

**Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the  
Part D Enhanced Medication Therapy Management Model**

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 & Medicaid Innovation (CMMI) of certain innovative payment and service delivery models. CMMI is testing the Part D Enhanced Medication Therapy Management Model (the MTM Model). Pursuant to section 1115A(d)(1) of the Act, this Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Part D Enhanced Medication Therapy Management Model (Notice) establishes a waiver applicable to arrangements entered into by individuals and entities participating in the MTM Model.

This Notice is composed of two parts. Part I sets forth the waiver for certain Beneficiary Incentives provided by PDP Sponsors to Eligible Enrollees and the conditions that must be met to qualify for the waiver. Part II consists of commentary explaining the waiver requirements in Part I. The waiver established by this Notice applies only to the MTM Model, and is not applicable outside of the MTM Model.

**I.       The Waiver and Applicable Requirements**

As used in this Notice, Approved Proposal, Beneficiary Incentives, Eligible Enrollee, Enhanced MTM, Part D Contract, and PDP Sponsor have the meanings set forth in the Contract Addendum.

Contract Addendum refers to the Addendum to Contract for the Operation of a Voluntary Medicare Prescription Drug Plan Pursuant to Section 1115A of the Social Security Act for Participation in the Part D Enhanced Medication Therapy Management Model Test, as amended from time to time.

Pursuant to section 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (the Beneficiary Inducements CMP) and sections 1128B(b)(1) and (2) of the Act (the Federal anti-kickback statute) are waived with respect to Beneficiary Incentives provided by the PDP Sponsor to Eligible Enrollees if all of the following conditions are met:

- A.     The PDP Sponsor has entered into a Contract Addendum with the Centers for Medicare & Medicaid Services and has an Approved Proposal to provide Enhanced MTM.
- B.     There is a reasonable connection between the Beneficiary Incentive and (i) effective medication usage by the Eligible Enrollee or (ii) the Eligible Enrollee's participation in Enhanced MTM.
- C.     The Beneficiary Incentive is of the type detailed in the Approved Proposal, and the protocol contained in the Approved Proposal for offering or terminating each Beneficiary Incentive is followed, as applicable.

D. The PDP Sponsor complies with the record identification and maintenance requirements in Article VI.D.6 of the Contract Addendum for each Beneficiary Incentive provided.

E. The Contract Addendum does not provide that this Notice is inapplicable.

For Beneficiary Incentives that meet all of the preceding conditions, the waiver period will:

- (i) start on the Effective Date of the Contract Addendum, and
- (ii) end on the earlier of: (a) the expiration of the term of the Contract Addendum, including any renewals thereof, or (b) the date on which the Contract Addendum has been terminated.

An Eligible Enrollee may keep items received under this waiver before the Contract Addendum expired or terminated and may receive the remainder of any service covered by this waiver initiated before the Contract Addendum expired or terminated.

## II. Explanation of Waiver Requirements

The waiver in this Notice applies only with respect to PDP Sponsors that are participating in the MTM Model. This Notice has no applicability to other programs or arrangements, even those that may bear some similarity to the arrangements described in this Notice.

The waiver set forth in Part I of this Notice applies to Beneficiary Incentives that squarely meet all of the conditions of the waiver. A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) does not implicate the specific fraud and abuse law; (2) implicates the law, but fits within an existing exception or safe harbor; or (3) 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 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. Failure to fit in a waiver is not, in and of itself, a violation of the laws.

The waiver in this Notice has been developed in consultation with CMMI, which is administering and testing the MTM Model. Section 1115A(d)(1) of the Act states the legal standard that has guided development of the waiver. Under this standard, the Federal anti-kickback statute and the Beneficiary Inducements CMP may be waived “as may be necessary solely for purposes of carrying out the testing” of the MTM Model. CMMI has determined that the Beneficiary Incentives covered by this waiver are necessary to carry out the testing of the MTM Model.

The design of the waiver is premised on the expectation that the requirements of the Contract Addendum will mitigate risks of fraud and abuse. The waiver does not provide retrospective protection; an arrangement must meet all of the waiver conditions during the period for which waiver protection is sought.

The waiver in this Notice applies uniformly to arrangements entered into by each PDP Sponsor participating in the MTM Model. 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 a waiver. Parties need not apply for an individualized waiver.

Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other Federal or State laws and regulations. Moreover, nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations a PDP Sponsor may have under its Contract Addendum or the Part D Contract.

We reserve the right to reconsider this waiver and, where the public interest requires, to modify or terminate the waiver on a prospective basis. 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.

This waiver does not waive any requirement or prohibition set forth in the Contract Addendum or the Part D Contract; it waives only the Beneficiary Inducements CMP and the Federal anti-kickback statute with respect to Beneficiary Incentives permitted (or not prohibited) by the Contract Addendum.

The Beneficiary Incentive must be reasonably connected to (i) effective medication usage by the Eligible Enrollee or (ii) the Eligible Enrollee's participation in Enhanced MTM. For example, technology in the form of smart pillboxes could meet these requirements, but a device that solely plays games would not. Similarly, transportation to pick up prescriptions could be protected, but transportation to entertainment or recreational events would not be.

This waiver does not protect waivers of cost-sharing amounts (for example, copayments and deductibles) by a contract health care provider (for example, a network pharmacy) and any such practices must continue to comply with Federal fraud and abuse laws.<sup>1</sup> We note that Article VI.C of the Contract Addendum addresses a PDP Sponsor's reduction of the obligation to pay cost-sharing amounts as Enhanced MTM in a manner that does not require a waiver of the Federal anti-kickback statute or the Beneficiary Inducements CMP.

The waiver protects Beneficiary Incentives provided to Eligible Enrollees by a PDP Sponsor pursuant to an Approved Proposal to provide Enhanced MTM. Nothing in this Notice prevents PDP Sponsors from providing, or structuring arrangements to provide, other items or services to Eligible Enrollees if they can do so in a manner that complies with existing law and, as applicable, the Contract Addendum and the Part D Contract.

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<sup>1</sup> For additional guidance, see, e.g., OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (August 2002).

This waiver does not include a “tail” period after the Contract Addendum is terminated or expires. However, we have included provisions to ensure continuity of care for Eligible Enrollees who may be receiving items or services at the time the Contract Addendum is terminated or expires.

**Dated:** [June 2, 2016]

/Daniel R. Levinson/

Daniel R. Levinson

Inspector General

Department of Health and Human Services