

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 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.

(iii) Has achieved at least a 9-percent weight loss percentage as measured in accordance with § 410.79(e)(3)(iii) of this chapter 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)(7) of this chapter.

(iv) 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

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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.

(g) *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 preliminary, full, or full plus 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 National Diabetes Prevention Program curriculum furnished to the MDPP beneficiary during a core session or core 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:

(1) Items or services involving technology may not, in the aggregate, exceed \$1,000 in retail value for any one MDPP beneficiary.

(2) Items or services involving technology must be the minimum necessary to advance a clinical goal, as specified in paragraph (d) of this section, for an MDPP beneficiary.

(3) Items involving technology exceeding \$100 in retail value must—

(i) Remain the property of the MDPP supplier; and

(ii) Be retrieved from the MDPP beneficiary at the end of the engagement incentive period. The MDPP supplier must document all retrieval attempts, including the ultimate date of retrieval, in accordance with paragraph (e)(3) of this section. Documented diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(d) *Clinical goals of the MDPP expanded model.* The following are the clinical goals for MDPP beneficiaries that may be advanced through in-kind beneficiary engagement incentives:

(1) Attendance at core sessions or core maintenance sessions.

(2) Weight loss.

(3) Long-term dietary change.

(4) Adherence to long-term health behavior changes.

(e) *Documentation of beneficiary engagement incentives.* In addition to the documentation requirements at § 424.205(g), an MDPP supplier must maintain documentation of items and