

(d) The amount payable to the beneficiary is determined in accordance with § 410.152 of this chapter.

Subpart I—Requirements for Medicare Diabetes Prevention Program Suppliers and Beneficiary Engagement Incentives Under the Medicare Diabetes Prevention Program Expanded Model

SOURCE: 82 FR 53364, Nov. 15, 2017, unless otherwise noted.

§ 424.200 Scope.

This subpart specifies the requirements for Medicare Diabetes Prevention Program suppliers and beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 414.84(a) of this subchapter, the following definitions apply to this section:

Administrative location means a physical location associated with the MDPP supplier's operations where they are the primary operator in the space, from where coaches are dispatched or based, and where MDPP services may or may not be furnished.

Coach means an individual who furnishes MDPP services on behalf of an MDPP supplier as an employee, contractor, or volunteer.

Coach eligibility end date means the end date indicated by the MDPP supplier in submitting a change to the supplier's MDPP enrollment application in accordance with paragraph (d)(5) of this section that removed the coach's information, or the date the supplier itself was revoked from or withdrew its Medicare enrollment as an MDPP supplier.

Coach eligibility start date, means the start date indicated by the MDPP supplier when submitting the coach's information on the MDPP enrollment application.

Community setting means 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.

Eligible coach means an individual who CMS has screened and has determined can provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

Ineligible coach means an individual whom CMS has screened and has determined cannot provide MDPP services on behalf of an MDPP supplier in accordance with paragraph (e) of this section.

MDPP interim preliminary recognition means a status that CMS has granted to an entity in accordance with paragraph (c) of this section.

(b) *Conditions for MDPP supplier enrollment.* An entity may enroll as an MDPP supplier only if it satisfies the following requirements and all other applicable Medicare enrollment requirements:

(1) Has either an MDPP preliminary recognition, as defined in paragraph (c)(1) of this section or a full CDC DPRP recognition.

(2) Maintains an active and valid TIN and NPI at the organizational level.

(3) Has passed screening requirements as follows:

(i) Upon initial enrollment, at a "high" categorical risk in accordance with § 424.518(c)(2); and

(ii) Upon revalidation, at a "moderate" categorical risk in accordance with § 424.518(b)(2).

(4) Maintains, and submits to CMS through the CMS-approved enrollment application, a roster of all coaches who will be furnishing MDPP services on the entity's behalf that includes each coach's first and last names, middle initial (if applicable), date of birth, Social Security Number (SSN), active and valid NPI, coach eligibility start date, and coach eligibility end date (if applicable). This roster must be updated in accordance with paragraph (d)(5) of this section.

(5) The Medicare provider enrollment application fee does not apply to all Medicare Diabetes Prevention Program (MDPP) suppliers that submit an enrollment application on or after January 1, 2022.

(6) Meets and certifies in its CMS-approved enrollment application that it meets and will continue to meet the supplier enrollment standards described in paragraph (d) of this section.

(7) Revalidates its Medicare enrollment every 5 years after the effective date of enrollment.

(c) *MDPP preliminary recognition.* For the purposes of this section, an MDPP preliminary recognition may include either:

(1) Any preliminary recognition established by CDC for the purposes of the DPRP; or

(2) An MDPP interim preliminary recognition.

(i) *MDPP interim preliminary recognition application period.* Entities may apply to CDC for CMS' MDPP interim preliminary by submitting information at the time and in the form and manner specified by CMS.

(ii) *MDPP Interim preliminary recognition requirements.* An entity may qualify for MDPP interim preliminary recognition if—

(A) The entity has pending CDC recognition.

(B) The entity submits a full 12 months of performance data to CDC on at least one completed cohort. The 12 month data submission 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, at least 60 percent of whom attended at least 9 sessions in months 1 through 6, and at least 60 percent of whom attended at least 3 sessions in months 7 through 12.

(d) *Medicare Diabetes Prevention Program supplier standards.* An MDPP supplier must meet and must certify in its CMS-approved enrollment application that it meets and will continue to meet the following standards.

(1) The MDPP supplier must have and maintain MDPP preliminary recognition, as defined under paragraph (c)(1)

of this section, or a full CDC DPRP recognition.

(2) The MDPP supplier must not currently have its billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(3) The MDPP supplier must not include on the roster of coaches, described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section, nor permit MDPP services to be furnished by, any individual coach who meets any of ineligibility criteria outlined in paragraph (e)(1) of this section.

(4) The MDPP supplier must maintain at least one administrative location. All administrative locations maintained by the MDPP supplier must be located at an appropriate site and be reported on the CMS-approved enrollment application. An appropriate site for such an administrative location would include all of the following characteristics:

(i) Signage posted on the exterior of the building or suite, in a building directory, or on materials located inside of the building. Such signage may include, for example, the MDPP supplier's legal business name or DBA, as well as hours of operation.

(ii) Open for business during stated operational hours.

(iii) Employees, staff, or volunteers present during operational hours; and

(iv) Not a private residence.

(5) The MDPP supplier must update its enrollment application within 30 days of any changes of ownership, changes to the coach roster (including due to coach ineligibility or because the coach is no longer an employee, contractor, or volunteer of the MDPP supplier), and final adverse action history, and report all other changes, including but not limited to changes in the MDPP supplier's administrative location(s), to CMS within 90 days of the reportable event.

(6) The MDPP supplier must maintain a primary business telephone that operates either at administrative locations described in paragraph (d)(4) of this section or directly where services are furnished, if services are furnished in community settings. The associated telephone number must be listed with either the legal or doing business as

name of the supplier in public view, including on Web sites, flyers, and materials.

(7) The MDPP supplier must not knowingly sell to or allow another individual or entity to use its supplier billing number.

(8) Subject to paragraph (d)(8)(i) of this section, the 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.

(i) Suppliers may deny an MDPP beneficiary access to MDPP services during the MDPP services period only under one of the following conditions:

(A) The MDPP beneficiary no longer meets the eligibility criteria for MDPP services under § 410.79(c)(1) of this chapter.

(B) The MDPP supplier lacks the self-determined publicly-posted capacity to furnish MDPP services to a given MDPP beneficiary.

(C) The MDPP supplier determines that the MDPP beneficiary significantly disrupts the session for other MDPP beneficiaries or becomes abusive.

(ii) MDPP suppliers must maintain a record of the number of MDPP beneficiaries for whom it declined access away for the reasons outlined in paragraphs (d)(8)(i)(B) and (C) of this section, to include the date each such beneficiary was declined access. For beneficiaries who were declined access for the reasons described in paragraph (d)(8)(i)(C) of this section, the MDPP supplier must document details of the occurrence(s), including date(s) of the behavior, any remediation efforts taken by the MDPP supplier, and final action (for example, dismissal from an MDPP session or denial from future sessions) in the beneficiary's MDPP records.

(9) The MDPP supplier and other individuals or entities performing functions or services related to MDPP services on the MDPP supplier's behalf must not unduly coerce 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.

(10) Except as allowed under paragraph (d)(8) of this section, the MDPP supplier must offer an MDPP beneficiary no fewer than all of the following:

(i) 16 in-person core sessions no more frequently than weekly for the first 6 months of the MDPP services period, which beginnings on the date of attendance at the first such core session.

(ii) 1 in-person core maintenance session each month during months 7 through 12 (6 months total) of the MDPP services period.

(iii) 1 in-person ongoing maintenance session each month for months 13 through 24 of the MDPP services period, as long as the beneficiary maintains eligibility to receive such services in accordance with § 410.79(c)(1)(ii) and (iii) of this chapter.

(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. Such information must include all of the following:

(i) Eligibility requirements under § 410.79(c)(1) of this chapter, including the once-per-lifetime nature of MDPP services.

(ii) Minimum coverage requirements under § 410.79(c)(2).

(iii) The MDPP supplier standards as specified in paragraph (d) of this section.

(12) The MDPP supplier must answer MDPP beneficiaries' questions about MDPP services and respond to MDPP-related complaints within a reasonable timeframe. An MDPP supplier must 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 actions on behalf of the MDPP supplier. Failure to maintain a complaint resolution protocol or to retain information regarding MDPP related complaints in accordance with paragraph

(g) of this section may be considered evidence that the MPPP supplier standards have not been met. This information must be kept at each administrative location and made available to CMS or its contractors upon request.

(13) The MDPP supplier must maintain a crosswalk file which indicates how beneficiary identifications for the purposes of CDC performance data requirements correspond to corresponding beneficiary health insurance claims numbers or Medicare Beneficiary Identifiers for each MDPP beneficiary receiving MDPP services from the MDPP supplier. The MDPP supplier must submit the crosswalk file to CMS or its contractor.

(14) The MDPP supplier must submit performance data for MDPP beneficiaries who attend ongoing maintenance sessions with data elements consistent with the CDC's DPRP standards for data elements required for the core services period.

(15) The MDPP supplier must allow CMS or its agents to conduct onsite inspections or recordkeeping reviews in order to ascertain the MDPP supplier's compliance with these standards, and must adhere to the documentation requirements as outlined in paragraph (g) of this section.

(e) *Coach eligibility*—(1) *Criteria*. To furnish MDPP services to a beneficiary, an MDPP coach must not:

(i) Currently have Medicare billing privileges revoked and be currently subject to the reenrollment bar.

(ii) Currently have its Medicaid billing privileges terminated for-cause or be excluded by a State Medicaid agency.

(iii) Currently be excluded from any other Federal health care program, as defined in 42 CFR 1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Act.

(iv) Currently be debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with the Federal Acquisition Streamlining Act implementing regulations and the Department of Health and Human Services nonprocurement common rule at 45 CFR part 76.

(v) Have, in the previous 10 years, one of the following State or Federal felony convictions:

(A) 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.

(B) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud 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.

(C) Any felony that placed Medicare or its beneficiaries at immediate risk, such as a malpractice suit that results in the individual being convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion of criminal neglect or misconduct.

(D) Any felonies for which the individual was convicted, as defined under 42 CFR 1001.2, had a guilty plea or adjudicated pretrial diversion that would result in mandatory exclusion under section 1128(a) of the Act.

(2) *CMS determination of coach eligibility*. CMS will screen each individual identified on the roster of coaches included with the supplier's enrollment application described in paragraph (b)(4) of this section and updated in accordance with paragraph (d)(5) of this section to verify that the individual coach does not meet any of the conditions specified in paragraph (e)(1) of this section and that the coach can provide MDPP services on behalf of an MDPP supplier. For each individual coach successfully screened by CMS, his or her eligibility start date becomes effective and remains effective until an MDPP supplier or CMS takes action that results in an eligibility end date.

(f) *Effective date for billing privileges*.

(1) For MDPP suppliers initially enrolling and for newly established administrative locations that result in a new enrollment record or Provider Transaction Access Number, the effective date for Medicare billing privileges for MDPP suppliers is—

(i) The later of—

(A) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor;

(B) The date of filing of a corrective action plan that was subsequently approved by a Medicare contractor; or

(C) The date that the supplier first began furnishing services at a new administrative location that resulted in a new enrollment record or Provider Transaction Access Number.

(ii) Under no circumstances should the effective date of billing privileges for any MDPP supplier be prior to April 1, 2018.

(2) For any newly established administrative locations that do not result in a new enrollment record or Provider Transaction Access Number, the existing billing privilege effective date for their Provider Transaction Access Number will apply, but not earlier than April 1, 2018.

(g) *Documentation retention and provision requirements.* An MDPP supplier must maintain all documentation related to participation in the MDPP in accordance with all applicable Federal and State laws. The MDPP supplier must 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 with the MDPP expanded model's requirements, including the MDPP expanded model requirements for in-kind beneficiary incentive engagements in §424.210 of this chapter in the event that the MDPP supplier chooses to offer such incentives to any MDPP beneficiary.

(1) The documentation for the first core session must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) Organizational information, including MDPP supplier name, CDC DPRP number, and NPI.

(ii) Basic beneficiary information for each MDPP beneficiary in attendance,

including but not limited to beneficiary name, HICN, or MBI, age.

(iii) Evidence that each such beneficiary satisfied the eligibility requirements under §410.79(c) of this chapter at the time of service.

(2) The documentation for each MDPP session attended by an MDPP must be established contemporaneous with the furnishing of MDPP services and must include at least all of the following:

(i) 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.

(ii) Identification of which CDC-approved DPRP curriculum was associated with the session.

(iii) The NPI of the coach who furnished the session.

(iv) The date and place of service of the session.

(v) Each MDPP's beneficiary's weight and date weight taken, in a form and manner as specified by CMS.

(3) If an MDPP supplier chooses to offer in-kind beneficiary engagement incentives to MDPP beneficiaries as permitted under §424.210, the records maintained by the MDPP supplier in accordance with this section must also include the information required by §424.210(e).

(4) An MDPP supplier is required to maintain and handle any beneficiary information related to MDPP, including Personally Identifiable Information (PII) and Protected Health Information (PHI), as would be required under HIPAA, other applicable state and federal privacy laws, and CMS standards.

(5) The MDPP supplier's records must include an attestation from the MDPP supplier that, as applicable, the MDPP beneficiary for which it is submitting a claim—

(i) Has attended their first, fourth or ninth core session, as applicable, if the claim submitted is for a performance payment under §414.84(b)(1), (2), or (3) of this chapter.

(ii) Has attended at least three core maintenance sessions, achieved required minimum weight loss, or both, as applicable, if the claim submitted is for a performance payment under §414.84(b)(4) of this chapter.

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(iii) Has achieved the required minimum weight loss and attended at least three ongoing maintenance sessions within an ongoing maintenance session interval, if the claim submitted is for a performance payment under § 414.84(b)(5) of this chapter, if the claim submitted is for a performance payment under § 414.84(b)(6) of this chapter.

(iv) Has achieved required minimum weight loss as measured in-person during a core session or core maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(6) of this chapter.

(v) Has achieved at least a 9-percent weight loss percentage as measured in-person during a core session, core maintenance session, or ongoing maintenance session furnished by that supplier, if the claim submitted is for a performance payment under § 414.84(b)(7) of this chapter.

(6) The MDPP supplier must maintain all records required under this section for a period of 10 years from the last day of the MDPP beneficiary's receipt of MDPP services provided by the MDPP supplier or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless either of the following apply:

(i) 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

(ii) There has been a dispute or allegation of fraud or similar fault 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, as defined at § 405.902 of this chapter.

(h) *Denial or revocation of MDPP supplier enrollment.* (1) An MDPP supplier is subject to enrollment denial or revocation of its MDPP supplier enrollment for one or more of the following reasons:

(i) *Failure to meet enrollment requirements.* The MDPP supplier does not satisfy the conditions specified in paragraph (b) of this section.

(A) An enrollment denial under this paragraph (h)(1)(i) is considered an enrollment denial under § 424.530(a)(1).

(B) A revocation under this paragraph (h)(1)(i) is considered a revocation under § 424.535(a)(1).

(C) An MDPP supplier that does not satisfy the requirements in paragraph (b)(1) of this section may become eligible to bill for MDPP services again if it successfully achieves MDPP preliminary recognition or full CDC DPRP recognition, and successfully enrolls again in Medicare as an MDPP supplier after any applicable reenrollment bar has expired.

(ii) *Failure to meet MDPP supplier standards.* The MDPP supplier fails to meet the standards specified in paragraph (d) of this section.

(A) An enrollment denial under this paragraph (h)(1)(ii) is considered an enrollment denial under § 424.530(a)(1).

(B) A revocation under this paragraph (h)(1)(ii) is considered a revocation under § 424.535(a)(1).

(iii) *Application of existing enrollment denial reasons.* One of the enrollment denial reasons specified in § 424.530(a) applies.

(iv) *Application of existing revocation reasons.* One of the revocation reasons specified in § 424.535(a) applies.

(v) *Use of an ineligible coach.* (A) The MDPP supplier knowingly allows an ineligible coach to furnish MDPP services to Medicare beneficiaries. Knowingly means that the MDPP supplier received an enrollment denial or revocation notice based on failing to meet the standard specified in § 424.205(d)(3), was provided notice by CMS or contractors working on its behalf of this coach's ineligibility including the reason(s) for ineligibility, submitted a corrective action plan (CAP) to remove the coach and become compliant therefore maintaining its enrollment, but continued to allow the coach to provide MDPP services in violation of the CAP.

(B) Revocation under this paragraph (h)(1)(v) is subject to the following requirements:

(1) The revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the MDPP supplier.

(2) For the revocation authority under this paragraph (h)(1)(v), MDPP

suppliers are barred from participating in the Medicare program from the date of the revocation, which begins 30 days after CMS or its contractor mails notice of the revocation, until the end of the reenrollment bar, which lasts a minimum of 1 year, but not greater than 3 years, depending on the severity of the basis for revocation.

(3) 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.

(2) An MDPP supplier may appeal an enrollment denial or revocation decision in accordance with the procedures specified in part 498 of this chapter. References to suppliers in that section apply to MDPP suppliers.

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§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definition applies to this section:

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. This period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary and ends when one of the following occurs, whichever occurs first:

(i) The MDPP beneficiary's MDPP services period ends as described in § 410.79(c)(3) of this chapter.

(ii) The MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier.

(iii) 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.

(b) *General.* An MDPP supplier may choose to furnish an item or service as

an in-kind beneficiary engagement incentive to an MDPP beneficiary only during the engagement incentive period, subject to the following conditions:

(1) 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.

(2) The item or service must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session furnished by the MDPP supplier.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary by engaging him or her in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside of the MDPP services.

(5) The item or service must not be tied to the receipt of items or services from a particular provider, supplier, or coach.

(6) 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.

(7) The cost of the item or service must not be shifted to another Federal health care program, as defined at section 1128B(f) of the Act.

(8) The cost of the item or service must not be shifted to an MDPP beneficiary.

(c) *Technology furnished to an MDPP beneficiary.* In-kind beneficiary engagement incentives involving technology furnished by an MDPP supplier to an MDPP beneficiary are subject to the following conditions: