Extract

This document contains Medicare Advantage-related extracts from the MDPP calendar year 2018 Physician Fee Schedule <u>Final Rule</u>. These extracts are taken from the 2018 PFS final rule in their entirety but have been organized by topic. Please refer to pages 52976-52977 of the final rule for definitions on the many acronyms used. This extract is provided as a resource to efficiently locate MA-related MDPP information that is otherwise spread throughout the MDPP final rule.

MDPP Services Start Date

82 Fed. Reg. 53236 (November 15, 2017)

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 providers 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 item/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, 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 unless, as established under 422.101(b)(2), the criteria is superseded by MA regulations or guidance in connection with coverage of basic benefits, in which case MA plans must authorize coverage of the basic benefit 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, MA plans must authorize coverage of MDPP on at least the same terms as those established in §410.79(c) of this final rule. We note that Medicare health plans may generally also provide more generous coverage than Original Medicare as a supplemental benefit.

82 Fed. Reg. 53236 (November 15, 2017)

<u>Comment</u>: We received several comments related to our proposed delay of the MDPP start date 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 MDPP start date 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 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, 42 C.F.R. §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 other Medicare health plans, such as §1876 cost plans, 42 CFR § 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 MDPP start 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.

General Implementation within Medicare Advantage

82 Fed. Reg. 53237 (November 15, 2017)

Comment: In addition to a number of comments supporting a delay to the MDPP original effective date 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 effective date delay to April 1, 2018 on the implementation of MDPP services.

<u>Response</u>: 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

Evidence of Coverage Documents

82 Fed. Reg. 53237 (November 15, 2017)

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 42 CFR §422.111(d) and follow existing guidance at Medicare Managed Care Manual 60.7 "Other Mid-Year Changes Requiring Enrollee Notification."

Coverage of MDPP Services in Medicare Advantage

82 Fed. Reg. 53238 (November 15, 2017)

<u>Comment</u>: 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 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.

MDPP Services Curriculum

82 Fed. Reg. 53238 (November 15, 2017)

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.

MA Reporting of MDPP Services

82 Fed. Reg. 53239 (November 15, 2017)

<u>Comment</u>: 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)).

Beneficiary Eligibility for MDPP Services

82 Fed. Reg. 53243 (November 15, 2017)

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.

<u>Comment</u>: 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 service 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.

82 Fed. Reg. 53248 (November 15, 2017)

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 is the plan itself or where the MDPP supplier 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.

Medicare Enrollment of MDPP Suppliers

82 Fed. Reg. 53301 (November 15, 2017)

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 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.

82 Fed. Reg. 53301 (November 15, 2017)

<u>Comment</u>: 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 42 C.F.R. §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.

Integrated Systems as MDPP Suppliers

82 Fed. Reg. 53317 (November 15, 2017)

<u>Comment</u>: 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 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 nonenrollees 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 nonenrollees, 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 within an integrated system, were to furnish MDPP services to nonenrollees 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

Exclusion of Fully Virtual DPP Services

82 Fed. Reg. 53338 (November 15, 2017)

<u>Comment</u>: 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.

Payment for MDPP Services

82 Fed. Reg. 53279 (November 15, 2017)

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 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.