

Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Part D Payment Modernization 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 (Innovation Center) of certain innovative payment and service delivery models. The Innovation Center is testing the Part D Payment Modernization Model. The Part D Payment Modernization Model tests certain innovations in the Medicare Part D program starting with the 2020 plan year. A Medicare Part D Prescription Drug Plan Sponsor that wishes to participate in the Part D Payment Modernization Model must annually execute a contract to operate a Medicare Part D prescription drug plan with the Centers for Medicare & Medicaid Services (CMS) that contains an addendum setting forth the terms of the Part D Payment Modernization Model, which may be amended from time to time (Contract Addendum). 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 Payment Modernization Model (Notice) establishes a waiver applicable to arrangements entered into by individuals and entities participating in the Part D Payment Modernization Model.

This Notice is composed of two parts. Part I sets forth the waiver for certain rewards and incentives provided by Medicare Part D Prescription Drug Plan Sponsors to Targeted Enrollees and the specific conditions that must be met to qualify for the waiver. The waiver protects specific beneficiary rewards and incentives that are part of the Part D Payment Modernization Model and described in the Contract Addendum. Part II consists of commentary explaining the waiver requirements set forth in Part I as well as general limitations. The waiver established by this Notice applies only to the Part D Payment Modernization Model and is not applicable outside of the Part D Payment Modernization Model.

I. The Waiver and Applicable Requirements

Terms defined in the Contract Addendum that are used in this Notice have the meanings set forth in the Contract Addendum. These terms include, but are not limited to, the following: Targeted Enrollee, Part D Sponsor, and Part D RI Program.

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 rewards and incentives provided by the Part D Sponsor to Targeted Enrollees pursuant to a Part D RI Program provided that all of the following conditions are met:

- A. The Part D Sponsor has entered into a Contract Addendum with CMS for the plan year in which the rewards and incentives will be furnished.
- B. The Part D Sponsor has a proposal approved by the Innovation Center for the plan year to provide the rewards and incentives pursuant to a Part D RI Program.
- C. There is a reasonable connection between the reward and incentive and the Targeted Enrollee's healthcare needs.
- D. The rewards and incentives are of the type detailed in the proposal approved by the Innovation Center to provide rewards and incentives pursuant to a Part D RI Program and are offered and terminated, as applicable, in compliance with the proposal approved by the Innovation Center to provide rewards and incentives pursuant to a Part D RI Program.
- E. The rewards and incentives are not tied to the receipt of items or services not covered by the Part D Sponsor for the Targeted Enrollees.
- F. The Part D Sponsor must make available to the Department of Health and Human Services, Office of Inspector General (OIG), upon request, materials and records sufficient to establish whether the rewards and incentives were distributed in a manner that meets the conditions of this waiver.
- G. The Part D Sponsor shall not receive or use funding, in-kind resources, or any kind of remuneration provided directly or indirectly by a drug manufacturer or a pharmacy (including any entity that owns or operates pharmacies) for rewards and incentives provided by the Part D Sponsor to Targeted Enrollees pursuant to a Part D RI Program.
- H. The Contract Addendum does not provide that this Notice is inapplicable.

For rewards and incentives that meet all of the preceding conditions, the waiver period will:

- (i) start on the date of this Notice, and
- (ii) end on the earlier of: (a) the expiration of the term of the Contract Addendum for the plan year during which the Part D Sponsor has a proposal approved by the Innovation Center to provide rewards and incentives pursuant to a Part D RI Program; or (b) the date on which the Contract Addendum has been terminated.

A Targeted 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 time period for the waiver in this Notice extends to each plan year that a Part D Sponsor: (1) participates in the Part D Payment Modernization Model, (2) enters into a Contract Addendum with CMS for the plan year in which the rewards and incentives will be furnished, and (3) has a proposal approved by the Innovation Center to provide rewards and incentives pursuant to a Part D RI Program. Protection under this waiver is afforded to Part D Sponsors only during the plan year in which all waiver conditions, including these three conditions, are met. For example, if a Part D Sponsor enters into a Contract Addendum and meets all waiver conditions for a plan year but does not enter into a Contract Addendum for a subsequent plan year, then waiver protection in this Notice does not extend to the subsequent plan year. 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 in this Notice has been developed in consultation with the Innovation Center, which is administering and testing the Part D Payment Modernization 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 Part D Payment Modernization Model. The Innovation Center has determined that the rewards and incentives covered by this waiver are necessary to carry out the testing of the Part D Payment Modernization Model.

The design of the waiver is premised on the expectation that the requirements of the Contract Addendum, and compliance with those requirements by Part D Sponsor, will mitigate risks of fraud and abuse.

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

Under the Contract Addendum, the Part D Sponsor shall not receive or use funding, in-kind resources, or any kind of remuneration provided directly or indirectly by a drug manufacturer or a pharmacy (including any entity that owns or operates pharmacies) for rewards and incentives provided by the Part D Sponsor to Targeted Enrollees pursuant to a Part D RI Program.

The waiver protects rewards and incentives provided to Targeted Enrollees by a Part D Sponsor pursuant to a proposal approved by the Innovation Center to provide rewards and incentives pursuant to a Part D RI Program. We note that several of the waiver conditions incorporate requirements that appear in the Contract Addendum. We intend to interpret such waiver conditions in a manner consistent with how CMS interprets the corresponding model requirement. Similarly, we intend that the waiver condition requiring a reasonable connection between the reward and incentive and the Targeted Enrollee's healthcare needs would be met where a reward or incentive advances one or more of the goals stated in the Contract Addendum. Arrangements entered into as part of the Part D Payment Modernization Model must meet all of the conditions of the applicable waiver in this Notice. We expect individuals and entities to maintain sufficient materials and records to demonstrate compliance with the waiver conditions. We are not setting particular parameters regarding the materials and records that must be maintained to allow individuals and entities flexibility in demonstrating waiver compliance to OIG and CMS. Nothing in this Notice prevents Part D Sponsors from providing, or structuring arrangements to provide, other rewards and incentives to Targeted Enrollees if they can do so in a manner that complies with existing law and, as applicable, the Contract Addendum.

The Part D Sponsor must make available to OIG, upon request, all materials and records sufficient to establish whether the rewards and incentives were distributed in a manner that meets the conditions of this waiver.

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 Targeted Enrollees who may be receiving items or services at the time the Contract Addendum is terminated or expires.

General Limitations

- The waiver set forth in Part I of this Notice applies to arrangements or rewards and incentives that squarely meet all of the conditions in the waiver. If an arrangement or rewards and incentives do not meet all of the waiver conditions, they do not qualify for waiver protection.
- The waiver does not provide retrospective protection; an arrangement or reward and 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 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 the Contract Addendum.
- We reserve the right to reconsider any waiver and, where the public interest requires, to modify or terminate a 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.

Dated: [November 15, 2019]

/Joanne M. Chiedi/

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