

rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

(iv) The geographic requirements specified in paragraph (b)(4) of this section do not apply to the following telehealth services:

(A) Home dialysis monthly ESRD-related clinical assessment services furnished on or after January 1, 2019, at an originating site described in paragraphs (b)(3)(vi), (ix) or (x) of this section, in accordance with section 1881(b)(3)(B) of the Act; and

(B) Services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

(C) Services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis, for purposes of treatment of a substance use disorder or a co-occurring mental health disorder.

(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 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.

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph, changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency for the COVID-19 pandemic, 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. A list of the services covered as telehealth services under this section is available 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]

§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.

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 maintenance session interval means one of the two consecutive 3-month time periods during months 7 through 12 of the MDPP services period, during which an MDPP supplier offers an MDPP beneficiary at least one core maintenance session per month.

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.

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.

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

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, one or more ongoing maintenance session intervals during the ongoing services period described in paragraph (c)(2)(ii) of this section.

MDPP session means a core session, a core maintenance session, or an ongoing 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 means an MDPP service that—

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

(ii) Is approximately 1 hour in length; and

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

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.

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.

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

agnosis of diabetes, other than gestational diabetes; and

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

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Attends at least one in-person core maintenance session during the final core maintenance session interval; and

(B) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

(iii) An MDPP beneficiary is eligible for a subsequent ongoing maintenance session interval only if the beneficiary:

(A) Attends at least two ongoing maintenance sessions during the previous ongoing maintenance session interval, including at least one in-person ongoing maintenance session; and

(B) Maintains the required minimum weight loss at a minimum of one in-person ongoing maintenance session furnished during the previous ongoing maintenance session interval.

(iv) 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) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and

(B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

(ii) Subject to paragraph (c)(3) of this section, the ongoing services period, which consists of up to four 3-month ongoing maintenance session intervals offered during months 13 through 24 of the MDPP services period.

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

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ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(ii) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(3)(i) of this section, the MDPP services period ends upon completion of this first ongoing maintenance session interval or any subsequent ongoing maintenance session interval, unless the beneficiary meets the eligibility requirements under paragraph (c)(1)(iii) of this section.

(iii) Unless sooner ended in accordance with this paragraph (c)(3), the MDPP services period ends automatically upon the completion of the fourth ongoing maintenance session interval.

(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) No more than 3 virtual make-up sessions that are ongoing maintenance sessions.

(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) The MDPP beneficiary receives no more than 3 virtual make-up sessions that are ongoing maintenance sessions.

(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.

(2) MDPP requirement changes described in paragraph (e)(1) of this section are applicable to:

(i) Organizations that are enrolled as an MDPP supplier as defined in paragraph (b) of this section, as of March 1, 2020; and

(ii) MDPP beneficiaries as defined in paragraph (b) of this section, who are receiving the MDPP set of services as of March 1, 2020.

(3) The following changes apply under this paragraph (e):

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A), (c)(1)(iii)(A), and (c)(3)(ii) of this section are waived. MDPP suppliers shall not start new cohorts with MDPP beneficiaries who are unable to attend the first core session in-person;

(ii) The limit described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section to the number of virtual make-up sessions is waived for MDPP suppliers with capabilities to provide services virtually so long as the provision of virtual services complies with the following:

(A) The curriculum furnished during the virtual make-up session must address 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 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 make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(E) Virtual make-up sessions can only be furnished to achieve attendance goals and cannot be furnished to achieve weight-loss goals;

(F) An MDPP supplier can only offer virtual make-up sessions upon an individual MDPP beneficiary's request; and

(G) An MDPP supplier can offer to an MDPP beneficiary:

(1) No more than 15 virtual make-up sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(2) No more than 6 virtual make-up sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period; and

(3) No more than 12 virtual make-up sessions offered monthly during the ongoing maintenance session interval periods, months 13 through 24;

(iii) The once per lifetime requirement as described in paragraph (c)(1)(i)(B) of this section is waived to permit MDPP beneficiaries whose sessions were paused or cancelled due to the PHE to obtain the set of MDPP

services more than once per lifetime by electing to restart the MDPP set of services or resume with the most recent attendance session of record;

(iv) 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; and

(v) MDPP suppliers may pause or delay the delivery of the MDPP set of services and subsequently resume services on a delayed schedule. The time periods and intervals must be consistent with the MDPP requirements as described in paragraphs (c)(1)(i)(B), (c)(1)(ii)(A), (c)(1)(iii)(A), (c)(2)(i)(A) and (B), and (c)(3)(i) and (ii) of this section.

[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]

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, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter. Payment for CORF services are made in accordance with § 414.1105.

(a) *Physician's services.* CORF facility physician services are administrative in nature and include consultation with and medical supervision of non-physician staff, participation in plan of treatment reviews and patient care review conferences, and other medical and facility administration activities. Diagnostic and therapeutic services furnished to an individual CORF patient by a physician in a CORF facility