intend to solicit information specific to MDPP suppliers, as well as information consistent with existing reporting requirements applicable to all suppliers who enroll through the CMS-855B enrollment application, while excluding all reporting requirements that do not apply to MDPP suppliers. As a Medicare supplier enrolling under part 424 subpart P, MDPP suppliers are required to provide complete and accurate information on the MDPP enrollment application, or be subject to enrollment denial under §424.530(a)(4) or revocation under §424.535(a)(4). This requirement would include all information solicited on the MDPP-specific enrollment application. The MDPP-specific

enrollment application is under development and will be available prior to its use. While the application is being developed, we indicate some of the information we intend to include on the MDPP enrollment application, as further described in this section.

As finalized in the CY 2017 PFS final rule, §424.59(a)(5) requires that MDPP suppliers submit the active and valid NPIs of all coaches who will furnish services on the supplier's behalf, as well as their first name, last name, and SSN (in the proposed rule, §424.59(a)(5) was proposed to be redesignated and amended at §424.205(b)(4)). We proposed, at §424.205(b)(4), to require that MDPP suppliers provide this identifying information of the coaches directly through the enrollment application. This information will be used to complete background checks of the coaches. To accompany the coach identifying information, we proposed to require MDPP suppliers to provide an eligibility start and end date, if applicable, for each coach on the supplier's roster. Coach eligibility start and end dates are described at length in section III.K.2.e.iv.(2). As described in more detail in section III.K.2.e.iv., the background checks would be used to prevent MDPP suppliers from allowing coaches to furnish MDPP services when certain adverse histories may indicate potential to harm Medicare beneficiaries or undermine program integrity. We outline further details on our proposed enforcement of this provision in section III.K.2.e.iv. of this final rule.

To enable us to conduct background checks of coaches, we proposed that MDPP suppliers also submit to CMS the date of birth of all coaches who will furnish MDPP services (§424.205(b)(4)). Combined with other identifying information, date of birth plays a critical role in validating an individual's identity. By collecting date of birth, we would be able to more accurately screen coaches, including accurately conducting a background check, and distinguishing them in the Provider Enrollment, Chain and Ownership System (PECOS). In

addition, we want to ensure that we have the capability to most accurately identify individuals reported on the form. To mitigate potential confusion or error found when individuals have common names, we are proposing to collect coach's middle initial (if applicable) on the enrollment application (§424.205(b)(4)). We believe that this will help to lessen the possibility that CMS or its contractors misattribute the background of one individual for another.

We proposed, at §424.205(d)(4), that MDPP suppliers would identify their administrative location(s) by reporting these location(s) on their enrollment application. We proposed, at §424.205(a), to define administrative location as the physical location associated with the supplier's operations, from where coaches are dispatched or based, and where MDPP services may or may not be furnished. We proposed that an MDPP supplier must have at least one such administrative location, and report any additional administrative locations of the supplier, if MDPP services are either furnished at these locations and/or if the location reflects from where coaches are dispatched or based. For example, if an MDPP supplier operated 2 locations, but only 1 of the 2 locations associated with the entity offered MDPP, only the location offering MDPP would be considered an administrative location. If coaches began offering MDPP in community settings (described in the subsequent paragraph and defined at §424.205(a), but were dispatched and/or based out of the other non-administrative location, then this location would then be considered under the definition of an administrative location, and would need to be reported on the MDPP enrollment application within 90 days of the change. Given that MDPP suppliers are categorized as high risk under §424.518, these administrative locations may be subject to site visits prior to approval of an enrollment application. Collecting information on the MDPP supplier's administrative location (regardless whether they furnish services in this location) is important because we may utilize this information to verify that the organization is

operational per requirements under proposed §424.205(d)(4) and (6), discussed in detail in section III.K.2.e.iii.(3) of this final rule.

Although we recognize that many suppliers furnish MDPP services outside of their administrative locations in community settings, we proposed to only require enrollment of the administrative locations. In §424.205(a), we define "community setting" as a location where the MDPP supplier furnishes MDPP services outside of their administrative locations. A community setting is a location open to the public, not primarily associated with the supplier. Community settings may include, for example, church basements or multipurpose rooms in recreation centers. When determining whether a location is considered an administrative location or a community setting, MDPP suppliers should consider whether their organizational entity is the primary user of that space and whether coaches are based or dispatched from this location. If so, the location would be considered an administrative location, even if this location dually serves as a community setting. In comparison, community settings are locations not primarily associated with the supplier where many activities occur, including MDPP services.

We sought public comments on these proposals.

The following is a summary of the public comments received on these proposals regarding what information CMS will collect on the MDPP supplier enrollment application and our responses:

Comment: Several commenters expressed disagreement with previously finalized policies out of scope of these proposals, including MDPP suppliers collecting information on MDPP coaches, requiring coaches to obtain NPIs, and tracking and reporting coach NPIs to CMS. One commenter broadly requested that CMS reconsider these policies citing a preference for a less intrusive way for staff to participate. Another suggested that instead of issuing and

tracking coaches through NPIs, CMS should allow DPP organizations to self-regulate their coaches using their own management practices. Another commenter expressed a broad concern regarding the burden of the recordkeeping requirements under MDPP, listing the tracking and submission of coach NPIs as one of these burdens.

Response: These comments are out of scope of this final rule. None of the comments received addressed the policies in the proposed rule, which built on previously finalized policies in the CY 2017 PFS final rule. We do not intend to change these policies at this time.

In the absence of public comments on our proposal to collect the date of birth and middle initials, if applicable, of MDPP coaches or our proposal to collect coach identifying information from their roster through the MDPP supplier enrollment application, we are finalizing these policies as proposed.

Comment: Several commenters requested clarity and expressed concern related to differences between an administrative location and community setting.

Response: A location may either meet the definition of an administrative location or a community setting based on whether or not the MDPP supplier is the primary user of that space, including both MDPP services and any other services provided by the supplier. The difference can be easily illustrated by examining two scenarios where MDPP services are furnished in a community center, and the community center can quality as either an administrative location or a community setting, depending on the circumstance. For example, if the MDPP supplier is also a community-based organization which primarily operates at a community center which offers many services including MDPP, the address of the community center would fall under the definition of an administrative location which, as proposed under §424.205(a), means a physical location associated with the MDPP supplier's operations. However, if an advocacy organization

is enrolled as an MDPP supplier and opts to furnish services in a community center to increase beneficiary access or because the location where their primary business operations occur does not have sufficient space to hold a group meeting, the address of the community center would qualify as a community setting, because, as proposed under §424.205(a), a community setting means a location where the MDPP supplier furnishes MDPP services outside of their administrative locations, that is open to the public, and not primarily associated with the supplier. To make the distinction between these two definitions more clear, we will amend our proposed definition of an administrative location to include a physical location associated with the MDPP supplier's operations *where it is the primary operator in the space*, from where coaches are dispatched or based, and where MDPP services may or may not be furnished

Comment: Specifically, one commenter requested that CMS confirm that MDPP services furnished by an enrolled MDPP supplier can be offered in a setting that is not exclusively used for MDPP services, meaning that the location may be co-located with other non-covered MDPP services.

Response: We confirm the commenters' interpretation that MDPP suppliers may furnish MDPP services in locations where other, non-MDPP services occur.

Comment: Another commenter disagreed with the requirement that MDPP suppliers have at least one administrative location. Though this requirement was proposed in the MDPP supplier standards, the comment stemmed from the stakeholders' understanding of the proposed definition of administrative location, and thus it is discussed in this section of the rule. The commenter stipulated that requiring that MDPP suppliers have at least one administrative location does not align with how some DPP organizations currently deliver and schedule sessions. The commenter noted that DPP organizations may not have an administrative location

where coaches remain throughout the day and are scheduled or dispatched from, but rather, that a program coordinator (who may or may not also serve as a lifestyle coach) determines which coach will staff a series of sessions and the corresponding location.

We do not agree with the commenter who noted that our proposed definitions of administrative locations do not align with how DPP organizations currently operate. Though the commenter suggested a program coordinator, not a coach, may dispatch coaches to furnish sessions, this scenario would not disqualify the location from where the coordination dispatched the coach from being an administrative location. We clarify that we take no policy position on who dispatches the coaches, be they another coach, program coordinator, or other personnel working on behalf of the MDPP supplier. Our proposed definition of the administrative location means any physical location associated with the suppliers' primary business operations, regardless of whether coaches furnish MDPP services from that location or not. If the location serves as the supplier's primary operations, but MDPP services are furnished elsewhere, we assume that the supplier or individuals working on its behalf will dispatch coaches from this location, potentially house MDPP related materials at this location, or utilize this location to store records. We purposefully sought to define administrative location to accommodate the non-traditional nature and diversity of settings among current DPP organizations.

After considering the public comments, we are finalizing the requirement to report an MDPP supplier's administrative location(s) and community setting(s) on the enrollment application with minor amendments to the definition of an administrative location to provide greater clarity.

(3) Updating Information on MDPP Enrollment Application

We proposed, at §424.205(d)(5), that MDPP suppliers must update their enrollment application within 30 days of any changes of ownership, changes to the coach roster, or new final adverse action history of any individual or entity required to report such information on the enrollment application. We proposed that MDPP suppliers report all other changes to information required on the enrollment application within 90 days of the reportable event. Timely reporting and updating of information plays a critical role in our ability to protect Medicare beneficiaries and protect the integrity of the Medicare program and Trust Funds. We believe that these requirements are fair and consistent with existing reporting requirements for other Medicare suppliers.

All suppliers are required to report changes of ownership and new adverse action history within 30 days. Adding the requirement that any changes to the coach roster be reported within 30 days is consistent with IDTFs requirements at §410.33(g)(2). Although IDTFs differ from MDPP suppliers in many ways, IDTFs must report a roster of supervising physicians who serve functions on the supplier's behalf and must also report changes to this roster within 30 days. Given this similarity with IDTFs, we modeled our approach after this process. However, we note that while MDPP suppliers would be required to submit changes to the coach roster within 30 days, we would encourage them to submit such changes as soon as possible, due to reasoning explained further in section III.K.2.e.iv.(2) of this final rule.

We invited public comments on these proposals. We received no comments on our proposals relating to the timelines under which MDPP suppliers must update their enrollment applications, and thus are finalizing these policies as proposed at §424.205(d)(5).

(4) Enrollment Application Fee

In the CY 2017 PFS final rule, we finalized that MDPP suppliers would enroll in Medicare. We solicited comments on, but did not propose or finalize, an applicable application fee associated with the MDPP supplier's enrollment. In this final rule, we proposed to amend the definition of "institutional provider" as defined under §424.502, to include MDPP suppliers such that, §424.514, which governs the application fee, would similarly apply to MDPP suppliers. "Institutional providers" that are initially enrolling in Medicare, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. We highlight that while we proposed to include MDPP suppliers as an institutional provider, MDPP suppliers utilize administrative locations, not practice locations, and therefore the fee would not apply when adding a new administrative location to an existing enrollment record. The application fee is adjusted annually, and additional information about how the adjustment is calculated may be found in the November 7, 2016 **Federal Register** notice establishing the calendar year 2017 application fee (81 FR 78159). For calendar year 2017, the application fee is $560. Section 1866(j)(2)(C) of the Act requires the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier. This fee would be used for program integrity efforts including to cover the cost of screening and to carry out the provisions of sections 1866(j) and 1128J of the Act. Given that section 1866(j)(2)(C) of the Act does not require individual practitioners, such as physicians and nurse practitioners, to pay an enrollment application fee, we have previously determined that an "institutional provider" includes any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application[43]. MDPP suppliers are

[43] See CMS-6028-FC for further discussion, 76 FR 5862 and 5907 through 5908 (Feb. 2, 2011).

entities, and not individual practitioners. We believe that they would similarly qualify as a "provider of medical or other items or services" used to define institutional providers. Taken together, we believe that the definition of institutional provider would also apply to MDPP suppliers. Given that the CY 2017 PFS final rule established that MDPP suppliers would be screened under high categorical risk (codified at §424.59(a)(3), redesignated as §424.205(b)(3)(i)), the application fee would play an important role in executing particular aspects of the high-risk screening. As we noted in the CY 2017 PFS final rule, any organization that faces financial difficulty related to the application fee may apply for a hardship exception. For more information on the hardship exemption, see https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7350.pdf. We solicited comments on this proposal.

The following is a summary of the public comment received on the proposal to amend the definition of institutional provider for the purposes of applying an enrollment application fee, as well as our response.

Comment: We only received one comment on this proposal, which supported requiring MDPP suppliers to pay a $560 enrollment application fee.

Response: We clarify that the application fee amounted to $560 in 2017; however, this amount may vary from year-to-year based on adjustments made under the Consumer Price Index for Urban Areas (CPI-U). We encourage prospective MDPP supplier applicants to remain abreast of any changes in that amount. CMS publishes an annual **Federal Register** notice regarding an update of the enrollment application fee.

After considering the public comments, we are finalizing our amendment to the definition of institutional providers to include MDPP suppliers. Though the meaning of the proposal

remains the same, now that we have finalized the creation of an MDPP supplier specific form, CMS-2013, we will amend the language at §424.502 from the proposed which referenced any enrollment application designated for MDPP suppliers to refer to CMS-20134.

iv. MDPP Supplier Standards

We proposed to establish standards that MDPP suppliers must meet and remain in compliance with to be eligible to receive payment under the MDPP expanded model (described in 82 FR 34159 through 34160 and proposed at §424.205(d)). These supplier standards would build on the conditions for enrollment established under existing §424.59(a) (which in this final rule is redesignated and amended at §424.205(b)), as well as any existing Medicare requirements that apply to all suppliers. We proposed that an MDPP supplier wishing to participate in the MDPP expanded model must adhere to current Medicare MDPP supplier requirements as outlined in §424.59 (redesignated as §424.205), as well as all other requirements that apply to Medicare providers and suppliers. MDPP suppliers may choose to utilize a third party administrator, billing agent, or other entity to comply with the requirements of §424.59 (redesignated as §424.205). Regardless of any use of such entities, any failure to comply with the standards of §424.205(d) or other relevant Medicare requirements, may result in an enrollment denial under §424.530(a)(1), revocation of the MDPP supplier for non-compliance under §424.535(a)(1) or other revocation authority, as appropriate (as in §424.205(g)). Consistent with existing regulations, we proposed that MDPP suppliers would have appeal rights under part 498.

We stated that we believe that the standards outlined in this section are generally consistent with standards established for other Medicare suppliers while adding safeguards to help ensure compliance with MDPP rules and regulations specific to this expanded model.

Because this expanded model would pay MDPP suppliers based on a beneficiary's achievement of performance goals, we stated that we believe that it is prudent to include additional requirements consistent with the Office of Inspector's General's compliance guidance,[44] to promote adherence to applicable statutes, regulations, and program requirements and help reduce fraud, waste, and abuse. In addition to the standards, the MDPP expanded model will be routinely monitored for compliance with supplier standards, consistent with section 1893 of the Act (42 U.S.C. 1395ddd). Although we recognized that these standards may be new for MDPP suppliers and would impose additional requirements on these organizations that they may not otherwise face, both individually and collectively, we stated that these standards play an important role in ensuring the integrity of the Medicare program and the safety of our beneficiaries. Therefore, given the goals of these standards to mitigate fraud, waste, or abuse to the Medicare program and its beneficiaries, we stated that we believe that they are appropriate for governing MDPP suppliers and do not place an undue burden on suppliers. We invited public comments on our approach, as well as any unintended consequences or burdens that we may have not considered.

The following is a summary of the public comments and our responses regarding the proposal to establish standards for MDPP suppliers' general eligibility to furnish services to Medicare beneficiaries and program integrity safeguards that would protect both Medicare beneficiaries and the Medicare program:

Comment: Several commenters provided feedback on the proposal to establish MDPP supplier standards. The majority of these commenters expressed concern that by imposing additional requirements, the standards would pose additional burdens on MDPP suppliers. One

[44] https://oig.hhs.gov/compliance/compliance-guidance/.

commenter stated that the extensive requirements may delay access. Others expressed strong sentiments against CMS' decision to impose MDPP supplier standards. One commenter indicated that these impositions may deter organizations from deciding to enroll as MDPP suppliers even if beneficiaries already served by these organizations could benefit from MDPP services. Rather than establishing MDPP supplier standards to protect against fraud, waste, and abuse, one commenter recommended that CMS conduct random audits and site visits.

Response: We recognize that supplier standards pose additional burdens for MDPP suppliers; however, we believe that these standards play an important role in ensuring against fraud, waste, and abuse in the Medicare program as well as fidelity to the expanded model. Additionally, we have sought to structure these standards such that compliance would be feasible, and at times, even seamless for suppliers to abide by. For example, our proposals regarding MDPP suppliers' operational status were not intended to impose new requirements, but to notify prospective MDPP applicants of the standards by which they will be evaluated. We believe that MDPP suppliers that are operational, as opposed to organizations who wish to appear operational, will not need to make any changes in order to be able to meet these standards. Therefore, we do not agree with the commenter that overall, the supplier standard would pose any additional burden on these suppliers, dissuade legitimate and operational suppliers from choosing to participate, or even significantly delay enrollment. Though we recognize that implementing criteria for eligible coaches could result in an enrollment delay should a coach submitted on a suppliers' enrollment application be determined by CMS to be ineligible, the eligibility criteria narrowly focuses on excluding coaches with felony convictions for actions that, if repeated in MDPP, could jeopardize the integrity of the program and/or the

safety of its beneficiaries. Therefore, we believe that any delays caused by an ineligible coach are justified.

Comment: A few commenters expressed general support for the standards, noting that they were appropriate, and with few exceptions, generally straightforward to implement. Though MedPAC did not expressly support the proposed supplier standards, they recommended that CMS use all program integrity tools available to monitor MDPP suppliers, including significant oversight from the Office of Inspector General and limitations on supplier enrollment.

Response: We agree with commenters' views of the appropriateness of our proposals, the importance of implementing program integrity tools for this novel supplier type, and that the characterization of MDPP supplier standards as straightforward to implement.

Comment: Instead of establishing MDPP supplier standards to protect against fraud, waste, and abuse, one commenter recommended that CMS conduct random audits and site visits.

Response: We disagree with one commenter's characterization of audits and site visits as an alternative to MDPP supplier standards as the two support one another. Where the MDPP supplier standards establish some of the requirements under which MDPP suppliers must abide, an audit or site visit gives CMS an opportunity to ensure that an MDPP supplier is in compliance with such requirements. Furthermore, given the novelty of the expanded model and this new supplier type created to support its delivery, as well as concerns raised by MedPAC and others, we believe that establishing MDPP supplier standards provides important program integrity safeguards for a range of programmatic objectives.

For example, some of the MDPP supplier standards provide preemptive measures to dissuade organizations that may seek to enroll as an MDPP supplier without planning to actually furnish services, but instead, with the intention of fraudulently billing Medicare for MDPP

services not rendered. For example, requiring a working phone number that is listed in association with the supplier and having a physical location with signage associated with the supplier's legal business or doing business as name. These standards have also been implemented with other supplier types to avoid "shell" companies from being able to enroll. The supplier standard proposed at §424.205(d)(1) prevents an organization with a for-cause termination in Medicaid from replicating the same behavior in Medicare that had them terminated in Medicaid. A supplier standard at §424.205(d)(8) prohibits the MDPP supplier from proactively selecting beneficiaries who they perceive to be more likely to successfully meet the performance goals, which would subsequently generate more funds for the supplier. Another supplier standard at §424.205(d)(10) ensures that an MDPP supplier offers all services for which an MDPP beneficiary is eligible, which would prevent a supplier that may otherwise seek to cease providing the time investment of offering services to a beneficiary who they believe is unlikely to meet performance goals, and therefore resulting in less reimbursement for the supplier. We have included safeguards to ensure that MDPP suppliers do not engage in this type of discriminatory behavior that could limit access for certain beneficiaries who would benefit from receiving MDPP on the basis of the supplier's own financial benefit.

We believe that establishing these standards also plays an important role in enabling CMS to enforce certain actions and take appropriate administrative action when a supplier fails to comply.

Though MedPAC did not comment on these standards directly, we believe that the both the standards supplier standards and our ability to deny or revoke an MDPP suppliers' enrollment if they fail to comply aligns with their recommendation to utilize all available program integrity tools.

Comment: Many commenters requested that CMS provide technical assistance, subregulatory guidance, and other resources to help ensure MDPP supplier compliance and facilitate the enrollment process, particularly given that many MDPP suppliers may be enrolling in Medicare for the first time. One commenter specifically requested that documents utilize plain and directive language to facilitate understanding and correct implementation of the requirements. One commenter suggested that the MDPP expansion model create a level of technical assistance that occurs with other Innovation Center models, for example, Comprehensive Primary Care Model Plus.

Response: We thank commenters for highlighting the need for guidance and other MDPP supplier support resources. We appreciate the feedback in how we can facilitate MDPP suppliers' understanding of proposed MDPP supplier standards and in doing so, better equip MDPP suppliers to comply with our regulations. We similarly recognize the need to provide resources to support MDPP suppliers' success and are in the process of developing materials. We will also be establishing a Help Desk, which we believe will provide some of the guidance commenters requested. We will explore additional opportunities to assist suppliers, and will provide notification of any materials as they become available either through our website or through our MDPP list serv.

After considering the public comments received, we are finalizing our policy to establish MDPP supplier standards at §424.205(d), as proposed. Note that the specific MDPP supplier standard proposals outlined in the paragraphs of §424.205(d) are discussed further through this section of the final rule.

(1) Medicaid Terminations

In addition to establishing standards for MDPP suppliers with respect to their delivery of MDPP services, we also proposed standards for MDPP suppliers' general eligibility to furnish services to Medicare beneficiaries. These standards would establish program integrity safeguards that would protect both Medicare beneficiaries and the Medicare program. We proposed that MDPP suppliers must not currently have their billing privileges terminated for-cause from any State Medicaid program or be excluded from any State Medicaid program (§424.205(d)(2)). If a supplier's Medicaid billing privileges are currently terminated from or the supplier is excluded from any State Medicaid program, we stated that we do not believe that supplier should be able to furnish Medicare services. We stated that we believe that this is warranted given that a supplier's improper behavior in another federal health care program may be duplicated in Medicare. We stated that we believe that this requirement would mitigate the MDPP expanded model's susceptibility to fraud, waste, and abuse. Consistent with all standards in this section, any MDPP supplier who does not meet this requirement would be subject to a Medicare enrollment denial or revocation. We believe that this standard would serve to ensure continuity of safeguards across federal health care programs, and will help preserve the integrity of the Medicare program and protect beneficiaries by prohibiting suppliers found to be noncompliant in one federal health care program from enrolling in and furnishing services in another.

We sought comments on this proposal.

We received no comments on our proposal prohibiting that MDPP suppliers from being terminated for-cause or being excluded from a State Medicaid agency. Therefore, we are finalizing policies to prevent MDPP suppliers from having previous terminations or exclusions from State Medicaid Agencies as proposed at §424.205(d)(2).

(2) Ineligible Coaches: Individuals Prohibited from Furnishing MDPP Services to Medicare Beneficiaries

At §424.205(d)(3), we proposed that the MDPP supplier must report coach information on its enrollment application and the MDPP supplier must only permit MDPP services to be furnished by individual coaches who meet the eligibility criteria. At §424.205(e)(1), we proposed that MDPP coach eligibility criteria require that a coach must not:

- Currently have his or her Medicare billing privileges revoked and whose reenrollment bar has not yet expired. We believe that this proposed supplier standard would protect beneficiaries from receiving MDPP services from individuals already prohibited from furnishing other Medicare services. If an individual is precluded from maintaining enrollment in Medicare for a non-MDPP service, we believe that it is prudent that they similarly not furnish MDPP services.

- Currently have his or her Medicaid billing privileges terminated for-cause or be excluded from any State Medicaid Agency (§424.205(e)(1)(ii)). We believe that this proposed supplier standard is warranted given that an individual's improper behavior in another federal health care program may be duplicated in Medicare. We do not believe that we should permit MDPP suppliers to allow coaches with current for-cause terminations or exclusions in Medicaid to furnish MDPP services to Medicare beneficiaries.

- Currently be excluded from any other federal health care program, as defined in §1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act. This includes, but is not limited to, the Office of Inspector General (OIG)'s List of Excluded Individuals and Entities (LEIE). We proposed this supplier standard for similar

reasons we proposed not to permit coaches with revocations from Medicare or current exclusions from Medicaid to furnish MDPP services.

- Currently be debarred, suspended, or otherwise excluded from participating in any other federal procurement or non-procurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services non-procurement common rule at 45 CFR part 76. We note that this includes individuals who have an active status on the General Service Administration's System for Award Management list. We may also utilize the Bureau of the Fiscal Service, U.S. Department of the Treasury's Do Not Pay (DNP) List as a resource for determining which individuals fall under this category. The Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012 established the DNP to support Federal agencies with their efforts to prevent and detect improper payments by aggregating various data sources for pre-award, pre-payment eligibility verification. Data sources included in this list include Credit Alert System, Death Master File, LEIE, Office of Foreign Assets Control (OFAC), System for Award Management (SAM) Entity Registration Records, and SAM Exclusion Records. We believe that we may utilize the DNP as a method of determining whether a coach is excluded from participating in any other federal procurement or nonprocurement programs. Although coaches will not directly be receiving payment from us for furnishing MDPP services, we do not believe that payment should be made to MDPP suppliers for services furnished by individuals excluded from federal procurement or nonprocurement programs, particularly given that MDPP payments rely on beneficiary's achievement of performance goals that the coaches will document. Although the MDPP supplier is ultimately responsible for attesting to all claims submitted for MDPP services, we do not believe that it would be prudent to permit MDPP

suppliers to allow coaches excluded from other federal procurement programs to furnish MDPP services.

- Have, in the previous 10 years, one of the following state or federal felony convictions:

++ Crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion.

++ Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, as defined under §1001.2, had a guilty plea or adjudicated pretrial diversion.

++ Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under §1001.2, having a guilty plea or having adjudicated pretrial diversion of criminal neglect or misconduct.

++ Any felonies that for which the individual was convicted, as defined under §1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

We proposed that CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application to verify that the individual coach does not meet any of these conditions and that the coach can provide MDPP services on behalf of an MDPP supplier (§424.205(e)(2)). We proposed these requirements as a means to ensure the integrity and safety of the Medicare program and the beneficiaries whom we serve. We have selected these types of felony convictions based on the risk we believed they could pose to the

Medicare program and our beneficiaries. Additionally, it is consistent with existing criteria that we use to determine felonies that are detrimental to the best interest of the program and its beneficiaries as described in §424.535(a)(3)(ii). Although we selected these criteria to be consistent with how we evaluate other individuals, we also sought to create a more definite list such that MDPP suppliers would have the ability to conduct background checks on coaches prior to, as well as potentially after enrolling in Medicare, to avoid receiving an enrollment denial or revocation due to failure to meet this standard. Although coaches are not directly enrolled, and therefore, not directly receiving payment, we stated that we believe that it is prudent to prohibit MDPP suppliers from utilizing individuals convicted of certain felonies to furnish services to Medicare beneficiaries. Because coaches will be directly interacting with beneficiaries, recording their attendance and weight loss, we believe that a coach's trustworthiness is vital. Consequentially, we do not believe that such coaches should have a criminal history such as those described in §424.535(a)(3)(ii).

Coaches that meet any of these criteria would be considered ineligible to furnish MDPP services, and therefore, could not be on an MDPP supplier's roster. Coaches whose information was submitted in an MDPP supplier's enrollment application, screened, and determined as not meeting any of these criteria would be considered eligible coaches. Although the MDPP supplier is the entity that is enrolled in Medicare and submits claims, coaches furnish MDPP services, directly interacting with the beneficiary and documenting attendance and weight loss. Therefore, we stated that we believe that precluding individual coaches who meet any of the ineligibility criteria from directly furnishing MDPP services to Medicare beneficiaries would both help reduce fraud, waste, and abuse that could occur in the MDPP expanded model, as well as protect beneficiaries from harm.

If after screening, CMS or its contractors determine that a coach is eligible to furnish MDPP services, the coach would be assigned an eligibility start date, similar to a supplier's enrollment effective date. We proposed to define coach eligibility start date as follows: the start date indicated by the MDPP supplier when submitting an eligible coach's information on the MDPP enrollment application (§424.205(a)). On the enrollment application, the MDPP supplier will include a date indicating when the coach began furnishing MDPP services. Consistent with §424.205(d)(5), the MDPP supplier must report changes to the coach roster on its enrollment application, including any new coaches added, within 30 days of such a change. Thus, the start date associated with any new coach information must be within 30 days of the date the MDPP supplier actually reports the change on its application. If the coach has not yet begun furnishing MDPP services, the MDPP supplier should indicate the date the supplier is reporting the information. Though the date reflects either when the coach began furnishing services or when the coach could ultimately be determined as eligible to begin furnishing services, after the enrollment application was submitted, CMS must still determine whether the coach is eligible (§424.205(e)(2). If we determine the coach to be eligible, then his or her eligibility start date would be the date the MDPP supplier indicated on its enrollment application. We described in III.K.2.d.(10)(d) of the proposed rule (82 FR 34149 through 34152) that payment can be made for services furnished by this coach on or after his or her eligibility start date.

However, if a coach was determined to be ineligible at the onset, the coach would have its eligibility start and end date on the same date, effectively never being eligible to furnish MDPP services. If the coach later became ineligible, he or she would be assigned an eligibility end date. Consistent with §414.84, payment for MDPP services is made only if such services are furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable,

before his or her coach eligibility end date, to an MDPP beneficiary. This could pose a situation in which an MDPP supplier could submit an updated coach roster that includes a new coach, and allow him or her to begin furnishing services based on the belief that he or she is eligible. Should, after screening, CMS or its contractors determine that the coach is ineligible, the MDPP supplier could be revoked for non-compliance. Though the MDPP supplier would have an opportunity to submit a corrective action plan that removes the ineligible coach from their enrollment application, any claims for services furnished by the ineligible coach would be denied, and the MDPP supplier would not be paid for such services. For this reason, we encourage suppliers to report changes to the coach roster as soon as possible. If the MDPP supplier submits a claim that includes a coach NPI for a coach we have not yet determined to be an eligible coach for furnishing MDPP services as of the date of service, the claim will be rejected, and the supplier will need to refile the claim with the same information once CMS has made the eligibility determination. If at that time, CMS determined the coach to be ineligible, the claim for the service provided by the coach will be denied, as described in section III.K.2.d.iii.(10)(d) of the proposed rule (82 FR 34149 through 34152).

We stated that we believe that the majority of the coach ineligibility criteria described in this section is crafted in such a way that the MDPP supplier could, with reasonable certainty, conduct an independent background check on the coach, to determine whether he or she meets the ineligibility criteria. If the MDPP supplier has any uncertainty about whether the coach meets the ineligibility criteria, they may wish to preclude the coach from furnishing services to Medicare beneficiaries until CMS determines that the coach is eligible. This would avoid a potential situation of a coach furnishing services for which the MDPP supplier could not get paid. If the MDPP supplier believes the coach is eligible and wishes to allow the coach to

furnish services prior CMS determining his or her eligibility, then the MDPP supplier would assume the risk not receiving payment for claims for serviced rendered by the ineligible coach.

If a coach no longer provides MDPP services for an MDPP supplier, the supplier must remove that coach from its roster and indicate the date of such event to designate an eligibility end date for that coach. If the MDPP supplier voluntarily terminates its Medicare enrollment or is revoked, CMS will automatically reflect the date of this action as the coach's eligibility end date for that MDPP supplier. We proposed to define coach ineligibility end date as follows, the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

We proposed that CMS or its contractors would determine whether coaches submitted on MDPP rosters satisfy the previously stated criteria by using the identifying information MDPP suppliers submit on their enrollment applications (including any changes that MDPP suppliers would be required to report). This information would be checked against internal and publicly available data sources. We proposed that, upon identification of evidence that a coach met any ineligibility criteria, we may take administrative action to deny or revoke the MDPP supplier's enrollment as appropriate under §§424.530(a)(1) and 424.535(a)(1) (proposed at §424.205(g)(1)(ii)). Consistent with existing enrollment denial and revocation actions, we would notify the prospective or enrolled MDPP supplier via an enrollment denial or revocation notification and include the specific reason for the administrative action. The enrollment denial or revocation notification detailing the findings and the reasoning for the determination would follow requirements under §488.18. Consistent with similar processes at §§424.530(c) and 424.535(e), we proposed that an MDPP supplier could respond to the enrollment denial or

revocation by submitting a corrective action plan (CAP) that would include the removal of the coach from its roster within 30 days of receiving the enrollment denial or revocation notification, and therefore, come into compliance and enroll or maintain its enrollment status. If MDPP suppliers believe that the decision was made in error, they could exercise existing appeal rights under part 498.

We also proposed that if we determine that an MDPP supplier has continued to allow an ineligible coach to furnish MDPP services after having submitted a CAP removing the coach from its roster to enroll or maintain enrollment in Medicare, we would revoke the MDPP supplier without the opportunity for additional corrective action. This authority, outlined in §424.205(h)(1)(v), would allow us to revoke an MDPP supplier for knowingly using an "ineligible coach" to furnish MDPP services. "Knowingly," in this context, means that the supplier received an enrollment denial or revocation notice based on failing to meet supplier standards at §424.205(d)(3) (related to ineligible coaches), was provided notice by CMS or contractors working on its behalf of this action including the reason(s) for the administrative action, submitted a CAP to remove the coach, but continued to allow the coach to provide MDPP services in violation of the CAP. We proposed to define an "ineligible coach" in §424.205(a) as an individual whom CMS has screened and has determined ineligible to furnish MDPP services on behalf of an MDPP supplier based on the standard specified in §424.205(e), and we proposed in the same paragraph to define "eligible coach" in §424.205(a) as an individual who CMS has screened and has determined can furnish MDPP services on behalf of an MDPP supplier based on the standard specified in §424.205(e).

Although any individual may be eligible to become a DPP coach, provided that they meet requirements and trainings as dictated by the CDC's DPRP Standards, an individual can only

become an eligible coach for purposes of furnishing MDPP services after having their required identifying information submitted on an MDPP supplier's enrollment application, being screened by CMS or its contractors, and as a result, being determined to be eligible to furnish MDPP services on behalf of an MDPP supplier. If CMS or its contractors deem a coach ineligible, this would apply only to the furnishing of MDPP services and would not preclude the DPP organization from continuing to allow this individual to furnish administrative services or DPP sessions to non-Medicare beneficiaries. However, serving as a coach for Medicare beneficiaries would be prohibited and would be subject the MDPP supplier to this revocation authority.

We proposed this new revocation authority due to the novel program integrity risks that would be posed by MDPP suppliers who knowingly continue to permit ineligible coaches to furnish MDPP services to Medicare beneficiaries. We stated that we believe that this new basis for revocation is necessary because coaches are not enrolled in Medicare, even though they will undergo background checks by CMS or its contractors and must meet specified criteria. Although we considered using existing revocation authorities under §424.535(a)(1) (related to noncompliance), §424.535(a)(4) (related to false or misleading information), and §424.535(a)(9) (related to failure to report), we determined that these authorities were too general for purposes of specifically addressing MDPP coaches who become ineligible to furnish MDPP services. We proposed that this revocation authority would follow similar requirements under §424.535(c), (g), and (h). We stated that we do not believe that §424.535(e) (related to reversal of the revocation) should apply in this case, given that the MDPP supplier already had an opportunity to remove the coach from their roster by submitting a CAP, but continued to allow the ineligible coach to furnish MDPP services. The proposals that we would apply from the provisions of §424.535 stated in this section are as follows:

- The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier;
- For the revocation authority, MDPP suppliers are barred from participating in the Medicare program from the date of the revocation until the end of the re-enrollment bar, which begins 30 days after CMS or its contractor mails notice of the revocation and lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation; and
- A revoked MDPP supplier must, within 60 calendar days after the effective date of revocation, submit all claims for items and services furnished before the date of the revocation letter.

We believe that these proposals would appropriately govern this new revocation authority, given the consistency with existing revocation authorities. Given these consistencies, we stated that we do not believe that these proposals place an undue burden on MDPP suppliers, and any burden established would be warranted given the violation of the supplier standards that jeopardize both the integrity of the Medicare program and the safety of its beneficiaries.

We invited public comments on these proposals.

Comment: Many commenters provided general feedback related to coach requirements. Two commenters criticized coach-related proposals for differing so significantly from CDC's DPRP requirements.

Response: We have sought to align the MDPP expanded model with CDC's DPRP standards in many ways, largely in regards to the set of services itself – the curriculum, the setting in which it is provided, the qualifications of those who offer it. We recognize that the goals of CDC requirements and our requirements overlap, but differ in certain respects. For example, the DPRP requirements primarily serve as quality assurance aimed to ensure that DPP

organizations can effectively offer DPP to its participants. Given the focus on the efficacy, CDC requires submission of significant performance data beyond what is required by CMS, for example, participants reported minutes of physical activity. Where CDC's requirements for DPP organizations aims to ensure quality, CMS's requirements aim to protect the integrity of the Medicare program and the beneficiaries it serves through ensuring compliance. We rely on CDC requirements where appropriate for quality purposes, for example, we defer to CDC requirements to determine what credentialing or training coaches must acquire to successfully furnish DPP sessions. However, these requirements do not address potential program integrity concerns such as how to prevent a coach from harming beneficiaries or the Trust Funds. Thus, we have proposed the coach ineligibility criteria to fill this gap. In absence of any alternative approaches to address program integrity concerns that could harm Medicare beneficiaries or the program at large, we are not amending these proposals.

Comment: Although one commenter acknowledged that background tests may take time and delay enrollments, they did not recommend that CMS change this policy as a result of this delay.

Response: We acknowledge that an MDPP supplier may experience a delay in their enrollment should CMS determine that a coach on their enrollment application is ineligible, however, we believe that this delay would be necessary and appropriate to prevent ineligible coaches from furnishing services to Medicare beneficiaries.

Comment: One commenter suggested that the proposal assigns MDPP suppliers responsibility to credential MDPP coaches. When the commenter referenced credentialing requirements, they included oversight and guaranteeing the quality and competency of individual coaches. Given the proposal that having an ineligible coach could cause a denial or revocation of

an MDPP supplier's enrollment, this commenter highlighted a need for a standardized credentialing process for MDPP coaches that would provide oversight to ensure the quality, consistent delivery and fidelity of the MDPP set of services, as well as to appropriate program integrity standards and requirements.

Response: In response to the commenter's concern, we are providing some clarity on our proposals and some distinctions between a coach being eligible as compared to being credentialed, which we believe will address the commenter's concerns raised. The commenter suggested that because CMS holds the MDPP supplier accountable for knowing whether or not their coaches are eligible, then MDPP suppliers are effectively credentialing MDPP coaches. We disagree with this characterization of credentialing, which typically means that, based on an achievement or demonstration of competency, an individual is deemed qualified for a certain activity. We have previously determined that, consistent with CDC DPRP standards, coaches do not require any specific license or credentials that would deem them qualified to furnish DPP. We believe that the CDC is most appropriately suited to specify minimum training requirements for coaches and we do not wish to add any requirements for coaches to fulfill for the purposes of MDPP. Instead, our proposals seek the inverse. Rather than proposing additional requirements, for example a credential, and only allowing individuals with that credential to qualify as an eligible coach, we are allowing all individuals to be eligible to be a coach, with the exception of individuals with certain histories, which are detailed at§424.205(e)(1). We proposed these exceptions to protect the safety and integrity of the Medicare program and the beneficiaries we serve. Though the nuance may seem insignificant, we believe it is an important distinction given that requiring credentials has historically limited access for certain benefits, as raised by certain commenters with respect to requiring specific training.

While the commenter is correct in that our proposals will hold suppliers accountable for having ineligible coaches on their roster, and thus MDPP suppliers should independently verify eligibility, we disagree with the commenter's view that MDPP suppliers have this responsibility rather than CMS. Our proposal under §424.205(e)(2) highlights that CMS ultimately determines coach eligibility through screening. Thus, while the commenter highlighted a need for a standardized, national credentialing body for MDPP suppliers, we view this as a method of quality assurance to determine an individual's capability to successfully meet the requirements of being a coach. As previously stated in a separate comment response, we rely on CDC to implement quality assurance related to MDPP, and they have not created a national credentialing system or suggested that doing so would improve the quality of the program. In contrast, concerns exist that the creation of such a system would create a barrier to entry that could ultimately drive down the number of available coaches. In the absence of the CDC identifying a need for such a system, we believe that CMS conducting screening for MDPP coaches to determine eligibility would sufficiently address program integrity concerns without creating a bottleneck in the supply of coaches. Though not equivalent to creating a national credentialing system our proposals would establish a standard and streamlined system to check for MDPP coach eligibility run by CMS, and not individual suppliers. Therefore, we will not modify our proposals.

Comment: One commenter recommended that given that all coaches are required to have NPIs, CMS should create a new taxonomy code specifically for "lifestyle change coach." The commenter raised concerns that, absent such a policy change, coaches will select a wide variety of taxonomies and that given that MDPP coaches do not require credentialing or licensure, it is possible that none of the existing taxonomies may apply. The commenter suggested that a single

taxonomy with accompanying guidance to MDPP coaches could eliminate confusion in the NPI application process and facilitate tracking of coaches.

Response: We thank the commenter for the thoughtful consideration of the most appropriate taxonomy designation for MDPP coaches who obtain an NPI. In the CY 2017 PFS, we previously suggested that Health Educator [174H00000X] may be appropriate for MDPP suppliers. Though we have no current plans to track MDPP coaches through the taxonomy associated with their NPIs at this time, we recognize the commenter's concern and acknowledge that a new taxonomy code specific to MDPP suppliers may be more appropriate than current options, and may also result in a more straightforward process. We will explore the possibility and appropriateness of this suggestion, and will provide updates through guidance and other MDPP supplier support materials, as appropriate.

Comment: One commenter who expressed disagreement with the proposed coach eligibility criteria given that they did not align with CDC DPRP standards later went on to urge CMS to require that coaches be supervised by a licensed medical professionals as an alternative to coach eligibility requirements.

Response: Though supervision by a licensed medical provision has been previously discussed and not finalized in the CY 2017 PFS final rule, and is therefore out of scope as a standalone requirement, using this as an alternative to the coach eligibility requirements differs slightly from our previous consideration of this policy. While we do not believe that CDC's DPRP standards are appropriate for program integrity safeguards and have thus proposed coach ineligibility criteria to avoid any program integrity risks, we do believe that CDC is more appropriately suited to determine credentialing requirements of the individuals furnishing the curriculum it oversees for the DPP. The commenter's proposal that CMS should require licensed

medical professionals to supervise coaches does not align with CDC's DPRP standards, and thus, we do not believe it is necessary to add that requirement from a quality standpoint. Furthermore, we do not believe that supervision by a licensed medical professional would address all of the same program integrity risks that are mitigated by the coach eligibility criteria.

Comment: We received a number of comments on policies previously discussed as a part of the CY 2017 PFS final rule. Most commonly, commenters urged CMS to reconsider requiring coaches have a form of credentialing or medical license, or that they be supervised by an individual with either. Two commenters urged against requiring certain coach training requirements that they believed were costly and could potentially limit the number of coaches available to furnish MDPP services. Additionally, we received a comments opposing that coaches obtain national provider identifiers (NPIs).

Response: Each of these topics were previously discussed and final determinations made through the CY 2017 PFS final rule, and therefore, comments are out of scope of the policies proposed in this rule. More information on our previous discussion of these policies can be found in section III.J.7 of the CY 2017 PFS final rule. In response to commenters' concerns regarding the potential barriers of coach training, we clarify that MDPP does not require training beyond current CDC DPRP requirements. Should the commenter have additional questions or concerns related to DPRP requirements, we encourage them to share this feedback with appropriate contacts at the CDC.

After considering the public comments, we are finalizing all polices related to MDPP coach eligibility as proposed at paragraphs §424.205(d)(3), (e), and (h)(1)(v).

(3) Ensuring MDPP Suppliers Are Legitimate, Operational Organizations

We proposed a number of requirements that would help ensure that MDPP suppliers are operational, have the resources necessary to furnish MDPP services, and are in compliance with MDPP supplier standards. At §424.205(d)(4), we proposed that, regardless of whether the MDPP supplier furnishes services solely in community settings, it must maintain at least one administrative location (82 FR 34163). All administrative locations maintained by the MDPP supplier must be on an appropriate site available to the public and must be reported on the CMS-approved enrollment application. We proposed that this administration location may not be a private residence. We proposed that an appropriate site must have signage posted on the exterior of the building, as well as be open for business and have employees, staff, or volunteers present during operational hours. For the purposes of this requirement, such signage may include, for example, the MDPP supplier's legal business name or its "doing business as" (DBA) name, as well as hours of operation. This proposal sought to utilize measurable objective indicators to determine that organizations are legitimately operating and able to furnish MDPP services to Medicare beneficiaries. We stated that we believe that, regardless of whether the MDPP supplier furnishes services at its administrative location, establishing a physical location is necessary for associated requirements for furnishing MDPP services, including recordkeeping requirements, training facilities, and storage for any educational materials distributed during sessions.

We proposed, at §424.205(d)(6), that a MDPP supplier must maintain a primary business telephone number listed under the name of the organization in public view. Public view could signify, for example, that the phone number is listed on a website, on flyers and materials. This policy would require that calls must not automatically go to the answering machine or utilize an answering service during posted business hours. The purpose of this requirement is to help

verify that the organization is a legitimate organization and not simply posing as an organization and seeking to bill Medicare fraudulently.

We further proposed, at §424.205(d)(7), that an MDPP supplier must not knowingly sell to or allow another individual or entity to use its billing number, consistent with §424.535(a)(7). We included this proposal to avoid a situation in which another entity uses an existing MDPP supplier's billing number. We stated that we believe that this policy plays an important role in ensuring that payments are only being made to the intended recipient who has met all of the supplier and compliance standards and that we continue to hold entities responsible for maintaining compliance. Otherwise, we risk making payments to suppliers potentially engaging in fraudulent or potentially harmful behavior.

We stated that we believe that the requirements in this section would not pose an undue burden on MDPP suppliers as they are minimum requirements for any functional, operational organization. By establishing these requirements, we believe that we would ensure that MDPP suppliers that do not meet the baseline requirements for an operational organization would not be permitted to furnish MDPP services to or receive payment for such services. We proposed, at §424.205(d)(15), that an MDPP supplier must permit CMS or its agents to conduct onsite inspections to ascertain the supplier's compliance with these standards. Although we believe that any operational business that truly furnishes MDPP services would be able to meet these requirements, we invited public comments on any aspects of these standards.

The following is a summary of the public comments received on our proposals for requirements that would help ensure that MDPP suppliers are operational, have the resources necessary to furnish MDPP services, and are in compliance with MDPP supplier standards and our responses:

Comment: Many commenters provided helpful feedback on the applicability, or in some cases, the inability to apply these proposals in certain scenarios. Many commenters expressed concern with the requirement that MDPP suppliers have signage on the exterior of the building. Specially, commenters noted that many organizations lack the ability to post such signage, for example those in historical buildings, those in large, multi-story office buildings, as well as those leasing space who are not permitted to affix signage. One commenter suggested that as alternative to requiring signage, having the supplier's name listed in the building directory, if available, should suffice as an alternative method to meet this policy goal. The same commenter went on to suggest that CMS should leave advertisement decisions for the suppliers to implement rather than stipulate requirements, and that CMS should not impose such stringent requirements under the guise of preventing fraud, waste, and abuse. As an alternative, the supplier suggested that CMS conduct random audit and site visits to determine operational status.

Response: We appreciate the commenters' feedback about the challenges a signage requirement may pose on MDPP suppliers who are operational, but who lack the ability to affix signage on the exterior of the administrative location where they primarily operate. It was not our intention to impose a new requirement on MDPP suppliers or to require signage as a specified form of advertising. Rather, we intended this proposal to indicate to MDPP suppliers what criteria they would be checked against and be held accountable for during a site visit that is aimed at determining operational status. Given that MDPP suppliers enroll upon high categorical risk, a site visit is required as a prerequisite to enrollment. This site visit seeks to ensure both the veracity of what is reported on the applicant's enrollment form and to verify that the organization is operational.

Based on commenters' feedback, we understand that the proposed policy would not serve its intended goal, and therefore, we will amend the proposal to allow multiple methods that an MDPP supplier could use to demonstrate its association with a specific location. We believe that by restructuring the MDPP supplier requirement to require that MDPP suppliers have signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building provides sufficient flexibility such that any MDPP supplier who truly is operational would not need to change their current operations in order to meet this supplier standard.

Comment: One commenter disagreed with the proposal that MDPP suppliers must have employees, staff, or volunteers present during operational hours. This commenter did not support this proposal based on inconsistency with previous DPP requirements under the CDC and with how many in-person community programs operationalize their programs. One commenter indicated that current DPP organizations do not operationalize their in-person programs in a way where employees, staff, or volunteers were present at an administrative location during operational hours.

Response: We do not agree with the commenter that functioning DPP organizations could not meet this requirement. We appreciate the commenter for expressing these concerns and notifying CMS that not all MDPP suppliers operate their business with individuals present during stated operational hours. The commenter did not describe where employees, staff, or volunteers of the MDPP supplier operated during operational hours, if not at the administrative location itself; therefore, we have limited information to better understand how to structure this requirement in way that could determine whether or not a prospective MDPP supplier applicant truly operated its business without requiring current DPP organizations to change their business

operations. Though we can conceive of scenarios in which an MDPP supplier has stated operational hours, but furnishes an MDPP session at a community location, and therefore, may not be present at the administrative location during stated operational hours, we do not believe that removing this requirement altogether would be appropriate. Furthermore, we clarify that we are not imposing specific operational requirements on the MDPP supplier. Thus, each MDPP supplier can determine and disclose its operational hours when it plans to physically be at the administrative location. An MDPP supplier who operates many services outside of their administrative location can also disclose when its operational hours are either telephonic or in a location other than its administrative location. We also highlight the significant flexibility we are providing in this supplier standard in that employees, staff or volunteers can fulfill this requirement, and we take no position as to whether these individuals serve as MDPP coaches or in another function for the supplier. The intent of this proposal was to ensure that an MDPP supplier maintains operational hours and truly fulfills these hours. We do not agree with the commenter that functioning DPP organizations could not meet this requirement, thus, we will finalize this policy as proposed.

Comment: A number of commenters disagreed with the requirement that MDPP suppliers maintain a primary business telephone that operates either at an administrative location or directly where services are furnished. In particular, commenters did not agree with the discussion in the preamble of the proposed rule which indicated that the proposed requirement would not allow calls to automatically go to the answering machine or the utilization of an answering service during posted business hours. Many commenters highlighted that it is an unrealistic expectation to never allow a call to go to some form of message system, even during business hours. Though multiple commenters expressed practical concerns with this requirement, one

commenter went as far as to suggest that this proposal could potentially dissuade prospective MDPP supplier applicants from their decision to enroll. This commenter recommended establishing a call back standard, for example, that MDPP suppliers must return calls within 1 business day.

Response: We agree with commenters that a requirement that every phone call be answered during operational hours would be burdensome, unrealistic, and extend far beyond the intention behind the proposal. We want to clarify that the proposal at §424.205(d)(6) only requires that MDPP suppliers have a telephone that operates at an administrative location or the location where MDPP services are being furnished, and that the associated telephone number must be listed with either the legal or doing business as name of the supplier in public view, including on websites, flyers, and materials. However, we understand why commenters expressed concern that we were also requiring that phone calls to this number be answered and not automatically go to a machine based on language in the preamble that provided rationale for our proposal.

To clarify, when we noted that the proposal at §424.205(d)(6), would require that calls must not automatically go to the answering machine or utilize an answering service during posted business hours, we did not intend to add this as a standalone requirement. This sentence was intended to convey that by requiring MDPP suppliers to maintain a primary business telephone that operates either at administrative locations or directly where services are furnished, MDPP suppliers could not, by default use an answering machine or answering service as their primary contact number. We did not mean to suggest that MDPP suppliers may never use an answering machine. Thus, while we expect that MDPP suppliers may allow phone calls to go to an answering machine or service during operational hours, we believe the standard as proposed

at §424.205(d)(6) will achieve the intended goal of providing a mechanism to ensure that MDPP suppliers are operational. We believe that this clarification addresses concerns raised by commenters, and we thus will finalize the policy as proposed.

After considering the public comments, we are finalizing the policy requiring MDPP suppliers to have at least one administrative location at an appropriate site, as proposed at §424.205(d)(4); however, we are modifying §424.205(d)(4)(i) to allow for increased flexibility for signage requirements. After clarifying commenters' confusion about telephone requirements, we are finalizing policies as proposed at §424.205(d)(6). We received no comments on the proposal that MDPP suppliers may not knowingly sell to or allow another individual or entity to use its supplier billing number, and thus are finalizing as proposed at §424.205(d)(7).

(4) Beneficiary Access

We proposed, at §424.205(d)(8), that MDPP suppliers may not deny access to MDPP services to eligible beneficiaries based on any reason other than the supplier's own self-determined and published capacity limits to furnish MDPP services to additional people and, on a discretionary basis, if a beneficiary significantly disrupts the session for other participants or becomes abusive (82 FR 34163 through 34164). Given that we do not yet currently have data on optimal class size for MDPP services, we are currently allowing MDPP suppliers to self-determine any upper limitation on class size. Should they establish such a limit and intend to turn beneficiaries away once the capacity limit is reached, the MDPP supplier must have previously made this limit publicly available; for example, denoting the limit in any brochures, websites, or other materials that outline their MDPP services. We proposed that MDPP suppliers must maintain a record of the number of eligible Medicare beneficiaries turned away for each of these reasons, as well as the date the beneficiary was informed. We further proposed that if an

MDPP supplier denies a Medicare beneficiary access citing disruptive or abusive behavior, details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) must be documented in the beneficiary's MDPP records and adhere to documentation requirements outlined in §424.205(g). We note that one supplier's decision to dismiss a beneficiary for this purpose would not prevent that beneficiary from switching to another MDPP supplier.

We stated that we will seek to monitor compliance with this requirement, and investigate further if necessary, based on beneficiary complaints, rates of access denials citing capacity limits in comparison to estimated capacity based on claims submitted, as well as monitoring claims for success rates for achieving performance goals that are higher than what would be expected for a typical Medicare population. Illustrative examples of capacity limits could include that the MDPP supplier has met its self-determined and published class size maximum, or that the supplier is providing MDPP sessions in cohorts and does not have a new or upcoming cohort at the time the beneficiary is seeking MDPP services. Furnishing MDPP services in a cohort means that the DPP curriculum is delivered among a single group, or cohort, from start to finish with sessions furnished in a specific order, and not allowing any new individuals to join once the cohort has begun.

Given that our payment structure for MDPP services relies on the achievement of weight loss and attendance goals, there may be incentives for MDPP suppliers to seek to serve only those beneficiaries for which they are more likely to earn performance payments. This, in turn, could result in discriminatory treatment of beneficiaries. Through this supplier standard, we would expressly prohibit MDPP suppliers from conditioning access to MDPP services on the

basis of a beneficiary's weight or health status (except as provided in our regulations). We also would prohibit MDPP suppliers from conditioning access to MDPP services on the basis of a beneficiary's achievement of performance goals, except where the beneficiary becomes ineligible for additional sessions as a result of not meeting those goals, as discussed elsewhere in this final rule. We stated that we believe that it is appropriate to prohibit suppliers from denying access to MDPP services except in certain limited circumstances. If a supplier were to deny access to a beneficiary citing lack of capacity, but then furnish MDPP services to a different beneficiary, this may signal a violation of such standards. In addition, and for the same reasons, we proposed to prohibit MDPP suppliers, including any coaches or entities performing functions or furnishing services related to MDPP services on their behalf, from unduly coercing a beneficiary's decision to change or not change to a different or specific MDPP supplier, including through the use of pressure, intimidation, or bribery in §424.205(d)(9). Information that may result in a beneficiary changing to a different MDPP supplier provided in response to a beneficiary's request for information would not violate this provision.

The CY 2017 PFS final rule, at §424.79, established the set of services included in the expanded model, but did not stipulate that once a supplier began furnishing such services to a beneficiary, that it must continue to offer them to the beneficiary as a part of the MDPP expanded model. We proposed, at §424.205(d)(10), that MDPP suppliers must offer and provide beneficiary access to the *entire set* of MDPP services for which beneficiaries are eligible. This includes the requirement that suppliers offer at least 16 in-person core sessions, no more frequently than once per week, over the first 6 months of the core services period and offer at least 6 core maintenance sessions, at least once per month, over months 7 through 12 of the core services period (§410.79(c)(2)(i)). For beneficiaries to whom the supplier has begun furnishing

MDPP services, and who meet the eligibility requirements for ongoing maintenance sessions described in §410.79(c)(1)(ii) and (iii), MDPP suppliers are required to offer 24 ongoing maintenance sessions, furnished at least once per month over the course of months 13 through 36 of the MDPP services period, in 3-month consecutive increments. These requirements would also apply to any MDPP supplier which begins furnishing MDPP services to a beneficiary that had begun the MDPP services period with a different MDPP supplier. Should this MDPP supplier begin furnishing services to a beneficiary at any point during the 3-year MDPP services period, it must continue to offer the services for which the beneficiary is eligible but has not yet received. For example, if a beneficiary changed suppliers after the core sessions in month 6, the subsequent supplier would be required to offer core maintenance sessions for months 7 through 12, and ongoing maintenance sessions should the beneficiary remain eligible for these services.

We also solicited public comments on a potential future policy to require a specific class size limit for MDPP sessions. Although we acknowledge that MDPP services may be successfully furnished in group settings, we stated that we believe that it is important to ensure that the group's size is appropriately set such that each beneficiary gains the necessary interaction with the coach furnishing the session to properly learn the curriculum. We considered different mechanisms to ensure this program objective, and requested public comments on considerations to date. The mechanism that currently seems most viable would require a limitation on the number of total attendees in a given session taught by an individual coach. Based on CDC's experience with the DPP program and review of the literature on appropriate class sizes for educational settings, we considered including a class size limitation of 30 participants per coach in a given session (including Medicare beneficiaries). Given that limited data currently exist on this type of requirement among DPP sessions, we solicited public

comments on what an appropriate class size limitation would be, including any evidence to support such a proposal.

Furthermore, we solicited public comments on how MDPP suppliers who furnish sessions in no specific sequential order and allow drop ins would balance the requirement of providing beneficiary access with a class size requirement for a given session. For example, if a supplier offers classes multiple times a week and gives beneficiaries flexibility regarding when to participate, we questioned whether a certain class size limitation could force a supplier to turn away a beneficiary seeking to attend a session at a time when attendance is high, and in so doing potentially discourage attendance at MDPP classes . In addition, we are unsure of any implications that would result from establishing a class size restriction for MDPP services while acknowledging that MDPP beneficiaries may participate in DPP sessions with non-Medicare beneficiaries who may not face the same class size limitation. Given these considerations, we solicited public comments on how we could structure a proposal in the future that would achieve the programmatic goals of effectively furnishing the DPP curriculum to Medicare beneficiaries in a manner and setting that contributes to positive behavioral changes and ultimately less progression to type 2 diabetes. In providing comments on this approach, we encouraged the submission of data and evidence to justify what specific class size would be appropriate for MDPP suppliers.

The following provides a summary of and our response to the public comments received on our proposals to prohibit MDPP suppliers from denying access to MDPP beneficiaries with limited exceptions, to require that MDPP suppliers document when they deny a beneficiary access under two of these exceptions, and to prohibit MDPP suppliers or individuals working on

its behalf from unduly coercing a beneficiary's decision to or not to switch to a different MDPP supplier.

Comment: One commenter supported that CMS did not define the capacity limit for MDPP suppliers. The commenter agreed that MDPP suppliers should have the flexibility to determine the optimal class size to effectively deliver MDPP services.

Response: In the absence of data to support a specific class size, we agree with the commenter that providing MDPP suppliers' flexibility to determine capacity limits, such as a supplier's capacity to accommodate or effectively serve a given number of participants per cohort, which is appropriate for its method of delivery is the correct policy decision at this time. We believe that most MDPP suppliers, in absence of a specified limit, will identify a reasonable size class size that enables a sufficient level of beneficiary engagement that results in sustained attendance and weight loss.

Comment: MedPAC, however, contended that the proposal should have specified a class size. Their concerns on class size compounded with other concerns, including but not limited to not requiring eligible individuals to receive referrals from physicians or non-physician practitioners for MDPP services. To illustrate their concerns, they presented a specific scenario of a coach furnishing a large MDPP session in a nursing home without consideration of the clinical inappropriateness of MDPP services and the targeted weight loss for each individual in attendance.

Response: Though we acknowledge MedPAC's concerns that allowing class size flexibility would allow MDPP suppliers to furnish services in large class sizes, , we do not wish to impose a specific class size limitation without data to support such a decision. Further, we do not agree that our policy decisions could result in the scenario MedPAC illustrated in their

comment. We discuss a response to their concerns about referrals in section III.K.2.c of this final rule.

Furthermore, we believe that even in absence of a specific policy imposed by CMS, MDPP suppliers have incentives to furnish MDPP in smaller class sizes that are more conducive to engaging beneficiaries in behavioral change practices that will lead to weight loss and lowered diabetes risk. We believe that the payment structure rewards MDPP suppliers when MDPP beneficiaries meet weight loss goals. Thus, high levels of beneficiary engagement are to the benefit of both MDPP suppliers and beneficiaries, in order to achieve this weight loss. Based on experience with performance in the DPP indicating that beneficiary engagement plays a critical role with sustained attendance and weight loss, we believe that MDPP suppliers have greater incentives to furnish sessions in smaller settings with high levels of engagement than to furnish sessions with a high volume of participants, but low levels of engagement.

In addition to the importance of both sustained attendance and weight loss for MDPP payment, it also plays a significant role in maintaining CDC recognition. If suppliers conduct large sessions, beneficiary engagement is likely to be lower. Stakeholders have suggested that this may result in decreased attendance and/or failure to lose weight. If a supplier is furnishing MDPP services in extremely large classes where a large proportion of participants either do not attend or lose 5 percent of their body weight, this will negatively impact DPRP performance data that are necessary to maintaining recognition status. Should a supplier lose its recognition status, it will no longer be eligible for enrollment in Medicare.

Taken together, we believe that MDPP suppliers have larger incentives – both financial for MDPP reimbursement and sustainability of recognition status based on DPRP performance requirements – to furnish small sessions rather than large sessions.. If some suppliers initially

offer larger classes, we believe that lower per beneficiary reimbursement and threat of lost CDC recognition will motivate suppliers to self-correct. Regardless of this belief, we will monitor for activities that would indicate if an MDPP supplier is furnishing services in an overly large group. As a result of this monitoring and/or if we receive evidence to support an appropriate class size limitation, we may reconsider imposing a class size limit at a later date.

Comment: A number of other commenters responded to the request for information on suggested class sizes. In making their recommendations, many commenters noted that beneficiaries require a fairly high level of engagement in order to successfully adopt behavior changes that ultimately result in weight loss and decreased risk of type 2 diabetes. Two commenters recommended a maximum class size of 15, another recommended 20, another a minimum of 5 and maximum of 25, and a final with 30. One commenter recommended that the beneficiary to coach ratio not exceed 1:12-14, though they did not respond to the other challenges we outlined with imposing such a ratio.

Response: We thank the comments for providing this level of detail on their suggested class size and will consider these responses in the future should we decide to reconsider this proposal.

Comment: One commenter with experience offering the National DPP requested an additional exception that would allow MDPP suppliers to deny beneficiaries from joining an existing MDPP cohort that had already met three or four times. The commenter indicated that their experience providing the National DPP showed that the initial classes work to establish a group dynamic, and adding an individual to a recently established group can disrupt that dynamic.

Response: We understand the commenter to be requesting the addition of another exemption under §424.205(d)(8), which prohibits MDPP suppliers from denying an MDPP beneficiary access to MDPP services during the MDPP services period. We decline to adopt the commenter's recommendation as we stated in the proposal that this would constitute a capacity limit: "Illustrative examples of capacity limits could include that the MDPP supplier has met its self-determined and published class size maximum, or that the supplier is providing MDPP sessions in cohorts and does not have a new or upcoming cohort at the time the beneficiary is seeking MDPP services."

Though we specifically utilized the word capacity in order to capture the diversity of MDPP delivery styles, we understand that by framing this requirement as "lacking capacity" may have signified that a maximum number of participants had been reached, though in the scenario raised by the commenter, an MDPP supplier may consider furnishing MDPP services through cohorts, and once they have commenced, the capacity can be considered reached for additional MDPP beneficiaries. To more appropriately capture the above listed examples of capacity, we will modify the proposal such that an MDPP supplier may deny access to a beneficiary if the MDPP supplier lacks the self-determined and publicly-posted capacity. Though we discussed the need to publicly post the capacity in our proposal, we would like to emphasize this point by including it in our regulation. Additionally, we are changing the language from "an additional" beneficiary to "a given beneficiary" in the circumstance where an MDPP supplier establishes a minimum capacity to which to furnish services to beneficiaries, given that MDPP services are offered in group setting and some MDPP supplier may determine that an optimal capacity for engagement includes both a minimum and maximum number of participants. Other forms of capacity requirements are discussed further in this section in response to other commenters. We

would like to clarify that, denying an MDPP beneficiary access to a specific MDPP session due to capacity reasons, even if the MDPP supplier offered the beneficiary access to a different session at a later date would constitute a denial of MDPP services under §424.205(d)(8)(i)(B) until that beneficiary ultimately received MDPP services from the supplier.

Comment: One commenter requested that CMS allow integrated systems that develop and provide approved MDPP services to serve only their own enrollees.

Response: While the commenter did not point to a specific proposal that would prohibit an integrated system from serving only its own enrollees, we believe that the commenter is referencing the prohibition on denying beneficiaries access to MDPP services under §424.205(d)(8). Additionally, as the commenter specifically addresses "enrollees" we believe the commenter is contemplating Medicare Advantage enrollees in an MA plan who receive services and are provided coverage for those services within an integrated system. Under §424.205(d)(8), an MDPP supplier must not deny an MDPP beneficiary access to MDPP services during the MDPP services period described in §410.79(c)(2) of this chapter, including on the basis of the beneficiary's weight, health status, or achievement of performance goals, unless the denial falls under one of three exemptions listed at §424.205(d)(8)(i)(A)-(C). In the commenter's example, denying access to MDPP beneficiaries other than the MDPP supplier's own enrollees would clearly violate the prohibition established in §424.205(d)(8), as the MDPP supplier is affirmatively denying access to MDPP services for all non-enrollees. Therefore, to be permissible, the MDPP supplier's denial of non-enrollees must qualify as an exception under §424.205(d)(8)(i).

The exceptions found at §424.205(d)(8)(i)(A) (beneficiary no longer meets eligibility criteria for MDPP services) and §424.205(d)(8)(i)(C) (MDPP beneficiary significantly disrupts

the session for other MDPP beneficiaries or becomes abusive) would not apply to the example provided by the commenter. However, §424.205(d)(8)(i)(B) warrants further discussion. Under this provision, an MDPP supplier may deny an MDPP beneficiary access to MDPP services where the MDPP supplier lacks the self-determined and publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary. A supplier's "capacity" to furnish MDPP services encompasses several categories of capabilities that ultimately impact a supplier's capacity to furnish MDPP services to a MDPP beneficiary. For instance, a supplier could lack capacity to furnish MDPP services to a given MDPP beneficiary where the MDPP supplier lacks adequate physical space to accommodate the MDPP beneficiary if the MDPP supplier determines that its enrollment is at capacity for the space. Additionally, a supplier could lack capacity to furnish MDPP services to a given MDPP beneficiary where there are a finite number of coaches to hire to provide MDPP services, which in turn would reasonably limit the number of MDPP cohorts or classes that the MDPP supplier could provide as well as the number of MDPP beneficiaries that the MDPP supplier could accommodate.

Furthermore, an MDPP supplier could lack capacity to furnish MDPP services to a MDPP beneficiary where the MDPP supplier lacks business processes that would be required to furnish services to a MDPP beneficiary. In such a case, the MDPP supplier would need to determine that the burden of implementing the necessary business process rises to the level of a capacity limitation within the meaning of §424.205(d)(8)(i)(B). It is this type of capacity that we believe to be at issue in the example provided by the commenter as where an MA plan that is part of an integrated system furnishes MDPP services to MA plan enrollees in the role of an MDPP supplier, the MA plan may lack a number of business processes that would be required to

furnish MDPP services to non-enrollees and bill Original Medicare on a fee-for-service basis for those services.

Some of these required business processes could not reasonably be determined to rise to the level of a capacity limitation, such as the need for the MDPP supplier to develop processes to request and receive medical information from non-enrollees to determine eligibility for MDPP services. As an integrated system that is both payer and provider, the MDPP supplier would not need such processes as it would be able to pull lab values or recorded weights to determine eligibility for MDPP services from the enrollee's own health records kept by the system. Yet, such processes would be in place for the MA plan of which the MDPP supplier is apart given that the plan would commonly need to request and accept medical information on new enrollees. So, while this is an example of a business process that the MDPP supplier would be required to develop to serve non-enrollees, it likely does not rise to the level of a capacity limitation if it is a business process that the MA plan as a whole already has in place for the MDPP supplier to adopt as well.

However, the need for other business processes could reasonably be determined to rise to the level of a capacity limitation. For instance, MA plans do not bill Original Medicare on a fee-for-service basis for services provided to enrollees, and therefore lack the capacity to perform an operational requirement that would be necessary if the MA plan, as part of an integrated system, were to furnish MDPP services to non-enrollees under their MDPP supplier role. Given the administrative burdens associated with implementing the business processes required to bill fee-for-service Medicare, an MDPP supplier in this instance would be reasonable in determining that the complete lack of such a business process would rise to the level of a capacity limitation. As we believe that commenter's example is permitted under an existing exception to

§424.205(d)(8), we decline to adopt commenter's recommendation to articulate an additional, specific exception for an MDPP supplier that is part of an MA plan operating within an integrated system that wishes to exclusively provide MDPP services to its enrollees. However, we may continue to evaluate this issue for future rulemaking, as appropriate.

Comment: One commenter expressed concern regarding the exception that MDPP suppliers may deny access to MDPP services if a beneficiary is disruptive or abusive. The commenter questioned whether allowing MDPP suppliers to deny access based on behavioral issues would disproportionately affect individuals with serious mental illnesses (SMI) who may be more likely to be disruptive based on their SMI. Given that certain classes of medications used to treat SMI are known to increase the risk of both obesity and diabetes, individuals with SMI who would likely benefit from diabetes risk prevention may be more likely to be denied access based on this exception to the supplier standard. While the commenter did not explicitly suggest removing this exception, but instead, highlighted a potential issue with only offering in-person sessions delivered in a group to individuals with SMI, the commenter suggested that a virtual model may more appropriately suit the needs of individuals with SMI.

Response: We recognize the concerns raised by the commenter regarding the potential unintended consequences of such a proposal. In proposing the exemption to allow suppliers to deny access to an MDPP beneficiary who significantly disrupts a session for other beneficiaries or becomes abusive, we in no way intended to discriminate against individuals who, because of a condition, medication, or illness may be more prone to disruptive or abusive behavior. In the context of MDPP, disruptive behavior would entail preventing the information from being appropriately conveyed from the coach to other participants. Examples may include repeated interruptions unrelated to the session content, playing music or video content unrelated to MDPP

during a session, or raising discussions on topics unrelated to MDPP or its content. Should the beneficiary's communications relate to the MDPP content (for example, a beneficiary asking many clarifying questions about the material), this would not qualify as disruptive behavior in an MDPP group session. Abusive behavior would entail behavior that results in physical, emotional, or psychological harm to those participating in the MDPP session, include an MDPP coach, beneficiary, or other MDPP personnel. For example, any violent behavior or bullying could constitute abusive behavior in this context. Given that MDPP is furnished in group settings where one beneficiary's action can affect others, we believe that allowing MDPP suppliers to remove beneficiaries who engage in these behaviors is particularly appropriate.

Though we do not wish to subject other Medicare beneficiaries to disruptive or abusive behaviors, we agree with the commenter that individuals with those behaviors, either as a result of SMI or otherwise, who are eligible for MDPP services generally should have access to such services. MDPP sessions are furnished by coaches who do not have medical training beyond what the DPRP requires. Should an individual with SMI become abusive, it does not seem appropriate to require that the supplier continue to furnish services to that beneficiary. In such a scenario, the beneficiary may be better suited to be under the care of a professional with specific training to appropriately work with beneficiaries with SMI. Furthermore, given that MDPP coaches furnish sessions in a group setting, we must also consider the needs of all participating beneficiaries. With these considerations in mind, we believe that our original proposal is appropriate.

Comment: We received one comment on our proposal to require documentation when a beneficiary is denied for any reason other than losing eligibility. This commenter disagreed with

this proposal, citing that it creates yet another administrative requirement and burden on MDPP suppliers.

Response: While we recognize that this requires additional recordkeeping by suppliers, we believe that it serves an important purpose to dissuade MDPP suppliers from denying access based on any reasons other than those allowed. With such a requirement, CMS would be able to review MDPP suppliers' records related to denial of access to beneficiaries to ensure compliance. Given the performance-based nature of the MDPP payment, we believe some MDPP suppliers may wish to attract beneficiaries they perceive as more likely to achieve attendance and weight loss performance goals and may wish to deny those who they perceive as being less likely. We do not want to encourage cherry picking among suppliers where such behaviors occur, and thus are not altering our proposal.

Furthermore, we would like to take this opportunity to clarify our proposal. Under §424.205(d)(8)(ii), an MDPP supplier must maintain a record of the number of MDPP beneficiaries for whom it declined access for the reasons outlined in §424.205(d)(8)(i)(B) and (C), to include the date each such beneficiary was declined access. If a beneficiary is denied under §424.305(d)(8)(i)(B), stating in the record "self-determined capacity" alone as the reason the beneficiary was denied would not sufficiently address the documentation requirements. As stated in the proposal, we intended this documentation to provide insight into the specific capacity reasons a beneficiary was denied to ensure that it aligned with the MDPP supplier's previously published capacity limits.

Comment: We did not receive any comments on proposals at §424.205(9) which prevented an undue coercion of an MDPP beneficiary's decision to change or not to change to a

different MDPP supplier. We similarly received no comments on the proposal at §424.205(10) requiring that the MDPP supplier furnish all services for which an MDPP beneficiary is eligible.

Response: Given no feedback on these proposals, we are finalizing as proposed.

After considering the public comments, we are finalizing the policies as proposed under §424.205(d)(8) as proposed except to modify §424.205(d)(8)(i)(B) to state the MDPP supplier lacks the self-determined and publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary. Given no feedback from commenters, are finalizing §424.205(d)(9) and §424.205(d)(10) as proposed, with a modification to §424.205(d)(10) to align with changes in proposals at §410.79(c)(2) where ongoing maintenance sessions are only available for eligible beneficiaries for one year, rather than the proposed two.

(5) Disclosure

We proposed, at §424.205(d)(11), that MDPP suppliers must provide information about the MDPP expanded model to each beneficiary to whom it wishes to begin furnishing MDPP services (82 FR 34164 through 34165). This included detailed information on coverage for the set of MDPP services, the once-per-lifetime limit, on eligibility requirements, and the MDPP supplier standards. We recognized that many aspects of the MDPP expanded model are novel for both beneficiaries and suppliers, and we desire that both parties are well informed. Therefore, we stated that we believe that requiring the supplier to fully disclose information about the MDPP expanded model, coverage, and the MDPP supplier standards will help inform all parties. We intend to provide a specific template for the MDPP supplier to use to disclose this information to the beneficiaries. For this reason, we stated that we do not believe that requiring this type of disclosure places a significant burden on the supplier. Although we believed that this approach will help to address the policy goals of the MDPP expanded model,

we invited public comments on this approach, particularly upon the provision of a standard CMS disclosure notification as compared to CMS providing MDPP suppliers with information they could use to their own disclosure notification materials. Along these lines, we highlight that we also intend to publish information on the MDPP expanded model in the 2019 Medicare & You Handbook.

We invited public comments on these proposals.

The following is a summary of the public comments received on these proposals and our responses:

Comment: We received one comment regarding our supplier standard requiring MDPP suppliers to disclose information to beneficiaries about the program. The commenter expressed full agreement with our proposal, and endorsed the potential CMS-created template to ensure consistency of messaging. In particular, this commenter requested that any such information be provided during the 2018 enrollment period. Additionally, the commenter suggested that MDPP model information be included in the 2019 Medicare & You Handbook.

Response: We appreciate the support for our proposed policy and thank the commenter for expressing specific suggestions regarding how CMS can best equip suppliers to comply with this comment in a manner that is consistent across all MDPP suppliers. We will consider these suggestions as we create any resources to MDPP suppliers, and will release information through guidance as appropriate.

We are clarifying in this final rule that the disclosure requirements we proposed at §424.205(d)(11) specified that, before the initial core session is furnished, the MDPP supplier must disclose detailed information about the set of MDPP services to each MDPP beneficiary to whom it wishes to begin furnishing MDPP services. At §424.205(d)(11)(i) and (d)(11)(ii), this

requirement then goes on to specify that this disclosure must include eligibility requirements as outlined under §410.79(c)(1) and the MDPP supplier standards overall. In our proposal, we intended that detailed information about the set of MDPP services included which services, at minimum, were covered in the MDPP set of services. Given that the supplier standard proposed and finalized at §424.205(d)(10) outlines these services, and MDPP suppliers must disclose their standards to beneficiaries, we believe that under our ordinary proposal, MDPP suppliers have provide MDPP coverage information to beneficiaries. However, to avoid any potential uncertainly, we are amending our proposed supplier standard to explicitly require that the MDPP supplier disclose MDPP coverage information, in addition to information on eligibility and MDPP supplier requirements. Though we believe that this requirement was already implicit in the proposal, we believe that clarifying this point to more overtly stipulate that MDPP suppliers disclose coverage information will only help MDPP suppliers understand and comply with the disclosure requirements. Furthermore, we believe that providing this clarity to ensure that all suppliers are disclosing MDPP coverage information to beneficiaries aligns with the request that CMS make efforts to standardize practices across suppliers. Given the discussion on MDPP suppliers' ability to furnish more than the minimum required sessions during the core services period, but their inability to charge beneficiaries as discussed further in section III.K.2.d.iii.(10)(c) of this rule, we believe that this adjustment to our proposal is warranted to ensure MDPP beneficiaries are as informed as possible.

After considering the public comments, we are finalizing the supplier standard regarding disclosure as proposed at §424.205(d)(11), with a modification to specifically highlight that detailed information about the set of MDPP services not only includes eligibility and supplier

standards, as previously proposed, but also minimum coverage requirements under §410.79(c)(2).

(6) Beneficiary Complaints

We proposed at §424.205(d)(12) that MDPP suppliers must answer Medicare beneficiaries' questions about MDPP services and respond to MDPP related complaints within a reasonable timeframe in §424.205(d)(12) (82 FR 34165). We also proposed that MDPP suppliers implement a complaint resolution protocol and maintain documentation of all beneficiary contact regarding such complaints, including the name and Medicare Beneficiary Identifier of the beneficiary, a summary of the complaint, related correspondences, notes of actions taken, and the names and/or NPIs of individuals who took such action on behalf of the MDPP supplier. We proposed that this information must be kept at a supplier's administrative location and made available to CMS or its contractors upon request. These records would adhere to the same recordkeeping requirements in §424.205(g), and therefore, would need to be maintained for 10 years. Although other records are typically required to be held only for 7 years (per §424.516(f)), given that the MDPP expanded model includes beneficiary engagement incentives (described further in section III.K.2.f.v.) which require an extended documentation requirement, we considered it important to align all recordkeeping requirements for the MDPP expanded model. As noted earlier in this section, we proposed at §424.205(d)(15) that an MDPP supplier must allow CMS or its agents to conduct recordkeeping reviews to ascertain the supplier's compliance with these standards, as well as documentation requirements as outlined in §424.205(g).

We stated that we believe our proposal that MDPP suppliers must answer, respond to, and document beneficiary complaints and resolutions establishes a tracking mechanism to

determine whether or not suppliers are adequately addressing beneficiary concerns. We find this requirement particularly important given that complaint procedures provide a good way to ensure best practices by suppliers. Although we acknowledged that this method requires the MDPP suppliers to self-attest to their response to complaints, we stated that requiring such documentation as a required Medicare standard can help to build accountability to following through with complaint resolution. Additionally, mandating that suppliers take and maintain records of complaints may help to address situations where beneficiaries raise issues with us directly after failing to receive resolution from the supplier.

We stated that we believe that requiring this documentation would provide an additional mechanism for us to ensure that the supplier is fully disclosing information pertinent to the supplier standards, specifically those regarding beneficiary access, and other concerns. As an additional benefit of this policy, if a beneficiary is denied access, the MDPP supplier would be required to demonstrate the reasoning behind this approach, and we could have an opportunity to review if this reasoning complied with the standard under §424.205(d)(8).

This approach is consistent with supplier standards for other Medicare suppliers, including those for Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. Given that CMS has imposed similar standards regarding supplier responsibility for addressing beneficiaries' complaints among other supplier types, we stated that we do not believe that requiring a similar such requirement poses an undue burden on MDPP suppliers. Rather, we believed that this approach can facilitate beneficiary satisfaction with the services suppliers furnish by requiring that beneficiary complaints are acknowledged, resolved, and tracked appropriately. We stated that we believe that this approach will help ensure that the supplier is meeting beneficiaries' needs as they relate to the MDPP expanded model. In

addition, we stated that we believe that this will help ensure the integrity of the MDPP expanded model.

We invited public comments on these proposals.

We received no comments on our proposals requiring that MDPP suppliers respond to MDPP beneficiaries' questions and concerns within a timely manner or that they complete and maintain a complaint resolution protocol. Similarly, we received no comments on any of our proposed recordkeeping requirements to document beneficiary complaints. Thus, we are finalizing the MDPP supplier standards related to beneficiary complaints under §424.205(d)(12) as proposed.

(7) MDPP Expanded Model Evaluation Compliance

In the CY 2017 PFS final rule, we finalized a requirement for MDPP suppliers to maintain and submit to CMS a crosswalk file that documented how the beneficiary identifiers submitted to CMS for billing and the beneficiary identifiers submitted to CDC for session-level performance data linked to the same beneficiary as a documentation retention and provision requirement (formerly §424.59(b), redesignated and amended at §424.205(d)(13)) in this final rule) (82 FR 34165 through 34166). CMS will use this crosswalk for evaluation purposes so CMS can review session level data that MDPP suppliers provide to CDC to supplement the claims data we receive directly from MDPP suppliers. We indicated that we would provide additional information on format and frequency of this reporting requirement in future rulemaking or administrative guidance as appropriate. We proposed the maintenance and submission of the crosswalk as an MDPP supplier standard and are providing additional details regarding the format and frequency.

We proposed that the crosswalk file would contain Medicare Health Insurance Claims Numbers or Medicare Beneficiary Identifiers and the unique participant identifier assigned by the organization, for the purposes of CDC performance data reporting, for each beneficiary receiving MDPP services (§424.205(d)(13)). Beneficiaries for whom at least one Medicare claim was submitted by an MDPP supplier would be required to be included in the crosswalk. We proposed that the crosswalk be supplied to CMS, or our contractor, beginning 6 months after the organization begins furnishing MDPP services, and quarterly thereafter. The crosswalk would be maintained in a spreadsheet (for example, an Excel file or a CSV file), in a form and manner as specified by CMS. We invited public comments on this approach.

The following is a summary of the public comments received on this approach and our responses.

Comment: We received one comment on our supplier standard related to the crosswalk. The commenter did not request a specific change to the proposal, but expressed concern regarding the administrative burden of having to submit performance data to CDC and the crosswalk to CMS. Their specific concern centered on having two separate data submission requirements to two distinct entities – performance data to CDC and the crosswalk to CMS. They stipulated that these requirements would pose an administrative burden to all MDPP suppliers, though they particularly highlighted smaller suppliers and those new to Medicare.

Response: In the CY 2017 PFS, we proposed and finalized that MDPP suppliers would need to submit a document cross-walking beneficiary identifiers in Medicare with their CDC participant ID submitted on performance data to CDC. In this rule, we did not propose new data submissions, but simply incorporated this finalized requirement into the MDPP supplier standards. Thus, the commenters' concern on the burden of needing to submit both performance

data to CDC, as well as the crosswalk to CMS is out of scope with this rule. Should the commenter wish to revisit our rationale for this approach, it may do so in section III.J.4.f of the CY 2017 PFS final rule.

Rather that propose any new requirements in this rule, we sought to provide clarity on the information that MDPP suppliers must submit on the crosswalk and its frequency. In efforts to streamline data submission requirements for the crosswalk across all MDPP suppliers, we are further clarifying the requirement we outlined in the proposed rule (82 FR 34165 through 34166), that data must be submitted 6 months after an MDPP supplier begins furnishing services, and quarterly thereafter. Rather than apply crosswalk submission dates on a per supplier basis, which could conceivably result in different suppliers submitting their crosswalks each month of the year, moving forward, we intend to establish four distinct periods where MDPP supplier crosswalks are accepted. With this change in mind, we are adapting our proposal such that MDPP suppliers will become eligible to submit their crosswalk beginning 6 months after they begin furnishing services and must submit at the closest quarter, and continue submitting on a quarterly basis thereafter. We hope that streamlining the submission periods across all suppliers will decrease confusion among suppliers and work to alleviate some of the burden associated with the crosswalk submission. We will provide details on this submission process through guidance, as appropriate.

Additionally, to enable evaluation of MDPP services for a beneficiary's entire MDPP services period (that is, up to 2 years), we proposed that MDPP suppliers must submit performance data for any beneficiaries who attend ongoing maintenance sessions in a manner and form as specified by CMS (proposed §424.205(d)(14)). This proposal served to ensure that MDPP suppliers provide session-level data for ongoing maintenance sessions that are consistent

with the data they are already providing to CDC for the core MDPP services period. This requirement is necessary given that session-level performance data plays a critical role in the Innovation Center's evaluation of the entirety of the MDPP expanded model. Without such data, the Innovation Center would lack any streamlined method of obtaining session-level data for ongoing maintenance sessions furnished to MDPP beneficiaries. We proposed that this performance data must align with the performance date elements as required by CDC for the DPRP standards. We solicited public comments on this approach.

We received no comments on our proposal requiring MDPP suppliers to submit session-level data, consistent with performance data MDPP suppliers are already providing to CDC, for ongoing maintenance sessions. Thus, without any stakeholder input on this policy, we are finalizing as proposed at §424.205(d)(14). However, in light of concerns regarding the multiple and distinct data submission requirements MDPP suppliers must submit to CMS and CDC, we clarify that such MDPP suppliers shall submit any performance data for ongoing maintenance sessions, as required under §424.205(d)(14) to CDC along with the performance data they would already provide per the DPRP standards. We recognize stakeholders concerns raised both in this rule and in our previous policy proposals regarding potential burden associated with multiple and distinct submission requirements, and thus we will plan to align our requirements for data submission under this requirement with the DPRP data submission requirements for the initial core services period. We believe that this alignment with CDC will alleviate some of the potential burden associated with this MDPP supplier standard. We will release additional information through guidance, as appropriate.

We are finalizing our policies as proposed at §424.205(d)(13) and (14). However, this rule provided an update to the manner and form MDPP suppliers must submit the crosswalk §424.205(d)(13) that would provide greater consistency across suppliers.

v. MDPP Supplier Revalidation

In the CY 2017 PFS final rule, we specified that newly enrolling MDPP suppliers as high categorical risk in accordance with §424.518(c), but we did not address the risk level of MDPP suppliers upon revalidation. Section 6401(a) of the Affordable Care Act established that all Medicare suppliers must revalidate their enrollments as a program integrity measure. Upon revalidation, suppliers are screened for their continued enrollment in Medicare. Although MDPP suppliers enroll at the high risk level, we proposed, at §424.205(b)(3)(ii), that MDPP suppliers would revalidate under a moderate risk level in accordance with §424.518(b)(2). We believe that this approach is appropriate, given that fingerprint-based criminal history record checks through the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System (IAFIS) requirement for "high" categorical risk will have already been completed upon initial enrollment. In addition, we believe that this approach is appropriate, given its consistency with other providers and suppliers who initially enroll under "high" categorical risk, but revalidate under "moderate" categorical risk, such as DMEPOS suppliers and Home Health Agencies. We also proposed, at §424.205(b)(6), as a condition of enrollment, that MDPP suppliers must revalidate their enrollment every 3 years, consistent with DMEPOS suppliers who are initially screened under "high" categorical risk screening level (82 FR 34166). We welcomed public comments on these proposals.

The following is a summary of the public comments on the proposals to require that MDPP suppliers revalidate every 3 years at moderate categorical risk:

Comment: Generally, commenters supported the proposal that MDPP suppliers' risk categorization decrease from high to moderate upon revalidation. One of the commenters who supported this proposal justified its support because of its alignment with requirements for other high risk suppliers.

Response: We appreciate the support provided for this proposal and are finalizing the requirement that MDPP suppliers pass screening at moderate categorical risk upon revalidation.

Comment: One commenter raised concerns about designating MDPP suppliers as high categorical risk upon initial enrollment, a proposal which we finalized in the CY 2017 PFS final rule, no commenters opposed the current proposal regarding revalidating at moderate risk.

Response: This policy was not proposed in the rule, and therefore, is out of scope. Though we may consider revisiting MDPP supplier risk level upon initial enrollment in the future, we have no current plans to do so at this time. For our rationale for finalizing this policy, please refer to section III.J.7.a of the CY 2017 PFS final rule.

Comment: In response to the proposal that MDPP suppliers revalidate every 3 years, some commenters supported this proposal. Generally, those that expressed support for this policy did so in combination with the proposal that MDPP suppliers revalidate at moderate risk level, meaning that they treated the two proposals as a single policy without acknowledging specific support for the frequency of revalidation. As mentioned previously, one of the commenters in support of the proposal justified their support given its consistency with other high risk suppliers.

Response: We appreciate commenters' support for our proposal. Though we agree with commenters that the proposal for MDPP suppliers to revalidate at moderate categorical risk every 3 years aligns with existing policies for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, which also initially enroll at high categorical risk,

we also acknowledge that Home Health Agencies, which similarly initially enroll at high categorical risk, revalidate at moderate risk level every 5 years.

Comment: A few commenters did not support revalidation every 3 years, given concerns that the frequency of revalidation was high, particularly with respect to the duration of the MDPP services period. While one commenter simply requested that MDPP suppliers revalidate less frequently than every 3 years, another specifically proposed that CMS require MDPP suppliers to revalidate every 5 years. Both commenters stated that requiring MDPP suppliers to revalidate as frequently as every 3 years would pose unnecessary burdens.

Response: Given the novelty of the MDPP supplier type, our expectation that most MDPP suppliers will be non-traditional heath care providers, and general concerns about the potential vulnerabilities of fraud and abuse raised by MedPAC and others, we have sought to design stringent program integrity policies that will enable us to detect, monitor, and ultimately limit the ability for potential fraud, waste, or abuse from organizations which enroll as MDPP suppliers.

While a similar number of commenters expressed support for our original proposal, as well as recommended an alternative proposal that would require less frequent revalidations, we considered this proposal within the context of broader comments regarding the high degree of supplier burden as a result of our cumulative requirements. Though not expressly made in response to this proposal on revalidation, commenters frequently noted that the number of MDPP supplier requirements and burden from those requirements could potentially dissuade prospective MDPP suppliers from deciding to enroll. In light of these concerns and our desire to enable a strong supplier base to meet beneficiary demand for MDPP services, we looked for opportunities where we could alter requirements for MDPP suppliers to alleviate supplier burden without

posing vulnerabilities to the integrity of the Medicare program or the safety of our beneficiaries. Ultimately, we determined that decreasing the frequency with which MDPP suppliers revalidate could achieve this balance. As such, we are modifying our proposal such that MDPP suppliers will be required to revalidate every 5 years, instead of the proposed 3 years. That said, we acknowledge MedPAC's concerns against the potential for fraud and abuse, as well as their encouragement to apply all program integrity safeguards possible for this new expanded model and the suppliers who furnish it. Therefore, we will continue to monitor the level of risk posed by MDPP suppliers and will consider revalidating more frequently in the future, if appropriate.

Additionally, given the novelty of this model expansion, we are considering utilizing a provisional period of enhanced oversight authority under section 1866(j)(3) of the Act to monitor for program integrity safeguards. Should we take this approach, CMS would assume the responsibility of conducting any oversight action as a way of avoiding adding any increased burden to MDPP suppliers. We believe that this approach to require that MDPP suppliers revalidate less frequently, and instead, for CMS to assume responsibility for enhanced monitoring demonstrates our commitment to respond to stakeholder comments to both protect the Medicare program and its beneficiaries against fraud, waste, and abuse and also to avoid unnecessary burdens to the suppliers who service our beneficiaries.

After considering the public comments, we are finalizing our proposal at §424.205(b)(3)(ii) that MDPP upon revalidation, MDPP suppliers must pass moderate categorical risk. To make MDPP supplier risk levels more clear, we are adding Prospective (newly enrolling) MDPP suppliers to high categorical risk at §424.518(c)(1)(iii) and revalidating MDPP suppliers to the moderate risk level at §424.518(b)(1)(xi). Based on feedback from

suppliers' broader request for less administrative burden, we are finalizing a modification of our proposal at §424.204(d)(6) such that MDPP suppliers must revalidate every 5 years.

vi. Documentation Retention and Provisions Requirements

We proposed that the following requirements would apply to records related to a MDPP supplier's compliance with the MDPP expanded model (codified at §424.59(b), redesignated as amended at §424.205(g)) (82 FR 34166). We stated that we believe that these proposals would increase supplier recordkeeping accuracy, and clarify documentation retention requirements. Specifically, we proposed that an MDPP supplier must:

- Provide to CMS or its contractors, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the supplier's compliance with MDPP requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements found in §424.210 in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

- Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services furnished by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the MDPP supplier at least 30 calendar days before the normal disposition rate; or

++ There has been a dispute or allegation of fraud or similar fault, as defined at §405.902, against the MDPP supplier, in which case the records must be maintained for an

additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We stated that we believe these proposals increase the likelihood of operationalizing MDPP program integrity strategies that include audits, evaluations, inspections, or investigations, and that they provide additional clarity on documentation retention for ongoing program integrity. In addition, in the CY 2017 PFS we established supplier requirements for documentation and recordkeeping (codified at §424.59(b), redesignated and amended at §424.205(g). In this final rule, we are revising these requirements to improve clarity. We proposed at §424.205(g)(1) and (g)(2) to require that documentation must be established contemporaneous to the furnished MDPP services, which we believe is important for accuracy. We also proposed that for the initial core session, these records must include the following organizational information:

- The organizational name, CDC DPRP organization number, and organizational NPI;
- Basic beneficiary information including but not limited to beneficiary name, HICN, and age; and
- Evidence that each such beneficiary satisfied the eligibility requirements under §410.79(c) at the time of service.

For each additional session, we proposed that these records must include:

- Documentation of the type of session, whether a core session, a core maintenance session, an ongoing maintenance session, an in-person make-up session, or a virtual make-up session.
- Identification of which CDC-approved DPRP curriculum was associated with each session.

- The NPI of the coach who furnished the session.
- The date and place of service of the session.
- Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

We stated that we believe that this information will play an important role in documenting the provision of MDPP services and fidelity to the requirements established for the expanded model. Finally, at §424.205(g)(4), we proposed that MDPP suppliers must maintain and handle any beneficiary Personally Identifiable Information (PII) and Personal Health Information (PHI) in compliance with HIPAA, other state and federal privacy laws, and CMS standards. We believe these proposals will improve supplier recordkeeping accuracy and lessen the possibility of incomplete records and supplier recordkeeping variations.

We invited public comments on our proposed documentation and maintenance of records requirements, including whether additional or different requirements may provide better program integrity safeguards.

The following is a summary of the public comments received on our proposal for documentation and maintenance of records requirements, including whether additional or different requirements may provide better program integrity safeguards and our responses:

Comment: The majority of commenters who provided feedback on this section did so generally across the recordkeeping requirements overall. For example, a few commenters did not support the documentation requirements proposed in this rule, and instead, urged CMS to reconsider the necessity of the requirements. The commenter did not specify which requirements they believed to be unnecessary. These commenters suggested that requiring MDPP suppliers to maintain significant documentation may pose burdens to MDPP suppliers, particularly smaller

organizations. One commenter drew a parallel to the recordkeeping-related burden experienced by suppliers who offer chronic care management. Though no commenter recommended that CMS remove any specific documentation requirements, one commenter suggested that if CMS chose not to minimize burdensome requirements, which included, but was not limited to recordkeeping-related proposals, some form of compensation should be provided to support the necessary infrastructure costs required in recordkeeping.

Response: While we recognize commenters' concerns regarding the level of burden posed by MDPP supplier requirements overall, and in particular documentation requirements, we believe that recordkeeping plays an integral role in CMS' ability to investigate and eventually protect against fraud, waste, or abuse in the program. While CMS does not want to impose unnecessary burdens on MDPP suppliers, we consider our proposed recordkeeping requirements as necessary means for both accountability for MDPP suppliers and ability to verify compliance for CMS. Thus, will not be adopting commenters request for less recordkeeping requirements and will be finalizing the policies as proposed.

Comment: One commenter criticized the proposed documentation requirements stating that they omitted a range of variables that could predict an MDPP beneficiary's likelihood of losing weight over the core services period. The additional variables suggested by the commenter included the number of weigh-ins per week, the number of steps per day, the percentage of weeks with 5 or more food logs, the number of highly active minutes per week, and the number of coach interactions. The commenter urged CMS to reconsider whether MDPP suppliers should report this data to CMS so that it could be utilized to determine the efficacy of the program.

Response: While CMS appreciates that a commenter suggested additional data be submitted to determine the efficacy of the MDPP expanded model, we do not believe that an

evaluation to test the efficacy of the MDPP expanded model would require the additional variables suggested by the commenter. Thus, we are not adopting the suggestion to require MDPP suppliers document additional predictors of weight loss. While we do not see a need to require such documentation, we encourage MDPP suppliers to utilize and record any additional data that they believe will be valuable or will help predict a beneficiaries' success. Collecting this data through the MDPP beneficiaries' services period may assist the MDPP supplier or coach in determining how best to engage beneficiaries and assist them in achieving lasting behavioral change that will decrease their risk of type 2 diabetes. At this time, however, we are not finalizing any documentation requirements beyond what we proposed.

Comment: Several commenters requested that CMS provide guidance, technical assistance, and clarifications with regards to recordkeeping requirements. Two commenters generally requested that CMS provide more guidance on maintaining information on MDPP sessions provided to beneficiaries. One of these commenters had specific questions on when MDPP suppliers could submit certain claims, and requested that CMS provide further guidance with regard to the necessary documentation to support claims payment.

Response: Considering these requirements, coupled with the expectation that many MDPP suppliers will lack previous experience as a Medicare enrolled supplier, we are working to create resources that would facilitate MDPP suppliers' ability to comply with the recordkeeping requirements outlined in this rule. In considering these resources, we also intend to provide guidance on how to appropriately document services to support claims payment, as required under §424.205(g)(5).

Comment: One commenter raised questions regarding documentation requirements if an MDPP supplier provided more than the minimum amount of sessions required. In a scenario

where an MDPP supplier may have provided the total number of MDPP sessions required over the course of the MDPP services period within the first 6 months, the commenter wanted to understand how the supplier should document "PA minutes" in the second 6 months, when they believed that participants are less likely to self-report "PA minutes" in the second 6 months. Though the commenter did not indicate what PA stood for, given the context of MDPP, we assume this refers to "physical activity."

Response: The proposed requirement under §424.205(g)(2) requires that MDPP suppliers document various aspects of each MDPP session furnished to an MDPP beneficiary, therefore, these documentation requirements would apply to any session delivered to an MDPP beneficiary as a part of the MDPP services period, even if an MDPP supplier furnishes more MDPP sessions than are required under §410.79(c)(2). We clarify that we are not requiring any documentation of physical activity minutes, though the DPRP standards may require documentation of this variable, and any questions regarding the DPRP standards are beyond the scope of this rule and should be directed to the CDC.

Comment: One commenter requested clarification on whether MDPP suppliers who store records in electronic medical records would sufficiently meet these proposals. Specifically, the commenter requested clarification on whether the use of an electronic medical record which could produce a report would comply with the proposal at §424.205(g), which required that MDPP suppliers provide to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s) scheduled and unscheduled access to the MDPP supplier's records, including, but not limited to, all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the MDPP supplier's compliance. The commenter preferred the approach of

retaining records electronically given it does not rely on generating hard copies and assumes a similar approach to the reporting format required of the DPRP. The commenter also requested whether maintaining the documentation in an electronic medical record would comply with the requirement at §424.205(g)(6), requiring MDPP suppliers to maintain all records required under §424.205(g) for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services provided by the MDPP supplier, with limited exceptions.

Response: We do not require documentation or medical records in paper form and encourage the use of a secured electronic medical record system. Without familiarity with the specific electronic medical record system and the reports it may generate, we are not able to confirm whether the commenter's specific approach would satisfy the requirements as outlined under §424.205(g). In determining whether the system will comply with the requirements, organizations should evaluate whether their system may collect and obtain the required information securely, as required under §424.205(g)(4) and for the duration as required under §424.205(g)(6). If so, organizations should evaluate whether the information in this system can be provided to CMS, a contractor acting on CMS' behalf, the Office of the Inspector General, and the Comptroller General or their designee(s), as required. Identifying whether the supplier's current recordkeeping system can meet these requirements may help prospective MDPP suppliers evaluate their readiness to comply with the documentation retention requirements. Additionally, we are exploring possible resources CMS could create to help enable MDPP suppliers to understand how to comply with recordkeeping requirements in this section.

Comment: A commenter requested clarification on how to apply HIPAA requirements to an MDPP supplier when the supplier also provided additional, non-MDPP services as a part of a larger, non-health related business. In this scenario, the commenter suggested that the supplier

could designate itself a hybrid covered entity under HIPAA such that HIPAA requirements would only apply to its covered functions. The commenter requested that CMS confirm this understanding.

Response: We proposed the requirement at §424.205(g)(4) requiring an MDPP supplier to maintain and handle any beneficiary PII and PHI in compliance with HIPAA, other applicable state and federal privacy laws, and CMS standards as a means to protect any PII or PHI the MDPP supplier obtains. The intention of this requirement was to highlight that to protect beneficiary privacy, an array of federal and state privacy laws, including HIPAA, exist, as well as certain CMS standards, and CMS expects that MDPP suppliers would protect beneficiary information as required by these policies. Though in the CY 2017 PFS final rule, we finalized a similar requirement on HIPAA compliance, we proposed to modify this language to more broadly include applicable federal and state privacy laws as well. We did not intend to apply any new provisions that would not already apply to an MDPP supplier. Instead, though MDPP suppliers are already required to comply with all existing laws, including those related to privacy, we sought to highlight the need to comply with privacy-related laws, given that we anticipate that MDPP suppliers may not necessarily have previous experience in health care. MDPP suppliers will need to consult with their own counsel to determine their obligations and options under the HIPAA regulatory scheme, as well as other applicable privacy laws, such as state laws.

To more clearly state that the requirement at §424.205(g), we are amending the language to require that MDPP suppliers maintain and handle any beneficiary information related to MDPP, including Personally Identifiable Information (PII) and Protected Health Information (PHI), as appropriate under HIPAA, other applicable state and federal privacy laws, and CMS

standards. That said, we would highlight the "related to MDPP services" language. We hope that this language more clearly explains that this provisions applies only to beneficiary information related to MDPP, and not information collected by the MDPP supplier for other services they may provide. Any data an MDPP supplier would receive as a function of their non-MDPP related business would not be "related to MDPP services" if those non-MDPP business functions are truly separate from the MDPP ones. We believe that this clarification addresses the commenter's concern of how they would handle information related to their non-MDPP activities. Additionally, we hope that shifting the language from "in compliance with" to "as required under" more clearly signals that we are not imposing any additional requirements to comply with laws or standards that would not otherwise already apply to the MDPP supplier's handling or maintenance of beneficiary information. We proposed a requirement at §424.205(g)(4) to be more consistent with language at §424.205(g), and to state that an MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. We recommend that any prospective MDPP supplier applicants consult with counsel to determine whether they qualify as a HIPAA Covered Entity, and, if so, how it will comply with HIPAA as applicable to beneficiary information related to MDPP as opposed to other information collected for non-MDPP related purposes.

After considering the public comments, we are finalizing the proposals under §424.205(g) with a modification at §424.205(g) for additional clarity. We are finalizing that under §424.205(g)(4), MDPP suppliers must maintain and handle any beneficiary information related to MDPP, including PII and PHI, as would be required under HIPAA, other applicable state and federal privacy laws, and CMS standards.

f. Beneficiary Engagement Incentives under the MDPP Expanded Model

In the proposed rule (82 FR 34166), we stated our belief that the MDPP expanded model would encourage MDPP suppliers to furnish high quality and engaging health behavior change services to MDPP beneficiaries that lead to improved beneficiary health and reductions in Medicare spending. We believe that one mechanism that may be useful to the MDPP suppliers in achieving these goals would be allowing MDPP suppliers to furnish certain in-kind items and services to their MDPP beneficiaries during the core services period and ongoing services period (described at proposed §410.79(c)(2)). Under such an approach, the costs of these beneficiary engagement incentives would be borne by the MDPP supplier. However, we believe that certain conditions on these incentives would be necessary to ensure that they would be furnished solely for the purpose of achieving the MDPP goal of engaging beneficiaries in making sustainable, healthy behavior changes to reduce their risk of type 2 diabetes.

We proposed to establish the rules governing the furnishing of beneficiary engagement incentives to MDPP beneficiaries under the MDPP expanded model at new §424.210. As discussed in section III.K.2.a. of the proposed rule (82 FR 34131), we proposed that MDPP services would be available beginning on April 1, 2018.

i. Definitions Specific to Beneficiary Engagement Incentives

We proposed that if an MDPP supplier offers an in-kind beneficiary engagement incentive, the item or service offered as an incentive must be furnished by an MDPP supplier to an MDPP beneficiary during the engagement incentive period. An engagement incentive period would begin when an MDPP supplier furnishes any MDPP service to an MDPP beneficiary. We proposed at §424.210(a) that the term "engagement incentive period" means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. The

engagement incentive period would end upon the earliest of the following: the beneficiary's MDPP services period ends (as specified in proposed §410.79(c)(3)) for any reason; the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period.

We proposed that items and services may only be furnished as in-kind beneficiary engagement incentives during the engagement incentive period. This was to ensure that the flexibilities that MDPP suppliers would have under these proposed regulations to furnish free items and services to Medicare beneficiaries only apply while the beneficiary is an MDPP beneficiary being offered MDPP services by that MDPP supplier. Once the MDPP beneficiary's engagement incentive period ends with an MDPP supplier, all existing laws and regulations would apply to the furnishing of free items and services to a Medicare beneficiary by the entity that is an MDPP supplier. Limiting the furnishing of beneficiary engagement incentives under the MDPP expanded model to the engagement incentive period with a particular MDPP supplier would serve as a safeguard against the furnishing of free items and services to Medicare beneficiaries to steer them toward particular providers, suppliers, or other services, rather than to engage MDPP beneficiaries in healthy behavior changes that reduce their incidence of type 2 diabetes.

During the course of the MDPP services period, we noted that an MDPP beneficiary may begin and end multiple engagement incentive periods, and, to the extent feasible, the MDPP beneficiary would not be in more than one engagement incentive period at the same time. For example, where, after receiving MDPP services from MDPP supplier A, an MDPP beneficiary

notifies MDPP supplier A that he or she has chosen to receive MDPP services from MDPP supplier B and subsequently receives MDPP services from MDPP supplier B, the first engagement incentive period ends when MDPP supplier A is told by the MDPP beneficiary that he or she will no longer attend MDPP services with MDPP supplier A. A new engagement incentive period begins when the MDPP beneficiary receives his or her first MDPP service from MDPP supplier B. Additionally, where an MDPP beneficiary begins an engagement incentive period with an MDPP supplier and the engagement incentive period has ended because the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for 90 consecutive days during the MDPP services period, should that MDPP beneficiary receive MDPP services from that MDPP supplier on day 100, a new engagement incentive period would begin.

These proposals for the definitions specific to beneficiary engagement incentives were included at proposed §424.210(a). We invited public comments on these proposed definitions specific to furnishing in-kind beneficiary engagement incentives.

The following is a summary of the public comments received on the proposals for definitions specific to furnishing in-kind beneficiary engagement incentives and our responses:

Comment: One commenter urged CMS to begin the engagement incentive period 30 to 90 days prior to the start of MDPP services to allow for recruitment of beneficiaries into the DPP, rather than beginning the period when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary as CMS proposed.

Response: We continue to believe it is important to limit the furnishing of beneficiary engagement incentives under the MDPP expanded model to the time period when an MDPP beneficiary is receiving MDPP services from a particular MDPP supplier as a safeguard against

the furnishing of free items and services to Medicare beneficiaries to steer them toward particular providers, suppliers, or other services, rather than to engage MDPP beneficiaries in healthy behavior changes that reduce their incidence of type 2 diabetes. In addition, as discussed subsequently in this section, an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period, in order to safeguard against the advertisement of in-kind patient engagement incentives to beneficiaries based on their perceived ability to achieve the performance goals for attendance and weight loss. Thus, we do not believe it would be appropriate for the engagement incentive period to begin before an MDPP beneficiary receives any MDPP service from a particular MDPP supplier because such an approach would increase the risk of beneficiary steering.

Comment: One commenter stated that the proposal to define the end of the engagement incentive period would be difficult to operationalize, especially if a particular engagement incentive extends for a fixed period of time, such as a month-long gym membership, that would extend beyond the end of the engagement incentive period. The commenter added that the proposed definition also has implications for beneficiaries changing suppliers, such as when a month-long gym membership provided by supplier A to an MDPP beneficiary could overlap the new engagement incentive period that would begin once the beneficiary switches to supplier B for MDPP services.

Response: While we recognize the challenges identified by the commenter in operationalizing the proposed definition of the end of the engagement incentive period, we continue to believe that defining the beginning and end of the engagement incentive period to bound the time period during which a beneficiary can be furnished beneficiary engagement

incentives by an MDPP supplier provides an important program safeguard with respect to the flexibilities that allow MDPP suppliers to furnish such items and services. We understand that in some scenarios, a particular beneficiary engagement incentive that was furnished to an MDPP beneficiary could theoretically be used for a period of time after the engagement incentive period ends. However, we do not believe this possibility necessitates changing our definition of engagement incentive period to allow the continued use of the incentive beyond the time when the MDPP supplier is furnishing MDPP services to the MDPP beneficiary. If an engagement incentive period ends for any reason while a beneficiary otherwise could continue to use an incentive, such as a month-long gym membership, we expect the MDPP supplier to notify the beneficiary that the engagement incentive period has ended and that the beneficiary may no longer use the incentive at no cost under the provisions of the MDPP expanded model. We also expect the MDPP supplier to notify any other relevant organization, such as a gym for which a free membership was furnished by the MDPP supplier to the beneficiary during the engagement incentive period, to cancel the beneficiary's ability to use the incentive.

After considering the public comments received, we are finalizing the proposals, without modification, for the definitions specific to furnishing in-kind beneficiary engagement incentives at §424.210(a).

ii. General Conditions for Beneficiary Engagement Incentives

We proposed, at §424.210(b), that an MDPP supplier may choose to furnish items or services as in-kind beneficiary engagement incentives to an MDPP beneficiary only during the engagement incentive period, subject to a number of additional conditions as program safeguards. Under this proposal, the in-kind items and services furnished as beneficiary

engagement incentives under the MDPP expanded model would not be Medicare-covered items or services, nor would they be any cost-sharing amounts for Medicare-covered items or services.

We proposed that the engagement incentive must be furnished directly by an MDPP supplier or by an agent of the MDPP supplier under the MDPP supplier's direction and control, such as a coach, to an MDPP beneficiary. As established in the §410.79(b) in the CY 2017 PFS final rule, coach refers to an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer. We considered whether this policy on beneficiary engagement incentives should extend to entities other than MDPP suppliers and their agents that may refer to or furnish MDPP services during an engagement incentive period. However, given that MDPP suppliers maintain the responsibility to ensure the integrity of MDPP programs and would be best positioned to comply with beneficiary engagement incentive documentation and technology retrieval requirements proposed at §424.210(e) and (c), respectively, we believed that they would be best suited to furnished beneficiary engagement incentives.

We proposed that the item or service furnished as a beneficiary engagement incentive must be reasonably connected to the CDC-approved curriculum taught by an MDPP supplier to an MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session. For example, under this proposal, an MDPP supplier could furnish beneficiary engagement incentives such as gym memberships to reduce barriers associated with beneficiary achievement of physical activity recommended as part of the CDC-approved curriculum, but they could not furnish theater tickets, which would bear no reasonable connection to the CDC-approved curriculum. Similarly, MDPP suppliers may offer incentives such as onsite child care when the MDPP beneficiary attends MDPP services or transportation

vouchers to the site of MDPP services that may reduce barriers to beneficiary attendance at MDPP services, but they could not furnish attendance awards such as movie tickets or retail gift cards, which would have no reasonable connection to the CDC-approved curriculum. Likewise, this proposal would allow MDPP suppliers to furnish equipment that is reasonably necessary for the curriculum being taught to the beneficiary, such as digital scales to track and document patient weight or pedometers to track physical activity, but not broadly used technology that is more valuable to the beneficiary, such as a smartphone. If an MDPP supplier were to furnish a smartphone at no cost to an MDPP beneficiary, a reasonable inference arises that the technology would not be reasonably connected to the curriculum being taught to the beneficiary. Among other things, this safeguard would preclude incentives that might serve to induce beneficiaries inappropriately to receive other services than MDPP services from the MDPP supplier.

We also proposed that the beneficiary engagement incentive must be a preventive care item or service, or an item or service that advances a clinical goal for an MDPP beneficiary as described in section III.K.2.f.iv. of the proposed rule (82 FR 34169 through 34170) by engaging him or her in better managing his or her own health. This would ensure that a relationship between the incentive and the goals of the MDPP expanded model exists so that the beneficiary engagement incentive is necessary for testing the MDPP expanded model. Under this proposed condition, we noted that beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier and that it is a preventive care item or

service or it advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. Furnishing in-kind patient engagement incentives upon achievement of an outcome may not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health unless there are clinical goals that the incentive itself can continue to advance.

We further proposed that the item or service furnished as a beneficiary engagement incentive must not be tied to the receipt of items or services outside the MDPP services, and that the item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach. These provisions would provide safeguards against the furnishing of in-kind beneficiary engagement incentives to steer beneficiaries toward certain providers, suppliers, or coaches for services outside MDPP services.

We noted that in some circumstances, an item or service may be linked to an MDPP supplier and be offered to the MDPP supplier's MDPP beneficiaries as part of the CDC-approved curriculum that must be furnished during the MDPP services period, rather than being offered to steer the MDPP beneficiary to a particular provider, supplier, or coach. In these situations, we believed that the item or service may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of the items or services from a particular provider, supplier, or coach. For instance, where an MDPP supplier offers a gym membership as a beneficiary engagement incentive, we understood that the gym membership must be tied to a particular supplier of services so that the beneficiary can use the membership. However, in this case, the gym membership would be linked to the MDPP supplier that, in compliance with the curriculum that must be furnished during the MDPP services period, would be teaching MDPP beneficiaries how to utilize a physical fitness regime

to meet the MDPP goal of reducing an MDPP beneficiary's risk of developing diabetes, rather than being furnished to steer the MDPP beneficiary to a particular supplier. Therefore, we believed that gym memberships may be furnished as a beneficiary engagement incentive without violating the requirement that the item or service not be tied to the receipt of items or services from a particular provider, supplier, or coach, as long as the gym membership is reasonably connected to the CDC-approved curriculum and not being furnished to steer the MDPP beneficiary to a particular supplier.

We proposed that, in general, the availability of the items or services furnished as beneficiary engagement incentives must not be advertised or promoted as in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the MDPP supplier. However, an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period. This condition would provide a safeguard against the advertisement of in-kind patient engagement incentives to beneficiaries based on their perceived ability to meet the performance goals of attendance and weight loss as described at proposed §414.84(a) and associated with the MDPP performance payments proposed at §414.84(b). The proposed payment structure for MDPP services largely would rely on the achievement of these performance goals. Therefore, advertising patient engagement incentives to encourage participation of MDPP-eligible beneficiaries most likely to meet the attendance and weight loss performance goals could produce financial gain for MDPP suppliers that would not be related to the quality and efficacy of the MDPP supplier's MDPP services.

In addition, prohibiting the advertisement or promotion of in-kind beneficiary engagement incentives available to an MDPP beneficiary receiving MDPP services from the

MDPP supplier (except that an MDPP beneficiary may be made aware of the availability of the items or services at the time the MDPP beneficiary could reasonably benefit from them during the engagement incentive period) would provide a safeguard against using the incentive to steer a beneficiary toward a particular MDPP supplier. Beneficiaries would not be made aware of the availability of beneficiary engagement incentives until the MDPP beneficiary was in an engagement incentive period, which would begin when an MDPP supplier furnished its first MDPP service to the beneficiary. At that point in time, the beneficiary would have already selected that MDPP supplier to furnish his or her MDPP services so the incentive could not be used to steer the beneficiary to that MDPP supplier. We noted that we did not intend for beneficiary engagement incentives proposed for the MDPP expanded model to alter an MDPP supplier's market share for an MDPP or non-MDPP item or service.

Finally, we proposed that the cost of the items or services offered as in-kind beneficiary engagement incentives must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act. This requirement would affirm that the cost of any beneficiary engagement incentive offered by an MDPP supplier is the sole responsibility of the MDPP supplier, and the furnishing of a beneficiary engagement incentive, for instance, must not result in increased payments to the MDPP supplier by federal health care programs for other items or services.

These proposals for the general conditions for in-kind beneficiary engagement incentives were included at proposed §424.210(b). We invited public comments on these proposed general conditions for furnishing beneficiary engagement incentives. In addition, we invited public comments on additional or alternative program integrity safeguards.

The following is a summary of the public comments received on the proposals for the general conditions for in-kind beneficiary engagement incentives and our responses:

Comment: Many commenters supported the proposal to allow MDPP suppliers to furnish beneficiary engagement incentives that support beneficiaries in their pursuit of the clinical goals of the MDPP. The commenters stated that items or services that are not traditionally covered by Medicare may significantly improve beneficiary access and use of MDPP services and even further enhance the savings potential of the MDPP expanded model, and that the findings from such incentive use may be studied by CMS to inform the agency's consideration of engagement incentives in other parts of the Medicare program. Several commenters noted in further support of CMS' proposal that MA plans already provide beneficiaries with non-covered items and services, which the commenters stated have helped those plans lower chronic disease costs among their plan enrollees. The commenters reasoned that this MA plan cost experience in furnishing non-covered items and services to plan enrollees was consistent with the goal of the MDPP expanded model to reduce Medicare expenditures for MDPP beneficiaries with prediabetes.

Response: We appreciate the support from many commenters for our proposal to allow MDPP suppliers to furnish in-kind beneficiary engagement incentives that we believe may be useful in augmenting the effects of high quality health behavior change services furnished to MDPP beneficiaries that lead to improved beneficiary health and reductions in Medicare spending. We agree that these incentives have the potential to increase beneficiary engagement in MDPP services and health behavior change that lead to achievement and maintenance of the required minimum weight loss which is associated with a reduction in the incidence of type 2 diabetes.

Comment: In the context of their view that the proposed performance payments to MDPP suppliers for MDPP services were low, several commenters speculated that it would be unlikely that MDPP suppliers would have sufficient funds to furnish beneficiary engagement incentive in-kind since they would be functioning at a financial deficit. The commenters stated that not all supplier organizations would have the resources available to furnish such incentives that could engage more beneficiaries and result in greater rates of attendance and weight loss, thereby placing these lower-resource suppliers at a distinct disadvantage for maintaining full CDC recognition of their DPPs, which would in turn affect the availability of the program for Medicare beneficiaries, as well as other eligible participants.

To address their concerns about MDPP suppliers having funds to furnish beneficiary engagement incentives, several commenters recommended that CMS alter the proposal that the costs of the beneficiary engagement incentives be borne by the MDPP supplier. The commenters urged CMS to pay MDPP suppliers for furnishing beneficiary engagement incentives such as transportation, child care for grandchildren, and other incentives that support session attendance, especially for MDPP suppliers serving high-risk populations. One commenter observed that CMS currently allows payment to be made for transportation to medical appointments in some Medicaid populations. Another commenter advocated for direct payment by CMS to MDPP suppliers for tools such as digital scales and fitness trackers, noting they are useful to DPP participants, whether enrolled in virtual or in-person programs.

Finally, one commenter stated that consumer engagement in services and programs occurs in a well-designed, evidence-based program that offers easily accessible services that consumers need. The commenter urged CMS to shift its focus away from the detailed proposed conditions for beneficiary engagement incentives that could be furnished by MDPP suppliers to

engage MDPP beneficiaries to instead focus on establishing the right MDPP services, making appropriate MDPP services payments, and minimizing the administrative burden associated with becoming an MDPP supplier.

Response: MDPP suppliers are not required to furnish beneficiary engagement incentives, although we proposed a framework for in-kind beneficiary engagement incentives to allow MDPP suppliers the flexibility to furnish these incentives under certain conditions to ensure that they would be furnished solely for the purpose of achieving the MDPP goal of engaging beneficiaries in making sustainable, health behavior changes to reduce their risk of type 2 diabetes. As part of each DPP organization's decision-making about offering in-kind beneficiary engagement incentives under the MDPP expanded model, we expect that each MDPP supplier will consider the potential additional value of these incentives to MDPP beneficiaries and its operations. Relevant considerations may include whether greater beneficiary engagement may lead to a greater likelihood that beneficiaries will achieve the performance goals and, therefore, higher Medicare performance payments to the supplier, in the context of the resource costs of the incentives that would be borne by the MDPP supplier.

We understand that some MDPP suppliers may not have funds available that allow them to furnish beneficiary engagement incentives to MDPP beneficiaries, especially early in the supplier's experience furnishing MDPP services. However, once an MDPP supplier begins to receive performance payments from CMS for MDPP beneficiary achievement of performance goals, the supplier may have more information about the potential for beneficiary engagement incentives to reduce barriers to MDPP beneficiary achievement of performance goals, as well as additional funds that may be used for these incentives. For those MDPP suppliers with funds that may potentially be used to furnish in-kind incentives, this experience may allow the MDPP

supplier to make a more informed decision on furnishing beneficiary engagement incentives versus other MDPP supplier investments that have the potential to improve beneficiaries' achievement of performance goals under the MDPP expanded model.

While we acknowledge the suggestions of some commenters that CMS pay directly for certain beneficiary engagement incentives, we do not believe it would be appropriate in the context of the performance-based payment methodology for MDPP services discussed in section III.K.2.d. of this final rule for CMS to pay MDPP suppliers individually for specific incentives furnished to beneficiaries. Instead, we believe that MDPP suppliers are best positioned to determine the potential value of beneficiary engagement incentives toward achievement of performance goals by the MDPP beneficiaries they are serving and, in the context of the performance-based payment methodology for MDPP services, MDPP suppliers should appropriately bear the cost of the beneficiary engagement incentives they choose to furnish.

Comment: One commenter requested additional clarification of the meaning of "furnished directly" in the proposed condition, "The item or service must be furnished directly to an MDPP beneficiary by an MDPP supplier or by an agent of the MDPP supplier, such as a coach, under the MDPP supplier's direction and control." The commenter asked CMS to specify how MDPP suppliers could contract with other entities to provide items that cannot be furnished by the MDPP supplier, such as gym memberships or transportation services.

Response: The commenter's request for clarification was made in the context of MDPP suppliers considering establishing contractual relationships with other entities to provide items as beneficiary engagement incentives that the MDPP supplier is unable to furnish. For purposes of this proposed condition, we consider that an entity under contract with an MDPP supplier to furnish items or services specified by the MDPP supplier for an MDPP beneficiary as beneficiary

engagement incentives would be an agent of the MDPP supplier. The proposed condition permits beneficiary engagement incentives to be furnished directly to an MDPP beneficiary by an agent of the MDPP supplier, as long as the agent is under the MDPP supplier's direction and control when furnishing the incentive. Thus, we believe that this condition does not limit MDPP suppliers' ability to contract with entities to provide items as beneficiary engagement incentives, as long as the contractual relationship complies with all applicable laws and regulations, including those specific to beneficiary engagement incentives under the MDPP expanded model.

Comment: One commenter who expressed appreciation for the proposed program safeguard that the item or service must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or ongoing maintenance session furnished by the MDPP supplier also identified the potential for confusion resulting from the phrase "reasonably connected to the CDC-approved DPP curriculum." The commenter urged CMS to review beneficiary engagement incentives suggested by MDPP suppliers and provide additional guidance on the types of incentives that are "reasonably connected to the CDC-approved DPP curriculum" and those that would not meet this condition.

Response: We appreciate the commenter's support for this proposal. However, because only the MDPP supplier knows the specific CDC-approved DPP curriculum that is furnished to an MDPP beneficiary during a particular session and in view of the large number of types of potential beneficiary engagement incentives, we are not able to further clarify the types of beneficiary engagement incentives that would be reasonably connected to the DPP curriculum furnished to a particular MDPP beneficiary during a session. We note that as finalized at §424.205(g)(2)(ii), the MDPP supplier must maintain documentation of each MDPP session

furnished to an MDPP beneficiary that identifies which CDC-approved DPRP curriculum was associated with that session. Thus, the MDPP supplier will have available the information necessary to make a determination about whether a specific beneficiary engagement incentive being considered for an MDPP beneficiary meets this condition.

If the MDPP supplier determines that the incentive being considered is reasonably connected to the DPP curriculum furnished to a beneficiary during a session, the MDPP supplier must also make a determination about whether the incentive meets the other requirements for beneficiary engagement incentives under the MDPP expanded model before deciding whether or not to furnish the item or service to the beneficiary as a beneficiary engagement incentive. Through information from claims for MDPP services and the MDPP supplier documentation required under the MDPP expanded model, we plan to monitor beneficiary engagement incentives furnished to MDPP beneficiaries by MDPP suppliers for compliance with the final conditions for the incentives, including that incentives furnished to MDPP beneficiaries are reasonably connected to the DPP curriculum furnished to those beneficiaries during sessions.

Comment: One commenter questioned how a beneficiary engagement incentive could meet the proposed condition that it be reasonably connected to the CDC-approved DPP curriculum and also be a preventive care item or service, which the commenter noted is another condition that each beneficiary engagement incentive must also meet. The commenter stated that not all items would meet both criteria and provided the example of a digital scale that would be connected to the DPP curriculum but is not itself a preventive care item or service.

Response: We believe the commenter may have misunderstood our proposal related to the condition for beneficiary engagement incentives that includes reference to a preventive care item or service. We proposed that the item or service must be a preventive care item or service

or an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. The proposed clinical goals of the MDPP expanded model are attendance at core sessions, core maintenance sessions, or ongoing maintenance sessions; weight loss; long-term dietary change; and adherence to long-term health behavior changes. While we agree with the commenter that a digital scale is not a preventive care item or service, it is an item that may advance the clinical goal of weight loss for an MDPP beneficiary. Therefore, we believe it is possible for a digital scale and other items and services furnished as beneficiary engagement incentives to both be reasonably connected to the CDC-approved DPP curriculum furnished to an MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session by the MDPP supplier *and* be an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her health.

Comment: Several commenters expressed concern about the potential for MDPP suppliers to shift the cost of beneficiary engagement incentives to MDPP beneficiaries. The commenters requested that CMS solicit additional public input on this topic, noting that it may be difficult for MDPP suppliers to amass the resources needed to provide such incentives without cost-shifting before the supplier receives payment for MDPP services based on claims that are submitted to Medicare. The commenters urged CMS to clarify that MDPP suppliers are prohibited from requiring MDPP beneficiaries to shoulder any of the costs of beneficiary engagement incentives and that incentive structures that financially penalize beneficiaries for lack of adherence to health behavior changes taught in the DPP curriculum or failure to achieve a performance goal are not permitted.

Response: We appreciate the interest of the commenters in ensuring that the costs of beneficiary engagement incentives furnished to MDPP beneficiaries by MDPP suppliers are borne by the suppliers, as we proposed, and not shifted to beneficiaries. We note that our proposal for beneficiary engagement incentives specifies that these are items and services that may be furnished in-kind by MDPP suppliers and, therefore, MDPP suppliers would bear the costs of the incentives.

In response to the concerns about MDPP suppliers lacking sufficient resources to furnish beneficiary engagement incentives early on in the MDPP services period before receiving performance payments, we note that there is no requirement that MDPP suppliers furnish beneficiary engagement incentives. Thus, MDPP suppliers could wait until they have amassed enough payments to bear the costs of the incentives or forgo furnishing incentives to MDPP beneficiaries altogether.

We proposed at §424.210(b)(7) that the cost of the item or service furnished as a beneficiary engagement incentive must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act, but did not explicitly prohibit cost-shifting to MDPP beneficiaries. Shifting the cost of beneficiary engagement incentives to MDPP beneficiaries would not be permitted under our proposal, and we agree with the commenters that MDPP beneficiaries should not bear any of these costs. Therefore, in view of the concerns of the commenters over the potential for MDPP suppliers to shift the costs of beneficiary engagement incentives to MDPP beneficiaries and our interest in safeguarding against such a shift, we believe it would be appropriate to add an additional condition in new §424.210(b)(8) to specify that the cost of the item or service furnished as a beneficiary engagement incentive must not be shifted to an MDPP beneficiary. For example, under this condition the beneficiary engagement

incentive structure used by an MDPP supplier may not financially penalize an MDPP beneficiary through a cost to the beneficiary for lack of adherence to health behavior changes taught in the DPP curriculum or failure to achieve performance goals.

As we stated in the proposed rule (82 FR 34168) in the context of our proposal that the beneficiary engagement incentive must be a preventive care item or service, or an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health, beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier. Similarly, beneficiary engagement incentive structures that financially penalize beneficiaries for lack of adherence to health behavior changes taught in the DPP curriculum or failure to achieve a performance goal would not meet the requirements for beneficiary engagement incentives under the MDPP expanded model, including that the item or service be a preventive care item or service or an item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in betting managing his or her own health. Such an approach would shift all or part of the cost of the beneficiary engagement incentive to the MDPP beneficiary, which is explicitly not permitted under the new condition we are finalizing at §424.210(b)(8).

Comment: A few commenters requested that CMS closely monitor the use and impact of beneficiary engagement incentives to ensure they are not being used as a reward for reaching certain MDPP goals or in any way that may be discriminatory. Other commenters recommended

that CMS provide more information on how it will enforce the regulations regarding beneficiary engagement incentives.

Response: We plan to monitor beneficiary engagement incentives furnished to MDPP beneficiaries by MDPP suppliers under the MDPP expanded model for compliance with the final conditions for the incentives. Should issues of non-compliance with the conditions or other concerns arise, CMS will utilize established enforcement mechanisms to address these issues.

Comment: Many commenters strongly supported the proposal to disconnect furnishing beneficiary engagement incentives from the achievement of outcomes under the MDPP expanded model.

Response: We appreciate the commenters' support for separating the provision of beneficiary engagement incentives by MDPP suppliers to MDPP beneficiaries from the beneficiary's achievement of outcomes. However, we note that we did not propose to completely disconnect furnishing beneficiary engagement incentives from the achievement of specific outcomes in all cases. Instead, we proposed that beneficiary engagement incentives may not be offered to an MDPP beneficiary as a reward for achievement of a specified outcome, such as losing weight or attending a certain number of sessions, unless the beneficiary engagement incentive meets all the proposed conditions, including that it is reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, a core maintenance session, or an ongoing maintenance session by the MDPP supplier. That is, if a beneficiary engagement incentive meets all of the proposed conditions for such incentives and is offered to the MDPP beneficiary as a reward for the achievement of a specified outcome, we would consider that beneficiary engagement incentive to be permitted under the MDPP expanded model. We continue to believe that our proposed policy is appropriate because it ensures that the

beneficiary engagement incentive itself is a preventive care item or service or an item or service that advances a clinical goal by engaging a beneficiary in better managing his or her own health, including under those circumstances where the incentive is offered by the MDPP supplier as a reward for the achievement of an outcome.

Comment: One commenter observed that CMS did not propose to limit the aggregate retail value of items and services furnished as beneficiary engagement incentives that are not items of technology, which the commenter noted could invite competition among MDPP suppliers for beneficiaries based on the value of the incentives and not based on quality or clinical outcomes of the MDPP services furnished by the MDPP supplier.

Response: As the commenter stated, we did not propose a maximum aggregate retail value limit for beneficiary engagement incentives other than items and services involving technology that are furnished to an MDPP beneficiary by an MDPP supplier. We do not believe the risk of misuse of non-technology items and services furnished as beneficiary engagement incentives warrants the greater administrative burden on MDPP suppliers that would result from limiting the aggregate retail value of these items and services. Such an aggregate limit would require documentation of all beneficiary engagement incentives of any retail value, thereby significantly increasing the MDPP supplier administrative burden beyond that required by our proposal for documentation of only those incentives with a retail value of greater than $25. In contrast, we believe that items and services involving technology, which we address in detail subsequently in this section, have a higher risk of misuse so we proposed enhanced safeguards for those types of incentives, including a maximum aggregate retail value limit of $1,000 per beneficiary from a single MDPP supplier during the MDPP services period.

In addition, we proposed a number of other conditions for beneficiary engagement incentives discussed throughout this section that provide program safeguards, including protection against competition among MDPP suppliers for beneficiaries based on the value of incentives and not based on the quality or clinical outcomes of MDPP services.

Comment: One commenter stated that smaller MDPP suppliers that furnish MDPP services with equally effective outcomes as larger MDPP suppliers may not be able to sustain their programs if Medicare beneficiaries are lured to receive MDPP services at the larger suppliers by the beneficiary engagement incentives offered by these bigger organizations. While the commenter acknowledged CMS' intent to disallow advertisement of available incentives, the commenter reasoned that in the community individuals talk to one another, and thus, word would spread within the community. The commenter urged CMS to further clarify the difference between MDPP suppliers furnishing a specific non-covered item or service as a beneficiary engagement incentive and CMS' intent that use of specific incentives would not "steer" particular beneficiaries away from or to the supplier furnishing the incentive.

Response: We proposed that the availability of the item or service must not be advertised or promoted as an in-kind beneficiary engagement incentive available to an MDPP beneficiary receiving MDPP services from the MDPP supplier except that an MDPP beneficiary may be made aware of the availability of the item or service at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period. While we understand that individuals within communities speak to one another so that a person may become aware of beneficiary engagement incentives furnished by certain MDPP suppliers before the individual becomes an MDPP beneficiary, we believe this condition still provides a reasonable safeguard against MDPP suppliers acting directly to recruit beneficiaries for MDPP services based on the

availability of a beneficiary engagement incentive. Beneficiaries would not be made aware by the MDPP supplier of the availability of beneficiary engagement incentives until the MDPP beneficiary was in an engagement incentive period, which would begin when the MDPP supplier furnished its first MDPP service to the beneficiary. At that point in time, the beneficiary would have already selected that MDPP supplier to furnish his or her MDPP services so the incentive could not be used to steer the beneficiary to that MDPP supplier.

Comment: One commenter generally supported the concept of not advertising beneficiary engagement incentives to deter MDPP suppliers from encouraging Medicare beneficiary participation in their DPP only for purposes of gaining the incentives. However, the commenter further reasoned that the MDPP supplier's having the ability to advertise some incentives (including transportation and childcare) that remove barriers to session attendance could enable more Medicare beneficiaries to participate in MDPP services. The commenter concluded that transportation and childcare are not incentives but instead services that reduce barriers and should be in another category with different rules tied to them.

Response: Regarding the commenter's recommendation that we apply different rules to certain beneficiary engagement incentives, such as transportation or childcare, that advance the clinical goal of attendance at MDPP services rather than the clinical goal of weight loss, long-term dietary change, or adherence to long-term health behavior changes, we disagree that we should treat these types of incentives differently by allowing them to be advertised to Medicare beneficiaries. If advertised to beneficiaries by an MDPP supplier prior to the start of the beneficiary's engagement incentive period, incentives such as transportation or childcare could steer beneficiaries toward that particular MDPP supplier. We believe that in-kind items and services furnished by MDPP suppliers to MDPP beneficiaries to reduce barriers to session

attendance are similar to other beneficiary engagement incentives that advance different clinical goals of the MDPP expanded model because they assist the beneficiary in better managing his or her own health. An MDPP supplier may make a beneficiary aware of a beneficiary engagement incentive at the time the MDPP beneficiary could reasonably benefit from it during the engagement incentive period, and we believe this condition provides sufficient flexibility for MDPP suppliers to be able to remove attendance barriers when beneficiaries participate in MDPP services.

Comment: Several commenters requested that CMS clarify whether certain items and services would be permitted to be furnished as beneficiary engagement incentives to MDPP beneficiaries by MDPP suppliers under the proposal. One commenter reported that some managed care organizations and DPP organizations have experienced success providing retail gift cards to socially at-risk populations. The commenter further explained that individuals may use the retail gift cards at their discretion to buy healthy food, scales, pedometers, work-out shoes and clothes, thereby reducing the burden on DPP organizations, as not all direct service suppliers have the capacity to buy equipment in sufficient quantities or to buy different types of items that anticipate each beneficiary's need. Another commenter urged CMS to permit supermarket gift cards to be furnished as a beneficiary engagement incentive, reasoning that these would allow some beneficiaries to purchase more produce and healthy foods.

Response: We disagree with the commenters' suggestion that we globally permit retail gift cards to be considered as a form of beneficiary engagement incentive under the MDPP expanded model. Because we are testing the model to determine if MDPP services improve the quality and reduce the cost of health care for Medicare beneficiaries, we continue to believe that it is important to maintain the requirements of a reasonable connection between the item or

service furnished as a beneficiary engagement incentive and the CDC-approved DPP curriculum furnished to the MDPP beneficiary during MDPP services and that the item or service must be a preventive care item or service or an item or service that advances a meaningful clinical goal for the MDPP beneficiary. These conditions both protect against MDPP suppliers' incentives to influence the beneficiary's choice of MDPP supplier and other types of care and ensure that the MDPP expanded model is implemented in accordance with consistent standards across MDPP suppliers in order to allow for evaluation of the model.

Therefore, regarding the potential for retail gift cards, including supermarket gift cards, to be furnished by MDPP suppliers as beneficiary engagement incentives, we encourage MDPP suppliers considering furnishing these items to assess whether the specific gift cards meet all the requirements for beneficiary engagement incentives, including that they are reasonably connected to the CDC-approved curriculum and advance a clinical goal for the MDPP beneficiary. Whether these requirements are met may be related to the particular retailer at which the beneficiary could purchase items with the gift card. To the extent the retailer sells a large variety of items and a substantial percentage of those items would not meet the requirements for beneficiary engagement incentives if furnished directly to the MDPP beneficiary by the MDPP supplier, we would consider a gift card furnished by an MDPP supplier to that retailer *not* to meet the beneficiary engagement incentive conditions under the MDPP expanded model.

Comment: One commenter stated that incentives targeted to food access and physical activity access support the goals of the MDPP expanded model and requested that CMS clarify that MDPP suppliers would be permitted to offer these items as beneficiary engagement incentives.

Response: Beneficiary engagement incentives targeted to food access or physical activity access would be permitted to be offered as beneficiary engagement incentives only if the specific item or service meets all of the requirements for beneficiary engagement incentives finalized for the MDPP expanded model. These types of potential incentives need to be assessed by the MDPP supplier that is considering offering them with respect to their connection to the CDC-approved DPP curriculum furnished to the MDPP beneficiary at sessions and their potential to advance the MDPP expanded model clinical goals for the MDPP beneficiary, as well as with regard to the other conditions for beneficiary engagement incentives.

Comment: One commenter recommended that CMS clarify that certain items or services would not be beneficiary engagement incentives, and therefore, would not be subject to the conditions for these incentives. The items and services the commenter requested be excluded from the requirements for beneficiary engagement incentives were: assistance in enrolling in public benefits; assistance connecting to emergency food services (for example, food pantries); and provision of meals during the MDPP session.

Response: To the extent that MDPP suppliers want to assist MDPP beneficiaries in enrolling in public benefits, connect MDPP beneficiaries to emergency food services, or provide meals during MDPP sessions at the MDPP supplier's expense. The MDPP supplier must determine whether furnishing the item or service meets the requirements of all applicable laws and regulations. The conditions for beneficiary engagement incentives under the MDPP expanded model are intended to provide MDPP suppliers with additional flexibilities to furnish in-kind items and services, rather than further limiting an MDPP supplier's provision of items and services beyond existing laws and regulations.

Comment: One commenter, who supported the proposal to allow beneficiary engagement incentives to be furnished to increase beneficiary engagement toward achieving the goals of MDPP services, sought confirmation from CMS that if a beneficiary engagement incentive is furnished to an MDPP beneficiary covered under an MA plan, this action would not violate the guidance in the Medicare Managed Care Manual, Chapters 3 and 4, for MA program rules.

Response: We appreciate the commenter's support for our proposal to allow MDPP suppliers to furnish beneficiary engagement incentives to MDPP beneficiaries under certain conditions, as well as their request for clarification about the relationship between these provisions and MA program rules. We are clarifying that the beneficiary engagement incentive regulations at §424.210 strictly apply to MDPP services furnished under the MDPP expanded model, including when furnished or covered by an MA plan. Because the beneficiary engagement incentive regulations are more specific than the Medicare Advantage Rewards and Incentives Program regulations at §422.134 (outlined in Chapter 4 of the Medicare Managed Care Manual) and the corresponding Rewards and Incentives Program marketing guidelines (outlined in Chapter 3 of the Medicare Managed Care Manual), the MDPP regulations will apply to MDPP services furnished under the MDPP expanded model.

After considering the public comments received, we are finalizing the proposals for the general conditions for in-kind beneficiary engagement incentives at §424.210(b), with modifications. We are adding another condition for beneficiary engagement incentives at §424.210(b)(8) that specifies that the cost of the item or service must not be shifted to an MDPP beneficiary.

iii. Technology Furnished to an MDPP Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives because they can advance a clinical goal of the MDPP expanded model by engaging an MDPP beneficiary in managing his or her health. However, in the proposed rule (82 FR 34169) we stated our belief that specific enhanced safeguards are necessary for these items and services to prevent abuse.

First, we proposed that items or services involving technology furnished by an MDPP supplier to its MDPP beneficiary may not, in the aggregate, exceed $1,000 in retail value for any one MDPP beneficiary. We believed that this proposed limit would be appropriate, in conjunction with our proposed enhanced requirements for items of technology with a retail value greater than $100 as discussed subsequently. The proposed $1,000 limitation would allow sufficient MDPP supplier flexibility to furnish items or services involving technology as beneficiary engagement incentives to improve the likelihood of the beneficiary's achievement and maintenance of the required minimum weight loss.

For example, under this proposal, an MDPP beneficiary who begins receiving MDPP services from an MDPP supplier and who, after receiving MDPP services from that MDPP supplier, is furnished items or services of technology with a total retail value of $1,000 may not receive additional items or services of technology from that MDPP supplier. Therefore, an MDPP beneficiary may receive from an MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model and also receive from the same MDPP supplier a fitness tracking watch valued at $200 that uploads and monitors fitness data to the tablet, but he or she

could not then receive additional items of technology from the MDPP supplier with an aggregate retail value greater than $100 as this would exceed the $1,000 limit.

In addition, we proposed that if the same MDPP beneficiary chooses to receive MDPP services from another MDPP supplier, the subsequent supplier would be under no obligation to determine the value of any items or services of technology furnished to the MDPP beneficiary by other MDPP suppliers, and may furnish items or services of technology to the MDPP beneficiary so long as those items or services furnished by the subsequent supplier are the minimum necessary to advance a clinical goal for the MDPP beneficiary, are furnished during the engagement incentive period, and do not, in aggregate, exceed $1,000 in retail value.

We further proposed that items or services involving technology furnished to an MDPP beneficiary must be the minimum necessary to advance a clinical goal for MDPP beneficiaries as discussed in section III.K.2.f.iv. of the proposed rule (82 FR 34169 through 34170).

We proposed enhanced requirements for items of technology exceeding $100 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. In the proposed rule (82 FR 34169), we stated our belief that it would be inappropriate for MDPP suppliers to furnish items of technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to continue to receive MDPP services from that supplier, or to receive items or services from the supplier other than MDPP services. Therefore, we proposed that items of technology with a retail value of over $100 would remain the property of the MDPP supplier and be retrieved from the MDPP beneficiary at the end of the engagement incentive period. We did not believe that this requirement would substantially increase the administrative burden on MDPP suppliers because a central facilitator of the success of an MDPP beneficiary in meeting

MDPP performance goals is the MDPP supplier's ability to maintain contact with the MDPP beneficiary and engage him or her in MDPP services. We noted that items of technology with a retail value of $100 or less could be furnished as beneficiary engagement incentives and would remain the property of the beneficiary. In the case of these items of a technology with a lower retail value, we believed that the administrative burden of retrieving these items would outweigh the program integrity benefits of retrieval.

We further proposed that the MDPP supplier must document all technology retrieval attempts, including the ultimate date of retrieval. However, because we understood that MDPP suppliers may not always be able to retrieve these items, such as when a beneficiary dies or moves to another geographic area, documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement.

Our proposals for enhanced requirements for technology furnished to MDPP beneficiaries as beneficiary engagement incentives under the MDPP expanded model were included at proposed §424.210(c). We invited public comments on our proposed requirements for beneficiary engagement incentives that involve technology and welcomed comments on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the proposed financial thresholds were reasonable, necessary, and appropriate.

The following is a summary of the public comments received on the proposals for the requirements for beneficiary engagement incentives that involve technology and our responses:

Comment: Several commenters encouraged CMS to provide more information on the evidence base for the $100 maximum retail value threshold for items involving technology that can remain the property of the beneficiary and the $1,000 aggregate limit on the retail value of

items and services involving technology that can be furnished as beneficiary engagement incentives by one MDPP supplier to an MDPP beneficiary, including whether there are a similar beneficiary engagement incentive amount thresholds used elsewhere in Medicare or another program.

Response: We appreciate the interest of the commenters in additional information on the proposed $100 maximum retail value threshold for items involving technology that can remain the property of the beneficiary and the proposed $1,000 aggregate limit on the retail value of items and services involving technology that are furnished as beneficiary engagement incentives. We note that we finalized through notice and comment rulemaking these same thresholds for other Innovation Center payment models, including the Comprehensive Care for Joint Replacement Model (80 FR 73436). We refer readers to that discussion for further information on our reasoning for finalizing the thresholds for that model, which is similar to our rationale for these thresholds under the MDPP expanded model.

For example, we believe that the $100 retail value retrieval threshold for items involving technology would allow some types of electronic tablets that could be furnished to an MDPP beneficiary for activity and dietary monitoring during an engagement incentive period to remain the property of the beneficiary for permanent use following the end of that period. In addition, we believe the $1,000 aggregate limit on the retail value of items and services involving technology that may be furnished by one MDPP supplier to an MDPP beneficiary is sufficiently high to allow MDPP suppliers the flexibility to furnish a wide range of items and services involving technology that advance the goals of the MDPP expanded model, without significantly risking suppliers furnishing more broadly used technology that is more valuable to the beneficiary than reasonably necessary for the DPP curriculum being taught.

Comment: In the context of a commenter's request that CMS not limit the MDPP services period to once-per-lifetime per beneficiary, the commenter asked that CMS clarify whether the $1,000 technology incentive limit could "reset" if the MDPP beneficiary resumes MDPP services with an MDPP supplier after a long absence.

Response: As we stated in the proposed rule (82 FR 34169), the $1,000 aggregate retail value limit for items and services involving technology that may be furnished to any one MDPP beneficiary by any one MDPP supplier would not otherwise be affected by the engagement incentive period. In addition, we finalized the once-per-lifetime MDPP services period in the CY 2017 PFS final rule (81 FR 80470). Therefore, if an MDPP beneficiary begins and ends multiple engagement incentive periods with the same MDPP supplier spread apart after an absence that would be limited in the context of the maximum 24-month duration of the MDPP services period finalized in section III.K.2.b.i. of this final rule, we see no reason to allow the $1,000 aggregate retail value limit for items and services involving technology to "reset" at the beginning of a new engagement incentive period with the same MDPP supplier within the MDPP services period due to the risk that a high value technology incentive could be used to steer a beneficiary back to that MDPP supplier if we allowed the limit to "reset."

Comment: Because CMS proposed that the cost of beneficiary engagement incentives be borne by MDPP suppliers as in-kind incentives and that CMS would not pay for these incentives, several commenters urged CMS not to set any retail value dollar threshold for items involving technology that can remain the property of a beneficiary. The commenters stated that MDPP suppliers should not be required to retrieve any items from MDPP beneficiaries after the engagement incentive period ends, especially since CMS did not offer guidance on what should happen with these recovered items, such as refurbishing them for future use that could risk PII

being stored and transmitted. The commenters claimed that the proposed technology retrieval requirements and resulting returned equipment would have limited value to the ongoing work and effort of MDPP suppliers, especially because technology quickly becomes obsolete. They noted that in addition to contacting beneficiaries who may have discontinued their participation in MDPP services with the MDPP supplier that furnished the technology, MDPP suppliers would have to develop costly, administratively burdensome processes for maintenance, documentation, and tracking of inventory, which most likely would require a system different from their existing MDPP documentation systems. The commenters concluded that the proposed technology retrieval requirements would have the unintended consequence of a high level of effort invested by MDPP suppliers with marginal returns, so they recommended that CMS not finalize this proposal.

One commenter who urged CMS not to adopt a retail value dollar threshold for items that can remain the property of the beneficiary provided a list of potential beneficiary engagement incentives, including pedometers, water bottles, memberships at health clubs and exercise facilities, blood sugar monitors, slow cookers, and stretch bands, and claimed that it would not currently be the practice of DPP organizations to collect these items after the end of the program because reusing them is not practical and storing them would serve no purpose.

Response: We do not believe it would be appropriate to eliminate the retrieval threshold for items involving technology altogether, even for those items involving technology that may provide additional health benefits to beneficiaries after the engagement incentive period ends and/or lead to reduced expenditures on health care in the future. It would be inappropriate for MDPP suppliers to furnish items involving technology with a retail value of over $100 for beneficiaries' permanent use because the high value of such items could unduly influence the

beneficiary to continue to receive MDPP services from the MDPP supplier. We do not believe the potential longer-term benefits of continued use or the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweigh the program integrity benefits of retrieval.

In response to the commenter who disagreed with the retrieval of items involving technology of any retail value and provided a list of potential beneficiary engagement incentives where the commenter concluded that these items would generally not be reused and their storage would serve no purpose upon retrieval, we emphasize that the threshold of $100 maximum retail value for items that can remain in the MDPP beneficiary's permanent possession applies only to items involving technology, not to other types of beneficiary engagement incentives. We do not believe that the list of potential incentives provided by the commenter generally included items involving technology with a retail value of greater than $100 to which retrieval would apply.

Finally, we note that items involving technology with a retail value of greater than $100 that are furnished as beneficiary engagement incentives under the MDPP expanded model would always be the property of the MDPP supplier, and it would be up to the MDPP supplier to make all decisions about the item's treatment upon return and further use. To the extent the item of technology returned to the MDPP supplier includes PII, MDPP suppliers are required to maintain and handle any PII and PHI in compliance with HIPAA, as applicable, other applicable state and federal privacy laws, and CMS standards.

Comment: Several commenters urged CMS to increase the $100 threshold for the maximum retail value of items involving technology that can remain the property of the beneficiary to a $200 threshold in order for MDPP suppliers to furnish items involving technology for beneficiary permanent use, such as wearable trackers and other beneficiary

engagement incentives that often cost more than $100 per item. The commenters reasoned that the permanent use of these items involving technology could help beneficiaries sustain weight loss and healthy behaviors after MDPP services ended and, therefore, could be important for the maximum long-term reduction in the incidence of type 2 diabetes to be achieved.

Response: While we understand the administrative burden on MDPP suppliers that tracking and retrieval requires, we believe that a higher retrieval threshold, such as $200, is not warranted. As stated previously, it would be inappropriate for MDPP suppliers to furnish items involving technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to continue to receive MDPP services from the MDPP supplier. We do not believe the potential longer-term benefits of continued use or the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweigh the program integrity benefits of retrieval. We further note that wearable trackers with a retail value of less than $100 are widely available, so we do not believe that maintaining the retrieval threshold at $100 poses a significant risk that MDPP suppliers will be unable to furnish wearable trackers, the specific example cited by the commenters, to MDPP beneficiaries for their permanent use.

Comment: Several commenters requested that CMS address what the commenters observed may be an inconsistency between two separate discussions in the proposed rule. The commenters pointed out that in one location CMS stated, "This proposal would allow MDPP suppliers to furnish equipment that is reasonably necessary for the curriculum being taught to the beneficiary, such as digital scales to track and document patient weight or pedometers to track physical activity, but not broadly used technology that is more valuable to the beneficiary, such as a smartphone." The commenters further observed that in the specific proposal regarding the

maximum retail value for items and services involving technology furnished by an MDPP supplier to an MDPP beneficiary, CMS stated, "An MDPP beneficiary may receive from an MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model and also receive from the same MDPP supplier a fitness tracking watch valued at $200 that uploads and monitors fitness data to the tablet..." The commenters requested that CMS clarify its apparent distinction between smartphones and other forms of mobile technologies with apps.

Response: We appreciate the request for clarification about the discussions in the proposed rule that included examples of smartphones and tablets, two types of mobile technologies. We proposed that items or services involving technology must be the minimum necessary to advance a clinical goal for an MDPP beneficiary. We continue to believe this requirement is appropriate as a program safeguard against items involving technology being furnished to steer beneficiaries toward particular MDPP suppliers or other services, coupled with the additional requirement that items involving technology with a retail value greater than $100 must remain the property of the MDPP supplier and, therefore, cannot remain in the permanent possession of the beneficiary. As to whether individual items of equipment, including mobile technologies with apps such as tablets or smartphones, meet the requirements for beneficiary engagement incentives that are items and services involving technology, we believe that the principal uses of the items must be considered in making such a determination. As we stated in the proposed rule (82 FR 34168), we do not believe that a smartphone, which is broadly used technology with uses that generally extend far beyond the DPP curriculum and clinical goals of the MDPP expanded model, would be reasonably necessary for the DPP curriculum being taught

to the MDPP beneficiary, and we further do not believe that a smartphone would be the minimum technology necessary to advance a clinical goal for the MDPP beneficiary.

In the proposed rule (82 FR 34169), we included an example of an MDPP beneficiary who receives from an MDPP supplier a tablet valued at $700 that is preloaded with weight loss and fitness tracking apps that would support the beneficiary's weight loss goals under the MDPP expanded model. It was our expectation that the principal use for such a tablet would be related to the DPP curriculum being taught to the MDPP beneficiary and the advancement of the MDPP expanded model's clinical goals for that beneficiary. To the extent the tablet is also populated with apps whose uses extend far beyond the DPP curriculum and clinical goals of the MDPP expanded model, consistent with our discussion of a smartphone, we do not believe such a tablet would be reasonably necessary for the DPP curriculum being taught to the MDPP beneficiary, and we further do not believe it would be the minimum technology necessary to advance a clinical goal for the MDPP beneficiary.

Comment: One commenter reported that a major barrier to a beneficiary's attendance at MDPP services may be unstable access to a consistent phone number, and further speculated that while providing a smartphone might not solve this issue, assisting the beneficiary in signing up for a publicly available free cell phone could be a major tool for improved attendance. The commenter expressed concern that this assistance could be discouraged by the smartphone example included in the proposed rule.

Response: Given that one of the clinical goals of the MDPP expanded model is MDPP beneficiary session attendance, if an MDPP supplier believes erratic access to a consistent phone number creates a barrier to MDPP session attendance for a particular MDPP beneficiary, it is possible that furnishing a basic cell phone or assisting a beneficiary in signing up for a publicly

available free cell phone would meet the requirements for beneficiary engagement incentives under the MDPP expanded model. However, we do not believe that a smartphone, which is broadly used technology with uses that generally extend far beyond the DPP curriculum and clinical goals of the MDPP expanded model, would be reasonably necessary for the DPP curriculum being taught to the MDPP beneficiary, and we further do not believe it would be the minimum technology necessary to advance a clinical goal for an MDPP beneficiary.

After considering the public comments received, we are finalizing the proposals, without modification, for enhanced requirements for items and services involving technology furnished to MDPP beneficiaries as beneficiary engagement incentives under the MDPP expanded model at §424.210(c).

iv. Clinical Goals of the MDPP Expanded Model

As established at §410.79(b) in the CY 2017 PFS final rule, MDPP services furnished to MDPP beneficiaries must follow a CDC-approved curriculum, which outlines required and recommended topics for structured health behavior change sessions offered as MDPP services with the goal of preventing diabetes through long-lasting health behavior change. MDPP suppliers seeking recognition under the CDC's DPRP must furnish either the CDC-preferred curriculum, based on the current evidence base, or may develop their own curriculum. MDPP suppliers that wish to develop their own curriculum must submit it to the CDC for approval. This requirement ensures that all curricula furnished to MDPP beneficiaries meet the DPRP's curriculum content requirements and are based on evidence from efficacy and effectiveness trials consistent with the current evidence base. To be consistent with the current evidence base, all curricula offered by MDPP suppliers must furnish MDPP services focused on the overarching goal of preventing type 2 diabetes in persons at high risk for diabetes because they have

prediabetes. This requires MDPP suppliers to emphasize the need to make lasting health behavior changes, rather than simply completing a one-time set of MDPP services that result in the required minimum weight loss during the MDPP services period. MDPP services must also emphasize long-term improvements in nutrition and physical activity that contribute to beneficiaries sustaining weight loss. Therefore, in the proposed rule (82 FR 34170) we stated our belief that in-kind patient engagement incentives may appropriately be furnished to support and motivate MDPP beneficiaries in achieving dietary and health behavior change and to teach MDPP beneficiaries to problem-solve strategies to overcome challenges to maintaining weight loss and healthy behaviors, as well as to assist MDPP beneficiaries in meeting the attendance and weight loss performance goals of the MDPP expanded model.

Therefore, we proposed that the following would be the clinical goals of the MDPP expanded model, which may be advanced through beneficiary engagement incentives:

- Beneficiary attendance at MDPP core sessions, core maintenance sessions, or ongoing maintenance sessions during the MDPP services period.
- Beneficiary weight loss.
- Long-term dietary change for the beneficiary.
- Beneficiary adherence to long-term health behavior changes.

We noted that under this proposal, the MDPP supplier may not furnish multiple free meals or meal replacement services to an MDPP beneficiary over a substantial portion of the engagement incentive period because such a practice would not advance a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health.

When a beneficiary engagement incentive does not qualify as a preventive care item or service, our proposals for the clinical goals of the MDPP expanded model that a beneficiary

engagement incentive must be intended to advance were included at proposed §424.210(d). We invited public comments on our proposed clinical goals of the MDPP expanded model, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives may better advance the overarching goals of the MDPP expanded model, while maintaining appropriate program integrity safeguards.

We received no public comments on the proposals for the clinical goals of the MDPP expanded model.

We are finalizing the proposals, without modification, for the clinical goals of the MDPP expanded model that a beneficiary incentive must be intended to advance at §424.210(d).

v. Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under the MDPP expanded model, we proposed that, in addition to the documentation requirements for MDPP suppliers at proposed §424.205(g), MDPP suppliers must maintain documentation of items and services furnished as beneficiary engagement incentives that individually exceed $25 in retail value. We recognized that an MDPP beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. Therefore, we believed that it would be important to incorporate a documentation threshold at a modest level for all beneficiary incentives in order to monitor compliance with the proposed conditions for furnishing these items and services. Moreover, we believed that the proposed $25 retail value threshold would strike an appropriate balance between beneficiary and program protections and MDPP supplier administrative burden.

In addition, we proposed to require that the documentation must be established contemporaneously with the furnishing of the items and services and must include at least the

date the incentive was furnished; the identity of the beneficiary to whom the item or service was furnished; the agent of the supplier that furnished the item or service, if applicable; a description of the item or service; the retail value of the beneficiary engagement incentive; and documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period.

In addition to the requirements in the previous paragraph, we further proposed that the documentation regarding items or services furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items of technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. For example, if an MDPP supplier furnishes a gym membership to an MDPP beneficiary, the MDPP supplier would need to maintain contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary has access to the gym via the membership furnished by the MDPP supplier.

In addition to the above requirements, we further proposed that the documentation regarding items of technology exceeding $100 in retail value that MSPP suppliers would be required to retrieve from the MDPP beneficiary must also include contemporaneous documentation of any attempts to retrieve the item of technology furnished by the MDPP supplier from the MDPP beneficiary as required at proposed §424.210(c)(3)(ii). We reiterated that under our proposal documented, diligent, good faith attempts to retrieve items of technology would be deemed to meet the retrieval requirement. Finally, we proposed that the MDPP

supplier must retain and provide access to the required documentation in accordance with proposed §424.205(g).

Our proposals for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model were included at proposed §424.210(e). We invited public comments on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

The following is a summary of the public comments received on the proposals for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model and our responses:

Comment: Several commenters urged CMS to require MDPP suppliers to document all beneficiary engagement incentives furnished to MDPP beneficiaries, not just those items and services with a retail value greater than $25, to further the goal of data collection about the incentives used.

In contrast, other commenters stated that the proposal to require documentation of beneficiary engagement incentives that are in-kind with a retail value of greater than $25 would lead to an undue reporting burden for MDPP suppliers because of the large number of these incentives that could be furnished to an MDPP beneficiary. The commenters further stated the documentation burden would be particularly onerous for small suppliers with limited infrastructure and staffing. Multiple commenters claimed that while the administrative burden posed by the proposed documentation and tracking requirements would be large, the documentation would be of limited value to the ongoing work and effort of MDPP suppliers. The commenters urged CMS to not require documentation of beneficiary engagement incentives of any retail value.

Response: We appreciate the diversity of perspectives of the commenters on our proposed documentation requirements for beneficiary engagement incentives in the MDPP expanded model. We proposed to require MDPP suppliers to document certain information about beneficiary engagement incentives with a retail value of greater than $25 to allow us to monitor compliance with the proposed conditions for furnishing these items and services, while striking an appropriate balance between beneficiary and program protections and MDPP supplier administrative burden. We recognized that an MDPP beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. While we did not propose to limit the aggregate value of non-technology items and services that may be furnished as beneficiary engagement incentives to an MDPP beneficiary by an MDPP supplier, documentation of items with a retail value greater than $25 would allow us to monitor compliance with the conditions for these incentives, which safeguard against misuse of beneficiary engagement incentives in the MDPP expanded model.

We do not believe it would be appropriate to require documentation of all beneficiary engagement incentives of any retail value for purposes of data collection about incentives as recommended by some commenters, in view of the greater administrative burden this would place upon MDPP suppliers. We also do not believe that requiring no documentation of beneficiary engagement incentives of any retail value would be appropriate because we would be unable to monitor for compliance with the conditions for furnishing these items or services.

Given the substantial flexibilities we will be affording MDPP suppliers to furnish beneficiary engagement incentives under the MDPP expanded model, we believe that requiring documentation of items and services with a retail value of greater than $25 is a reasonable responsibility for MDPP suppliers to assume. Our rationale for establishing documentation

requirements for beneficiary engagement incentives is based on establishing program safeguards against misuse of beneficiary engagement incentives under the MDPP expanded model and not based primarily on the value of documentation of beneficiary engagement incentives to the ongoing work and effort of MDPP suppliers. The documentation threshold of $25 reflects our interest in balancing the additional administrative burden on MDPP suppliers resulting from the documentation requirements for beneficiary engagement incentives with the beneficiary and program protections that will result. Finally, while under the MDPP expanded model MDPP suppliers are not required to maintain documentation for beneficiary engagement incentives with a retail value of less than or equal to $25, we encourage MDPP suppliers to maintain such documentation for other purposes as they see fit.

Comment: One commenter observed that the proposed documentation requirements for beneficiary engagement incentives included many of the same variables as those required for claims submission, such as the date the incentive was furnished and the identity of the beneficiary to whom the item or service was furnished. The commenter claimed that documentation of beneficiary engagement incentives furnished to MDPP beneficiaries could more easily be achieved by adding a 'non-covered' (or otherwise) HCPCS service code(s) or code modifier(s) to the proposed coding and billing structure for MDPP services. Under the commenter's recommended approach, such a code or code modifier included on a claim would reflect that a beneficiary engagement incentive had been furnished by the MDPP supplier during the period of time where sessions were furnished that were reported on the claim for a performance payment. The commenter reasoned that this approach to documentation would: (1) reduce the administrative burden on the DPP supplier; (2) promote the use of automation in health care administration; (3) promote program integrity safeguards through the Medicare

claims system; (4) mitigate the risk of incentives as an inducement for MDPP supplier selection; and (5) support the comprehensive evaluation of the use of incentives under the MDPP expanded model.

Response: While we appreciate the potential benefits, including the availability of comprehensive information on incentives, of adopting the commenter's suggestion that we establish new HCPCS codes and/or modifiers that could be reported on claims in order to identify when beneficiary engagement incentives were furnished, we disagree with the commenter that this approach would reduce the administrative burden on the MDPP supplier or provide a sufficient program safeguard by mitigating the risk of incentives being furnished as an inducement for MDPP supplier selection.

In order to monitor for compliance with the conditions for these incentives, we need information on the date the incentive was furnished; the identity of the beneficiary to whom the item or service was furnished; the agent of the supplier that furnished the item or service, if applicable; a description of the item or service; the retail value of the beneficiary engagement incentive; and documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period. The complexity of the coding that would be required to allow all of this information to be reported on administrative claims would be great, and we believe such a reporting methodology for beneficiary engagement incentives would lead to significantly greater administrative burden on MDPP suppliers than our proposed documentation approach. Therefore, we do not believe it would be feasible for MDPP suppliers to report on administrative claims all of the information about beneficiary engagement incentives that is necessary for us to monitor compliance with the conditions for these incentives that have been adopted to protect beneficiaries and the program from their misuse.

Comment: Several commenters urged CMS to collect data on beneficiary engagement incentives from MDPP suppliers to study the effects of the various engagement incentives furnished to MDPP beneficiaries, including the amount and type of incentive; whether beneficiaries receiving the incentives actually maintained participation in MDPP services; and whether identified beneficiary engagement incentives contributed to beneficiaries meeting the weight loss performance goal or achieving other positive outcomes under the MDPP expanded model. The commenters stated that these data are needed to inform both effective incentive designs that could be offered to MDPP beneficiaries and best practices for future use.

Response: We appreciate the interest of the commenters in expanding the evidence-base on the use of beneficiary engagement incentives in payment models, both the MDPP expanded model and other innovative payment models. As discussed previously in this section, we are not requiring documentation of all beneficiary engagement incentives of any retail value in view of the greater administrative burden this would place upon MDPP suppliers. We also do not currently have a mechanism for collecting data from MDPP suppliers on beneficiary engagement incentives. While we agree with the commenters that this information could be useful in informing future incentive designs, MDPP suppliers are already expected to submit a significant amount of information to CMS on claims and under the requirement to submit a crosswalk (finalized in this final rule at §424.205(d)(13)) under the MDPP expanded model that will inform the evaluation of the model overall, including the totality of its design features which include the voluntary provision of beneficiary engagement incentives. Therefore, we believe that requiring MDPP suppliers to submit detailed information on the type and amount of all incentives that are furnished to MDPP beneficiaries would place an undue documentation and reporting burden on suppliers. Instead, we expect that MDPP suppliers choosing to offer in-kind beneficiary

engagement incentives, where the costs of these incentives are borne by the supplier, will be reviewing their experiences in their own DPP and making adjustments to their incentive practices based on their analysis of the MDPP performance of the population they are serving.

After considering the public comments received, we are finalizing the proposals, without modification, for the documentation requirements for beneficiary engagement incentives under the MDPP expanded model at §424.210(e). Table 43 summarizes the final documentation requirements for beneficiary engagement incentives under the MDPP expanded model.

TABLE 43: Final Beneficiary Engagement Incentive Documentation Requirements

Beneficiary Engagement Incentive	Documentation Requirement
Item or service with retail value greater than $25	• Contemporaneous documentation that includes at least: ▪ The date the incentive was furnished. ▪ The identity of the MDPP beneficiary to whom the item or service was furnished. ▪ Documentation establishing that the item or service was furnished to the MDPP beneficiary during the engagement incentive period. ▪ The agent of the supplier that furnished the item or service, if applicable. ▪ A description of the item or service. ▪ The retail value of the item or service. • Documentation regarding items or services that are furnished to the MDPP beneficiary for use on an ongoing basis during the engagement incentive period, including items involving technology exceeding $100 in retail value, must also include contemporaneous documentation establishing that the MDPP beneficiary is in the engagement incentive period throughout the time period that the MDPP beneficiary possesses or has access to the item or service furnished by the MDPP supplier. • The documentation regarding items involving technology exceeding $100 in retail value must also include contemporaneous documentation of any attempt to retrieve the technology.* • The MDPP supplier must retain and provide access to the documentation.

* = Items involving technology with a retail value greater than $100 remain the property of the MDPP supplier and must be retrieved from the MDPP beneficiary at the end of the engagement incentive period.

vi. Compliance with Fraud and Abuse Laws

Certain arrangements between MDPP suppliers and beneficiaries may implicate the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), or the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act). In many cases, arrangements that

implicate these laws can be structured to comply with them by using existing safe harbors and exceptions. Section 1115A(d)(1) of the Act authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of models under section 1115A(b) of the Act. A waiver is not needed for an arrangement that does not implicate the fraud and abuse laws or that implicates the fraud and abuse laws, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Accordingly, under section 1115A(d)(1) of the Act, the Secretary will consider whether waivers of certain fraud and abuse laws are necessary for the MDPP expanded model. Such waivers, if any, would be promulgated separately from this proposed regulation by OIG (as to sections 1128A and 1128B of the Act), to which the respective authorities have been delegated.

Because of the close nexus between the final regulations governing the structure and operations of the MDPP expanded model and the development of any fraud and abuse waivers necessary to carry out the provisions of the model, CMS and OIG may, when considering the need for or scope of any waivers, consider comments submitted in response to the proposed rule and the provisions of the final rule. No waivers of any fraud and abuse authorities are being issued in this final rule.

3. Virtual DPP and the MDPP Expanded Model

The CDC's DPRP Standards allow evidence-based DPP curricula to be furnished through a variety of modes, including through remote technologies. Similar to the description noted in section III.K.2.c.iv.3 of this final rule with respect to virtual make-up sessions, virtual DPP refers to any modality, or method of furnishing MDPP services, that is not in person. This includes, but is not limited to:

(1) Furnishing services online where the behavior change program is furnished 100 percent online, with participants accessing course resources and lifestyle coach via a computer, laptop, tablet, smart phone, or other device with internet access. This modality requires an internet connection to participate in all aspects of the DPP;

(2) Furnishing services online with other means of support by a coach (for example, telecommunications, video conferencing). This modality requires an internet connection for some aspects of the DPP, but not all; and

(3) Distance learning, where a coach is present in one location and participants are calling, video-conferencing, or otherwise using telecommunications technology to access the coach from another location. This modality does not require any internet connection for any of the aspects of the DPP.

These types of delivery modes are hereafter referred to as "virtual," and DPP furnished *exclusively* through these modes with no in-person delivery is hereafter referred to as "virtual DPP."

We acknowledge that the public comments in response to the MDPP expanded model in the CY 2017 PFS proposed rule supported the inclusion of virtual DPP in the MDPP expanded model. Many commenters stated that this proposal would increase access to MDPP services, referenced emerging evidence that suggests virtual DPP may be as effective as DPP furnished in a community setting, and stated that virtual delivery may be preferable to some beneficiaries. In the CY 2017 PFS final rule, we deferred policies pertinent to virtual DPP to future rulemaking.

Although in the CY 2018 PFS proposed rule, we proposed to allow a limited number of virtual make-up sessions in the MDPP expanded model (82 FR 34136 through 34137), we did not propose to include virtual DPP services (that is, DPP furnished *exclusively* through remote

technologies with no in-person delivery), (82 FR 34171 through 34172). We considered including virtual DPP services in the MDPP expanded model; however, the DPP model test that was used to make the statutorily required determination for expansion did not include virtual DPP services. Instead, we noted that we are considering a separate model under CMS's Innovation Center authority to test and evaluate virtual DPP services. Consistent with our regular practice for Innovation Center models, we would release details on any model test for virtual DPP services separately.

We noted that some DPP organizations currently offer DPP services through a combination of in-person and virtual delivery. We are finalizing to only allow this combination of delivery subject to the requirements on virtual make-up sessions, discussed in section III.K.2.c.iv.3 of this final rule. The combined-delivery DPP services that are currently offered are intended to offer a participant DPP services through both online and in-person methods. The MDPP expanded model, in contrast, is intended to offer participants in-person DPP services primarily, but allows a limited number of virtual make-up sessions on an individual basis. As discussed in section III.K.2.c.iv.3 of this final rule, there is substantial research on the effectiveness of DPP furnished virtually, and emerging evidence on DPP delivered virtually suggests that virtual delivery can show similarly successful participant weight loss and health benefits to DPP delivered in other settings, including among Medicare-age participants. However, since the DPP model test only included in-person delivery, we are finalizing a limit on the number of virtually-delivered make-up sessions to the limits discussed in section III.K.2.c.iv.3 of this final rule.

An organization may furnish separate DPPs where some participants receive only in-person DPP services, others receive only virtual DPP services, and others receive a combination

program where some sessions are offered in person and others virtually. If an organization that offers multiple distinct DPPs through different delivery modes enrolls as an MDPP supplier, we proposed that only DPP services furnished in person will be paid in the MDPP expanded model, with the exception of virtual make-up sessions as discussed in section III.K.2.c.iv.3 of this final rule.

The following is a summary of the public comments received on virtual DPP services and our responses:

Comment: We received many comments on virtual DPP services. The majority of commenters supported the use of virtual DPP services, either in the MDPP expanded model or in a separate virtual model test. These commenters noted that virtual options will expand access to DPP for individuals in rural areas, who are homebound, or who lack transportation options, and that including virtual DPP services would increase beneficiary choice of service provision and flexibility of program location. Commenters noted that virtual DPP has proven successful and has a strong evidence base, and some commenters noted that including virtual DPP in the expanded model would improve the effectiveness of MDPP services. Some commenters provided recommendations for a virtual DPP model test. Many commenters requested that CMS allow Medicare Advantage plans to offer virtual DPP services and requested clarity about the provision of virtual DPP services for MA plans. Only 2 commenters supported only including virtual DPP as a limited number of make-up sessions or deferring virtual DPP policies.

Response: We appreciate the comments received related to virtual DPP; however, we note that we did not propose any policies related to exclusively virtual services. We will, however, be clarifying issues regarding virtual DPP services and MA plan members in future guidance. The development of new voluntary Innovation Center payment and service delivery

models is not typically performed through notice and comment rulemaking, but we intend to utilize the comments received, as appropriate, to inform the development of any virtual model test that occurs as part of broader CMS efforts to promote expanded access to remote and telehealth services.

Comment: We received several comments requesting that CMS permit MA plans to provide both in-person and fully virtual MDPP services to enrollees as part of the MDPP Expanded Model. These MAOs noted that virtual services would provide more access to MDPP services for MA plan enrollees and would ensure the MA enrollees have a choice in how to access MDPP services.

Response: We believe that the reasons stated in this section regarding the exclusion of fully virtual MDPP services from the expanded model apply equally to the Medicare Advantage setting, and therefore, MA plans will not be able to provide fully virtual MDPP services to enrollees as a means to satisfy the requirement that an MA plan provide basic benefit MDPP services to its enrollees. However, we note that MA plans may continue to offer coverage of fully virtual MDPP-like services to enrollees as a supplemental benefit.

4. Evaluation

We intend to evaluate the MDPP expanded model using a combination of encounter and claims data to analyze the long-term utilization of services by beneficiaries who have received the MDPP services. As discussed in the CY 2017 PFS final rule, 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.

Among other possible questions we might explore, our analysis will specifically look at long-term utilization and expenditures that might suggest subsequent treatment of diabetes. We intend to use beneficiary-level encounter data and program data furnished by CDC and will match these data to Medicare claims using the crosswalk finalized at §424.59(b)(3) of the CY 2017 PFS final rule (redesignated and amended at §424.205(d)(13)). As with other Innovation Center model evaluation reports (which are currently published online at https://innovation.cms.gov/Data-and-Reports/index.html), we intend to publish the MDPP expanded model evaluation annual reports publicly on a CMS website. We refer readers to the supplier requirements discussed under section III.K.2.e.iv.(7) of this final rule regarding supplier compliance with this requirement, as well as specifications on the timing and format of the crosswalk. Although CMS did not propose specific evaluation criteria in this rule, and therefore, did not seek comment on the evaluation approach, CMS acknowledges the comments received. Some commenters requested that CMS test and evaluate the impact of changes to lifetime limits, diabetes diagnosis, incentives, and the ongoing maintenance session framework. A few commenters requested CMS evaluate the effects of the various incentives furnished to MDPP beneficiaries, including the amount and type of incentive and whether beneficiaries receiving the incentives actually maintained participation. Other commenters suggested that CMS evaluate the total cost of care for MDPP services based on various personnel types (for example, community health workers, RDNs, CDEs, other qualified health care professionals) as well as study the effectiveness of various methods of delivery of the MDPP services based on personnel. Some commenters recommended analyses stratified by income and race as a means to ensure that the program is reaching all eligible Medicare beneficiaries and that these programs are able to achieve good outcomes for these populations. A few commenters suggested incorporating risk-

adjustment for social factors or other methods to appropriately account for social risk factors in future years. One commenter requested that CMS continue to support further innovation and evaluation of these services through additional model tests and other pilots within Medicare and other populations who could benefit, specifically including children covered by Medicaid and the Children's Health Insurance Program. One commenter requested a continuous feedback loop among all entities involved in the MDPP on evaluation findings.

Response: CMS appreciates all of the recommendations commenters provided. These comments will be considered in informing the evaluation design.