MEDICARE DIABETES PREVENTION PROGRAM ENROLLMENT IS NOW OPEN

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U.S. Health Care Alert

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As of January 1, 2018, the Centers for Medicare & Medicaid Services ("CMS") began enrolling suppliers in its new Medicare Diabetes Prevention Program ("MDPP"). If successfully enrolled prior to April 1, 2018, MDPP suppliers may begin furnishing and billing for services under the MDPP program as of that date. [1] The MDPP model is an expansion of CMS's Center for Medicare and Medicaid Innovation ("CMMI") Diabetes Prevention Program ("DPP") model tested under the authority of Section 1115A of the Social Security Act. CMS first introduced the MDPP expanded model in its Medicare Physician Fee Schedule ("MPFS") final rule for Calendar Year ("CY") 2017 ("2017 Final Rule"). [2] In the MPFS final rule for CY 2018 ("2018 Final Rule"), CMS finalized additional program guidance and implementation information, including implementing supplier standards and enrollment requirements and establishing payment rates. [3] Recently, CMS released the new enrollment application form [4] for MDPP suppliers and subregulatory guidance on the enrollment process. [5]

BACKGROUND

In the United States, type 2 diabetes affects over 25 percent of individuals age 65 and over, and its prevalence is projected to double for all adults ages 18-79 by 2050 if current trends continue. [6] Given the substantial health care costs expended in treating diabetes and related comorbidities, the goal of the MDPP is to test a method of preventing the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes in hopes of decreasing the incidence rate of type 2 diabetes and ultimately cutting health care costs by creating a healthier population. MDPP seeks to prevent diabetes through a structured behavioral change program that emphasizes progression toward weight loss goals through dietary change and increased physical activity. [7] The MDPP is expected to save the Medicare program $182 million over 10 years by decreasing diabetes-related health care costs. [8]

Congressional appropriators in the House of Representatives seek to allocate $25 million to fund the National Diabetes Prevention Program ("NDPP") for fiscal year 2018 through the Centers for Disease Control ("CDC"). [9] The aforementioned appropriations bill has been approved by the House Appropriations Committee and will serve as the basis for negotiations with the Senate Appropriations Committee and its FY 18 Labor HHS Appropriations bill when they draft an omnibus appropriations package to fund the government for the remainder of FY 18.

MDPP SERVICES

The MDPP model consists of a set of group-based, classroom sessions offered over the course of a one to two

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year period to Medicare beneficiaries with an indication of prediabetes. In the first six months a beneficiary is with the program, MDPP suppliers must offer a minimum of 16 group training sessions offered at least once a week and led by supplier "coaches." [10] These "Core Sessions" in the first six months are aimed at providing weight loss and healthy behavior instruction. To achieve this, Core Session coaches must use a curriculum approved by the Centers for Disease Control and Prevention ("CDC") Diabetes Prevention Recognition Program. [11] In months six through twelve, MDPP suppliers must offer "Core Maintenance Sessions" at least monthly, also using a CDC-approved curriculum. [12] Once the first year is completed, MDPP suppliers must continue to offer monthly "Ongoing Maintenance Sessions" in months 13-24 for eligible beneficiaries who achieve and maintain weight loss goals and continue to meet attendance requirements. [13]

Beneficiaries are only eligible to receive MDPP services during this two-year period once per lifetime. [14] For this reason, once the two-year period begins, beneficiaries may not reenroll later if they do not complete the program attendance requirements. In response to commenters' concerns regarding scheduling and inflexibility for both beneficiaries and suppliers, the 2018 Final Rule allows beneficiaries who miss a regularly scheduled session to attend a make-up session or virtual make-up session for any Core Session, Core Maintenance Session or Ongoing Maintenance Session. [15] Make-up sessions must use the same curriculum as the missed session and may be scheduled only once per week and with only one make-up session on the same day as a regularly schedule session. [16] Virtual make-up sessions should also have the same curriculum as the missed session; however, virtual make-up sessions are only available at the beneficiary's request and beneficiaries are limited to a maximum of four Core Sessions, two Core Maintenance Sessions and three Ongoing Maintenance Sessions in a virtual format. [17] Suppliers are also instructed to append a "VM" modifier to the appropriate HCPCS code for any virtual make-up session. [18]

ENROLLMENT REQUIREMENTS AND SUPPLIER STANDARDS

CMS has created a new enrollment application specific to MDPP suppliers, Form CMS-20134, that it began accepting January 1, 2018. [19] Prospective MDPP suppliers must have either full CDC recognition or preliminary recognition in order to enroll. [20] Until the CDC establishes its own standards for preliminary recognition, suppliers that have demonstrated a capacity to furnish services may enroll under MDPP interim preliminary recognition. [21] Prospective suppliers should include a copy of the certificate or determination letter demonstrating preliminary or full recognition status, or a notification letter of enrollment from CMS or CDC if the supplier is enrolling with preliminary recognition or interim preliminary recognition. [22]

The enrollment application requires MDPP suppliers to submit the National Provider Identifiers ("NPIs") of all coaches who will furnish services on behalf of the MDPP supplier. [23] As discussed in the 2017 Final Rule, coaches are session leaders who do not need any clinical certification or formal training, but will need to have a registered NPI. [24] Enrollment applications listing ineligible coaches, such as those with revoked or terminated billing privileges or those with certain felony convictions, may be denied. [25]

In order to obtain and maintain enrollment, an MDPP supplier must also adhere to the supplier standards in 42 C.F.R. § 424.205, as well as other general requirements that apply to all Medicare providers and suppliers. [26] The supplier standards are generally aimed at preventing fraud, waste, and abuse, ensuring suppliers are operational, protecting beneficiary access and service quality, and providing program integrity safeguards. [27]

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These supplier standards include, among other things, onsite inspections by CMS representatives and maintenance of a primary business telephone that operates either at administrative locations or directly where services are furnished, if services are furnished in community settings. [28] A supplier must have at least one administrative location identified on the enrollment record to serve as the base of operations, from where coaches are dispatched and where services may or may not be furnished, and may have several community settings where sessions are held, such as a local church or a multipurpose room in a recreation center. [29] Each administrative location must meet certain requirements, including related to signage, in order to be considered an appropriate site. [30] Generally, additional administrative locations, whether in state or out of state, may be included on the same enrollment record, provided that (1) the location is not part of a separate organization (e.g. a separate corporation, partnership); (2) the location does not have a separate tax identification number ("TIN") and legal business name; and (3) the location has the same CDC organizational code. [31] The supplier standards also require an MDPP supplier to comply with detailed documentation requirements. [32]

CMS has assigned MDPP suppliers to the "high" categorical risk screening level for initial enrollments and "moderate" categorical risk for revalidations. [33] Both of these screening levels include a requirement for an onsite visit.

BENEFICIARY ENGAGEMENT INCENTIVES

CMS regulations also describe the circumstances under which an MDPP supplier may provide in-kind beneficiary engagement incentives to beneficiaries participating in the supplier's program. [34] An item or service provided as an incentive must, among other things, be reasonably connected to the supplier's approved curriculum, be preventive in nature or advance a clinical goal for a beneficiary as further described in the regulations, not be advertised or promoted, and not be tied to receipt of an item or service (1) outside the MDPP services or (2) from a particular provider, supplier, or coach. If certain additional requirements are met, in-kind beneficiary engagement incentives may include items or services involving technology. Notwithstanding these regulations, CMS indicates that the 2018 Final Rule does not include waivers of any fraud or abuse laws and that consideration will be given to whether such waivers are necessary for the MDPP expanded model. If so, they will be promulgated separately by the Office of Inspector General. [35]

PAYMENT

Payment for MDPP services is not made on a fee-for-service basis, but is instead based on performance, such that MDPP suppliers will be reimbursed when beneficiaries attend sessions and meet weight loss goals. In the first six months of Core Sessions, the MDPP supplier will receive $25.00 for the first Core Session attended, $50.00 if four Core Sessions are attended, and $90.00 if nine Core Sessions are attended, regardless of weight loss results. [36] After the first six months, payment is largely dependent on a beneficiary meeting his or her weight loss goals in addition to attendance. If the beneficiary does not meet his or her weight loss goals, the MDPP supplier may only receive $15.00 for the beneficiary's attendance of two or more Core Maintenance Sessions per three month interval, and may not receive any payment for attendance without weight loss in the Ongoing Maintenance Sessions. [37] If the beneficiary does meet his or her weight loss goals, the rate increases to $60.00 for attendance in each interval of Core Maintenance Sessions and $50.00 in each interval of Ongoing

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Maintenance Sessions. [38] The MDPP supplier may also receive an additional payment of $160.00 where five percent weight loss from baseline is achieved and an additional $25.00 where nine percent weight loss is achieved. [39] These figures will be updated annually based on the CPI-U. [40]

MDPP suppliers should bill for services using a new series of HCPCS G-codes to reflect attendance and weight loss. [41] Additionally, CMS has created a HCPCS code for a $25.00 bridge payment, a one-time payment for the first MDPP Core Session, Core Maintenance Session, or Ongoing Maintenance Session furnished to a beneficiary who has switched from another MDPP supplier to the current MDPP supplier within the two year program window. [42]

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[1] Centers for Medicare and Medicaid Services, Fact Sheet: Final Policies for the Medicare Diabetes Prevention Program Expanded Model in the Calendar Year 2018 Physician Fee Schedule Final Rule [hereinafter "Fact Sheet"], *available at* https://innovation.cms.gov/Files/fact-sheet/mdpp-cy2018fr-fs.pdf.
[2] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements, 81 Fed. Reg. 80,170 (Nov. 15, 2016) [hereinafter "2017 Final Rule"].
[3] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program, 82 Fed. Reg. 52,976 (Nov. 15, 2017) [hereinafter "2018 Final Rule"].
[4] Medicare Enrollment Application, Medicare Diabetes Prevention Program (MDPP) Suppliers, Form CMS-20134 (01/18), *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS20134.pdf
[5] CMS Transmittal 765, Medicare Diabetes Prevention Program (MDPP) Enrollment Process (CR 10356) (Eff. Jan. 1, 2018) (updating Chapter 15 of the Medicare Program Integrity Manual ("MPIM")), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R765PI.pdf.
[6] 2018 Final Rule at 53,352.
[7] *Id.* at 53,353.
[8] Medicare Diabetes Prevention Program Model (MDPP) Stakeholder Expansion Call Transcript (12/17), *available at* https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2017-12-05-Diabetes-Transcript.pdf.
[9] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill 2018, 115th Cong. (2017) *available at* https://appropriations.house.gov/uploadedfiles/23920.pdf.
[10] 2018 Final Rule at 53,235.
[11] *Id.* at 53,239.
[12] *Id.* at 53,235.
[13] *Id.* at 53,235.
[14] *Id.* at 53,248.
[15] *Id.* at 53,252.
[16] 2018 Final Rule at 53,253.
[17] *Id.* at 53,253-255.
[18] *Id.* at 53,287.

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[19] *Id*. at 53,304.
[20] Id. at 53,298-302.
[21] *Id.* To qualify for interim preliminary recognition, suppliers must meet the current 2015 CDC standards for data submission and submit twelve months of performance data on at least one cohort, including at least five participants who attended at least three sessions in the first six months and who attended sessions for at least nine months, with at least 60% of eligible participants attending at least nine sessions in the first six months and 60% attending at lease three in months seven through twelve. Id.
[22] CMS Transmittal 765, *supra* note 5 (MPIM, Ch. 15, Sec. 15.5.17).
[23] 2018 Final Rule at 53,304.
[24] 2017 Final Rule at 80,479.
[25] 2018 Final Rule at 53,309-10.
[26] *Id*. at 53,307-08.
[27] Fact Sheet, supra note 1.
[28] See 42 C.F.R. § 424.205(d).
[29] 2018 Final Rule at 53,305-06.
[30] See 42 C.F.R. § 424.205(d)(4).
[31] CMS Transmittal 765, supra note 5 (MPIM Ch. 15, Sec. 15.5.4.4).
[32] See 42 C.F.R. § 424.205(g).
[34] See id. § 424.205(b)(3).
[35] See id. § 424.210.
[36] 2018 Final Rule at 53,337.
[37] *Id.* at 53,280.
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] 2018 Final Rule at 53,281-82.
[41] *Id.* at 53,289-90.
[42] *Id.* at 53,290.

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