

§ 410.79

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not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) *Telepresenter not required.* A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) *Exception to the interactive telecommunications system requirement.* For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) *Limitations.* (1) A clinical psychologist and a clinical social worker, a marriage and family therapist (MFT), and a mental health counselor (MHC) may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(2) The physician visits required under § 483.40(c) of this title may not be furnished as telehealth services.

(3) The distant site practitioner who reports the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are

made through the annual physician fee schedule rulemaking process. During the Public Health Emergency, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency, taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

[66 FR 55330, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66423, Nov. 15, 2004; 70 FR 70330, Nov. 21, 2005; 72 FR 66399, Nov. 27, 2007; 73 FR 69934, Nov. 19, 2008; 74 FR 62005, Nov. 25, 2009; 75 FR 73615, Nov. 29, 2010; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 80 FR 71373, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27621, May 8, 2020; 85 FR 85027, Dec. 28, 2020; 86 FR 65666, Nov. 19, 2021; 87 FR 70224, Nov. 18, 2022; 88 FR 79528, Nov. 16, 2023]

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on April 1, 2018.

(b) *Definitions.* For purposes of this section, the following definitions apply:

Baseline weight means the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

CDC-approved DPP curriculum refers to the content of the core sessions, core maintenance sessions, and ongoing maintenance sessions. The curriculum may be either the CDC-preferred curriculum as designated by the CDC DPRP Standards or an alternative curriculum approved for use in DPP by the CDC.

Combination delivery. MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.

Core maintenance session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Core session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for core sessions.

Diabetes Prevention Recognition Program (DPRP) refers to a program administered by the Centers for Disease Control and Prevention (CDC) that recognizes organizations that are able to furnish diabetes prevention program (DPP) services, follow a CDC-approved DPP curriculum, and meet CDC's performance standards and reporting requirements.

Distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

Extended flexibilities refer to the flexibilities as described in paragraphs (e)(3)(iii) and (iv) of this section.

Extended flexibilities period refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

Full CDC DPRP recognition refers to the designation from the CDC that an organization has consistently furnished CDC-approved DPP sessions, met CDC-performance standards and met CDC reporting requirements for at least 24–36 months following the organization's application to participate in the DPRP.

Full-Plus CDC DPRP recognition refers to organizations that have met the Full CDC DPRP recognition, and at the time full recognition is achieved, has met the following retention criterion: Eligible participants in the evaluation cohort must have been retained at the

following percentages: A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions; A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

Make-up session means a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.

MDPP beneficiary means a Medicare beneficiary who meets the criteria specified in paragraph (c)(1)(i) of this section, 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 paragraph (c)(3) of this section.

MDPP services means 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.

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 paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section.

MDPP session means a core session or a core maintenance session.

MDPP supplier means an entity that is enrolled in Medicare to furnish MDPP services as provided in §424.205 of this chapter.

Medicare Diabetes Prevention Program (MDPP) refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP beneficiaries.

National Diabetes Prevention Program (National DPP) refers to an evidence-

based intervention targeted to individuals with pre-diabetes that is furnished in community and health care settings and administered by the Centers for Disease Control and Prevention (CDC).

Ongoing maintenance session interval means one of the up to four consecutive 3-month time periods during the ongoing services period described in paragraph (c)(2)(ii) of this section, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

Online delivery refers to an MDPP session that is delivered online for all participants and is furnished in a manner consistent with the DPRP Standards for online sessions. The program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Coach teaching the content. However, live Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.

Required minimum weight loss refers to the percentage by which the beneficiary's updated weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

Set of MDPP services means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and subject to paragraph (c)(3) of this section, ongoing maintenance sessions, offered over the course of the MDPP services period.

Virtual make-up session means 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.

Virtual session refers to an MDPP session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for distance learning sessions.

(c) Coverage for MDPP services—(1) *Beneficiary eligibility.* (i) A Medicare beneficiary is eligible for MDPP serv-

ices offered during the core services period described in paragraph (c)(2)(i) of this section if the beneficiary meets all of the following criteria:

(A) Is enrolled under Medicare Part B;

(B) Attended the first core session within the most recent 12-month time period and, prior to attending this first core session, had not previously received the set of MDPP services in his or her lifetime;

(C) Has, on 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;

(D) Has received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL;

(E) Has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) 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.

(2) *MDPP services period.* An MDPP beneficiary's MDPP services period is composed of the following periods and intervals:

(i) The core services period, which is the first 12 months of the MDPP services period, and consists of:

(A) Up to 16 core sessions offered at least 1 week apart during months 1 through 6 of the MDPP services period; and

(B) Up to 6 core maintenance sessions offered at least 1 month apart during months 7 through 12 of the MDPP services period.

(ii) [Reserved]

(3) *Limitations on the MDPP services period.*

(i) The MDPP services period ends upon completion of the core services

period described in paragraph (c)(2)(i) of this section.

(ii) [Reserved]

(d) *Make-up sessions.* (1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

(i) The curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed;

(ii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and

(iii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week.

(2) An MDPP supplier may offer virtual make-up sessions only if consistent with the requirements in paragraph (d)(1) of this section. Virtual make-up sessions are also subject to the following requirements:

(i) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(ii) An MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request; and

(iii) An MDPP supplier may offer to an MDPP beneficiary:

(A) No more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions are core maintenance sessions; and

(B) [Reserved]

(3) Make-up sessions furnished in accordance with paragraph (d)(1) of this section that an MDPP beneficiary attends in person are counted toward meeting the attendance requirements described in paragraph (c)(1) of this section and toward achieving the performance goals described in §414.84(b) of this chapter as if the MDPP beneficiary attended a regularly scheduled session. Virtual make-up sessions furnished in accordance with paragraph

(d)(2) of this section are also counted toward such attendance requirements and performance goals, subject to the following limitations:

(i) The MDPP beneficiary receives no more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and

(ii) [Reserved]

(e) *MDPP expanded model emergency policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph (e) apply during the Public Health Emergency (PHE) as defined in §400.200 of this chapter and during any future 1135 waiver event that CMS determines may disrupt in-person MDPP services (an "applicable 1135 waiver event"). For purposes of this paragraph (e), "1135 waiver event" means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized one or more waivers under section 1135 of the Act.

(2)(i) CMS determines that an 1135 waiver event may disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, the avoidance of transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and MDPP coaches, as defined in §424.205(a) of this chapter, during an 1135 waiver event.

(ii) If CMS determines that an 1135 waiver event may disrupt in-person MDPP services, CMS will communicate such determination for purposes of the policies described in this paragraph (e), to all affected MDPP suppliers.

(3) The following changes apply under this paragraph (e), when CMS has determined that an 1135 waiver event may disrupt in-person MDPP services:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A) and

(c)(1)(iii)(A) of this section do not apply.

(ii) MDPP suppliers may start new cohorts during the PHE as defined in § 400.200 of this chapter or an applicable 1135 waiver event only if a baseline weight measurement can be obtained as described in paragraph (e)(3)(iii) of this section.

(iii) MDPP suppliers can obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss based performance achievement goals in the following manner:

(A) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations;

(B) Via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, a date-stamped photo or video recording of the beneficiary's weight with the beneficiary visible on the scale, or a recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session.

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually, through distance learning or a combination of in-person or distance learning, during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the Extended flexibilities period, a PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may

continue to receive the Set of MDPP services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

(A) The curriculum furnished during the virtual session addresses the same CDC-approved DPP curriculum topic as the regularly scheduled session.

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session on the same day as a regularly scheduled session.

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week.

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for distance learning sessions.

(E) The MDPP supplier offers virtual sessions only upon an individual MDPP beneficiary's request or agreement to receive services virtually.

(F) The MDPP supplier offers to an MDPP beneficiary:

(1) Up to 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(2) Up to 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period.

(3) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24.

(v) MDPP suppliers may suspend the in-person delivery of the set of MDPP services, when necessary due to the applicable 1135 waiver event, and subsequently resume in-person services either upon the end date of the 1135 waiver event emergency period or an effective date specified by CMS. Upon resumption of the set of MDPP services on an in-person basis, the following paragraphs apply:

(A) Beneficiaries who were receiving MDPP services as of March 31, 2020 whose in-person sessions are suspended due to the PHE as defined in § 400.200 of this chapter may elect to restart the set of MDPP services at the beginning

or resume with the most recent attendance session of record.

(B) Beneficiaries who begin the set of MDPP services on or after January 1, 2021 who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may elect to restart the set of MDPP services at the beginning or may resume with the most recent attendance session of record.

(C) Beneficiaries who began the set of MDPP services between January 1, 2021 and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually can elect to attend ongoing maintenance sessions; and may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

(D) Beneficiaries whose in-person sessions are suspended due to the applicable 1135 waiver event who elect to continue with MDPP services virtually, as described in paragraph (e)(2)(i) of this section, are not eligible to restart the set of MDPP services at a later date, but may elect to suspend the virtual set of MDPP services and resume the set of in-person MDPP services with the most recent attendance session of record.

(E) Beneficiaries may make an election as described in paragraph (e)(3)(v)(A), (B), (C), or (D) of this section, as applicable, only one time per applicable 1135 waiver event.

(F) Beneficiary eligibility, as described in paragraph (c)(1)(i) of this section, will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or any intervening time in which a beneficiary has suspended the set of MDPP services. MDPP suppliers will utilize

the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements:

(1) For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts the set of MDPP services.

(2) For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either at the most recent attendance session of record or restarts the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

(vi) The minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) of this section are waived only for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021.

[81 FR 80552, Nov. 15, 2016; 81 FR 81698, Nov. 18, 2016, as amended at 82 FR 53358, Nov. 15, 2017; 85 FR 19287, Apr. 6, 2020; 85 FR 85027, Dec. 28, 2020; 86 FR 65666, Nov. 19, 2021; 88 FR 79528, Nov. 16, 2023]

Subpart C—Home Health Services Under SMI

§ 410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in subpart E of part 409 of this chapter.

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105,