

**Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the
Medicare Diabetes Prevention Program Expanded Model**

March 1, 2018

Section 1115A(d)(1) of the Social Security Act (Act) authorizes the Secretary to waive certain fraud and abuse laws as may be necessary solely for purposes of carrying out testing by the Center for Medicare and Medicaid Innovation (Innovation Center) of certain innovative payment and service delivery models. Section 1115A(c) of the Act provides the Secretary with the authority to expand, through rulemaking (including implementation on a nationwide basis), the duration and scope of a model that is being tested under section 1115A(b) of the Act. The Medicare Diabetes Prevention Program (MDPP) expanded model is an expansion of the Innovation Center's Diabetes Prevention Program (DPP) model test developed under the authority of section 1115A(b). Through the MDPP expanded model, the Innovation Center continues to test a method of prevention of the onset of type 2 diabetes among Medicare beneficiaries with an indication of prediabetes (as defined by the MDPP expanded model's beneficiary eligibility criteria). Pursuant to section 1115A(d)(1) of the Act, this Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Medicare Diabetes Prevention Program Expanded Model (Notice) establishes a waiver applicable to arrangements entered into by individuals and entities participating in the MDPP expanded model.

This Notice is composed of two parts. Part I sets forth the waiver established for the MDPP expanded model and the specific conditions that must be met to qualify for the waiver. The waiver protects only arrangements that meet all of the listed conditions and applies only with respect to the specific laws cited in the waiver. Part II consists of commentary explaining the waiver requirements set forth in Part I as well as general limitations.

I. The Waiver and Applicable Requirements

The waiver protects specific beneficiary engagement incentive arrangements that are part of the MDPP expanded model and described in the regulations governing the MDPP expanded model's beneficiary engagement incentives at 42 CFR § 424.210, 42 CFR § 410.79(b), and 42 CFR § 424.205(a), as amended from time to time (MDPP BEI Regulations). Terms defined in the MDPP BEI Regulations that are used in this Notice have the meanings set forth in the MDPP BEI Regulations. These terms include but are not limited to: Coach, Core Session, Core Maintenance Session, Engagement Incentive Period, MDPP Beneficiary, MDPP Services, MDPP Services Period, MDPP Supplier, and Ongoing Maintenance Session.¹

**1. Waiver for Beneficiary Engagement Incentives Provided to MDPP Beneficiaries
(BEI Waiver)**

Pursuant to section 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (the Beneficiary Inducements Civil Monetary Penalty (CMP)) and sections 1128B(b)(1) and (2) of the Act (the Federal anti-kickback statute) are waived with respect to an arrangement pursuant to which an

¹ We have capitalized the terms defined in the MDPP BEI Regulations and used in this Notice. The capitalized terms have the same meaning as the uncapitalized terms defined in the MDPP BEI Regulations.

MDPP Supplier furnishes an item or service as an in-kind beneficiary engagement incentive to an MDPP Beneficiary if all of the following conditions are met:

- a. The item or service is furnished to the MDPP Beneficiary during his or her Engagement Incentive Period.
- b. The item or service is furnished directly to the MDPP Beneficiary by an MDPP Supplier or by an agent of the MDPP Supplier under the MDPP Supplier's direction and control, such as a Coach.
- c. There is a reasonable connection between the item or service furnished to the MDPP Beneficiary and a Centers for Disease Control and Prevention (CDC)-approved DPP curriculum furnished to the MDPP Beneficiary by the MDPP Supplier during a Core Session, Core Maintenance Session, or Ongoing Maintenance Session.
- d. The items or services—
 - i. Are preventive care items or services; or
 - ii. Advance one or more of the following clinical goals for an MDPP Beneficiary by engaging him or her in better managing his or her own health:
 - A. MDPP Beneficiary attendance at Core Sessions, Core Maintenance Sessions, or Ongoing Maintenance Sessions;
 - B. MDPP Beneficiary weight loss;
 - C. MDPP Beneficiary long-term dietary change; or
 - D. MDPP Beneficiary adherence to long-term health behavior changes.
- e. The item or service is not tied to the receipt of items or services outside of the MDPP Services.
- f. The MDPP Supplier must make available to the Office of Inspector General (OIG), upon request, all materials and records sufficient to establish whether the items and services were distributed in a manner that meets the conditions of this waiver.

For a beneficiary engagement incentive arrangement that complies with all of the preceding conditions, the waiver period will start on the first day of the applicable MDPP Beneficiary's Engagement Incentive Period and end on last day of the applicable MDPP Beneficiary's Engagement Incentive Period.

An MDPP Beneficiary may keep items received under this waiver before the end of the MDPP Beneficiary's Engagement Incentive Period if the retention of the items is in accordance with the MDPP BEI Regulations.

II. Explanation of the Beneficiary Engagement Incentives Provided to MDPP Beneficiaries (BEI Waiver) Requirements

A. Commentary Applicable to the BEI Waiver

The waiver is intended to allow MDPP Suppliers and their agents flexibility to offer and provide

beneficiary engagement incentives under the MDPP expanded model without risking sanctions under the Beneficiary Inducements CMP or Federal anti-kickback statute. The waiver set forth in this Notice has been developed in consultation with the Innovation Center, which is administering the MDPP expansion. In accordance with section 1115A(d)(1) of the Act, the Secretary has determined that this waiver is necessary to continue testing the DPP model through the MDPP model expansion. The BEI Waiver is intended to allow MDPP Suppliers to offer and provide items or services as in-kind beneficiary engagement incentives to MDPP Beneficiaries to support beneficiaries in achieving the MDPP expanded model's performance goals, including attendance and weight loss. The MDPP BEI Regulations include requirements that are designed to mitigate risks of fraud and abuse. The objective of the waiver conditions is to ensure that protected beneficiary engagement incentive arrangements are consistent with the goals of the MDPP expanded model; are subject to safeguards designed to mitigate the risk of fraud and abuse; and can be readily monitored and audited.

Under the MDPP BEI Regulations, there must be a reasonable connection between the items and services provided to the MDPP Beneficiary and a CDC-approved DPP curriculum furnished to the MDPP Beneficiary by the MDPP Supplier during a Core Session, Core Maintenance Session, or Ongoing Maintenance Session.² We have incorporated this "reasonable connection" requirement into our waiver as a condition of waiver protection.

In addition, to receive waiver protection, the items and services furnished must be preventive care items or services or must advance one or more clinical goals for an MDPP Beneficiary by engaging him or her in better managing his or her own health. Such clinical goals must be one or more of the clinical goals specified in MDPP BEI Regulations and incorporated by the waiver in condition d.ii.

We note that several of the waiver conditions incorporate requirements that appear in the MDPP BEI Regulations. We intend to interpret such waiver conditions in a manner consistent with how the Centers for Medicare & Medicaid Services (CMS) interpret the corresponding regulatory requirement. For example, any particular item or service permitted by CMS as an in-kind beneficiary engagement incentive under the MDPP expanded model would be covered by the BEI Waiver, provided all waiver conditions are met. As of the date of this Notice, CMS has stated that the following items and services could be in-kind beneficiary engagement incentives under the MDPP expanded model, provided the requirements of the MDPP BEI Regulations are satisfied: gym memberships, certain gift cards, technology in the form of applications or devices to monitor and document patient weight (e.g., digital scales), and pedometers to track physical activity.³

Nothing in this Notice prevents MDPP Suppliers or others from providing, or structuring arrangements to provide, other items or services to MDPP Beneficiaries that do not fit in this waiver if they can do so in a manner that complies with existing law.

The MDPP Supplier must make available to OIG, upon request, all materials and records sufficient to establish whether the items and services were distributed in a manner that meets the conditions of the BEI Waiver.

² 42 CFR § 424.210(b)(2).

³ See, e.g., 82 Fed. Reg. 52,976 at 53,325–53,331 (Nov. 15, 2017), available at <https://www.gpo.gov/fdsys/pkg/FR-2017-11-15/pdf/2017-23953.pdf>.

The waiver period mirrors the Engagement Incentive Period in the MDPP BEI Regulations, which we believe allows MDPP Suppliers sufficient time to terminate the furnishing of services that may extend for a fixed period of time, such as a month-long gym membership. The MDPP BEI Regulations include provisions that require the retrieval of certain items involving technology from the MDPP Beneficiary at the end of the Engagement Incentive Period; MDPP Suppliers must comply with those provisions to be protected under this waiver.

B. General Limitations

- The waiver set forth in Part I of this Notice applies to beneficiary engagement incentives that squarely meet all of the conditions pertaining to the waiver. If a beneficiary engagement incentive does not meet all of the waiver conditions, it does not qualify for waiver protection. Waivers do not provide retrospective protection; a beneficiary engagement incentive must meet all of the waiver conditions during the period for which waiver protection is sought.
- Apart from meeting applicable waiver conditions, no special action (such as submission of a separate application for a waiver) is required by parties to be covered by this waiver.
- A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (i) does not implicate the specific fraud and abuse law; (ii) implicates the law but fits within an existing exception or safe harbor; or (iii) otherwise complies with the law. Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Federal physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (sections 1128B(b)(1) and (2) of the Act), the Beneficiary Inducements CMP (section 1128A(a)(5) of the Act), or any other applicable law.
- Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other applicable Federal or State laws and regulations, including, but not limited to, any anti-fraud laws, other than those specified above. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under applicable regulations.
- We reserve the right to reconsider any waiver and, where the public interest requires, to modify, suspend, or terminate a waiver on a prospective basis with respect to some or all MDPP Suppliers, some or all of their agents, and some or all MDPP Beneficiaries. The modification, suspension, or termination of part or all of the waiver does not require advance notice. We anticipate, however, that the circumstances under which no advance notice would be provided would be limited to egregious conduct that poses an imminent risk of harm to programs or patients.

Dated: March 1, 2018

/s/

Daniel R. Levinson
Inspector General
Department of Health and Human Services