

**Notice of Amended Waiver of Certain Fraud and Abuse Laws in Connection With
the Medicare Advantage Value-Based Insurance Design Model
August 18, 2020**

Introduction

This Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Medicare Advantage Value-Based Insurance Design Model (Notice) is being issued as a result of certain programmatic changes being made by the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) to the Medicare Advantage Value-Based Insurance Design Model (Model) for calendar year 2021. Accordingly, effective January 1, 2021, this Notice amends and restates the Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Value-Based Insurance Design Model dated November 15, 2019 (2019 Notice).

This Notice includes two waivers—the waiver for certain rewards and incentives issued in the 2019 Notice without substantive changes or limitations and a new waiver for the provision of cash or monetary rebates to Model enrollees in defined circumstances.

Background

Section 1115A(d)(1) of the Social Security Act (Act) authorizes the Secretary to waive defined fraud and abuse laws as may be necessary solely for purposes of carrying out testing by the Innovation Center of certain innovative payment and service delivery models. Under this Model, which began in the 2017 Plan Year, the Innovation Center is testing the provision of certain flexibilities to Medicare Advantage (MA) Organizations and certain modifications to MA plan benefit design, among other changes. An MA Organization that wishes to participate in the Model must annually execute a Medicare managed care contract with CMS that contains an addendum setting forth the terms of the Model, which may be amended from time to time. Pursuant to section 1115A(d)(1) of the Act, this Notice establishes two waivers applicable to certain mandatory supplemental benefits and rewards and incentives offered by MA Organizations that are approved to participate in those components of the Model.

This Notice is composed of two parts. Part I sets forth the waivers established for the Model and the conditions that must be met to qualify for the waiver. The waivers protect specified rewards and incentives and the provision of cash or monetary rebates as a mandatory supplemental benefit offered to beneficiaries under the Model and described in the Addendum to Medicare Managed Care Contract for Participation in the Medicare Advantage Value-Based Insurance Design VBID Model, as amended from time to time (Contract Addendum). Each waiver protects only arrangements that meet all 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. The waivers established by this Notice apply only to the Model and are not applicable outside of the 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: Approved Proposal, Cash or Monetary Rebates, Cash or Monetary Rebates Component, MA Organization, Plan Year, Rewards and Incentives Program, Targeted Enrollee, and VBID PBP.

A. Rewards and Incentives 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 MA Organization to Targeted Enrollees pursuant to a Rewards and Incentives Program provided that all the following conditions are met:

- A. The MA Organization has entered into a Contract Addendum with CMS for the Plan Year in which the rewards and incentives will be furnished.
- B. The MA Organization has an Approved Proposal for the Plan Year to provide the rewards and incentives pursuant to a Rewards and Incentives Program.
- C. There is a reasonable connection between the reward and incentive and the Targeted Enrollee's health care needs.
- D. The rewards and incentives are of the type detailed in the Approved Proposal pursuant to a Rewards and Incentives Program and are offered and terminated, as applicable, in compliance with the Approved Proposal and Contract Addendum.
- E. The rewards and incentives are not tied to the receipt of items or services not covered by the MA Organization for the Targeted Enrollees.
- F. The MA Organization 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 MA Organization 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 MA Organization to Targeted Enrollees pursuant to a Rewards and Incentives Program.
- H. The Contract Addendum does not provide that this Notice is inapplicable.

For rewards and incentives that meet all 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 MA Organization has an Approved Proposal to provide rewards and incentives pursuant to a Rewards and Incentives 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.

B. Cash or Monetary Rebates

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 Cash or Monetary Rebates provided by the MA Organization to all enrollees in a VBID PBP that has been approved by CMS to provide Cash or Monetary Rebates, provided that all the following conditions are met:

- A. The MA Organization has entered into a Contract Addendum with CMS for the Plan Year in which the Cash or Monetary Rebates will be furnished.
- B. The MA Organization has an Approved Proposal for the Plan Year to provide the Cash or Monetary Rebates to all enrollees in the VBID PBP(s) that are approved to provide the Cash or Monetary Rebates, and shall offer and terminate for all enrollees, as applicable, the Cash or Monetary Rebates in compliance with such Approved Proposal and Contract Addendum.
- C. The MA Organization shall not selectively market, offer, or terminate the Cash or Monetary Rebates to enrollees based on enrollees' health status or risk profile or in a discriminatory manner.

- D. The MA Organization shall not use the Cash or Monetary Rebates to encourage enrollment in a VBID PBP or any other plan offered by the MA Organization.
- E. The MA Organization shall not use the Cash or Monetary Rebates to incentivize rationing of care or the avoidance of medically necessary care.
- F. The MA Organization shall not use the Cash or Monetary Rebates as an inducement to generate business for, or tie the Cash or Monetary Rebates to an enrollee's receipt of, items or services not covered by the MA Organization.
- G. The MA Organization shall furnish the Cash or Monetary Rebates to enrollees via check, debit card, or other form approved by the Innovation Center, provided, in all instances, the MA Organization maintains records documenting: (1) the identity of each enrollee who received Cash or Monetary Rebates, (2) the nature and amount of the Cash or Monetary Rebates received by the enrollee, (3) the date that the enrollee received the Cash or Monetary Rebates, and (4) the per unit and total amount of Cash or Monetary Rebates received by the enrollee.
- H. The MA Organization shall provide Cash or Monetary Rebates only to enrollees: (1) during the Plan Year, (2) in accordance with the annual, per enrollee limit set forth in the Approved Proposal, and (3) in an amount that is equal to or less than the amount of beneficiary rebates paid to the MA Organization for the applicable VBID PBP under section 1854(b) of the Act and 42 C.F.R. § 422.266.
- I. The MA Organization shall not change the amount, timing, frequency, manner or form of the Cash or Monetary Rebates without advance written approval from the Innovation Center.
- J. The MA Organization 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 Cash or Monetary Rebates were distributed in a manner that meets the conditions of this waiver.
- K. The Contract Addendum does not provide that this Notice is inapplicable.

For Cash or Monetary Rebates that meet all 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 MA Organization has an Approved Proposal to provide Cash or Monetary Rebates, or (b) the date on which the Contract Addendum has been terminated.

II. Explanation of Waiver Requirements

A. Rewards and Incentives Program

The time period for the waiver in this Notice starts on the date of this Notice and extends to each Plan Year that an MA Organization: (1) participates in the 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 an Approved Proposal to provide rewards and incentives pursuant to a Rewards and Incentives Program. Protection under this waiver is afforded to MA Organizations only during the Plan Year in which all waiver conditions, including these three conditions are met. For example, if an MA Organization 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.

Any rewards and incentives provided by an MA Organization to Targeted Enrollees pursuant to a Rewards and Incentives Program on or after the date of this Notice must meet all the conditions of the applicable waiver in this Notice to receive waiver protection. Any rewards and incentives provided by an MA Organization to Targeted Enrollees pursuant to a Rewards and Incentives Program on or after November 15, 2019, that satisfies all the conditions of the Rewards and Incentives Program waiver in the 2019 Notice will also meet the conditions of the Rewards and Incentives Program waiver as set forth in this Notice. Such rewards and incentives do not require restructuring or modifications to receive continued Rewards and Incentives Program waiver protection under this Notice. We intend for the Rewards and Incentives Program waiver protection to be seamless and for the Rewards and Incentives Program waiver set forth in Part I.A. of this Notice to function as an effective continuation of the Rewards and Incentives Program waiver, as set forth in the 2019 Notice.

The waiver in this Notice has been developed in consultation with the Innovation Center, which is administering and testing the 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 Model. The Innovation Center has determined that the rewards and incentives covered by this waiver are necessary to carry out the testing of the Model.

The design of the waiver is premised on the expectation that the requirements of the Contract Addendum, and compliance with those requirements by MA Organizations, 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 by the Contract Addendum.

Under the Contract Addendum, the MA Organization 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 MA Organization to Targeted Enrollees pursuant to a Rewards and Incentives Program.

This waiver does not protect waivers of cost-sharing amounts (*e.g.*, copayments and deductibles) by a provider or supplier that contracts with an MA Organization (*e.g.*, a network pharmacy), and any such practices must continue to comply with all applicable Federal fraud and abuse laws.¹ As of the date of this Notice, we note, however, that Article 3.D of the Contract Addendum addresses an MA Organization’s reduction of the obligation to pay cost-sharing amounts as an additional supplemental benefit in a manner that does not require a waiver of the Federal anti-kickback statute or the Beneficiary Inducements CMP.²

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

² *See* 42 CFR 1001.952(l) (anti-kickback statute safe harbor relating to additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan). *See also* 1128A(i)(6)(B) of the Act (remuneration protected by an anti-kickback

The waiver protects rewards and incentives provided to Targeted Enrollees by an MA Organization pursuant to an Approved Proposal to provide rewards and incentives pursuant to a Rewards and Incentives Program. We note that several of the waiver conditions incorporate requirements that appear in the Contract Addendum. We will interpret such waiver conditions in a manner consistent with how CMS interprets the corresponding Model requirement. Similarly, the waiver condition requiring a reasonable connection between the reward and incentive and the Targeted Enrollee's health care 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 Model must meet all 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 on 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 MA Organizations 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 MA Organization 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.

B. Cash or Monetary Rebates

The time period for the waiver in this Notice starts on the date of this Notice and extends to each Plan Year that an MA Organization: (1) participates in the Model, (2) enters into a Contract Addendum with CMS for the Plan Year in which the Cash or Monetary Rebates will be furnished, and (3) has a proposal, for specific VBID PBPs, approved by the Innovation Center to provide Cash or Monetary Rebates. Protection under this waiver is afforded to MA Organizations offering VBID PBPs approved by the Innovation Center to offer Cash or Monetary Rebates only during the Plan Year in which all waiver

safe harbor is excepted from the definition of remuneration under the Beneficiary Inducement CMP).

conditions, including these three conditions are met. For example, if an MA Organization 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, arrangements, or MA PBPs not approved to participate in the Cash or Monetary Rebates Component of the Model, 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 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 Model. The Innovation Center has determined that the Cash or Monetary Rebates covered by this waiver are necessary to carry out the testing of the Model. The design of the waiver is premised on the expectation that the requirements of the Contract Addendum, and compliance with those requirements by MA Organizations, will mitigate risks of fraud and abuse.

The waiver protects Cash or Monetary Rebates provided by an MA Organization to all enrollees in an eligible VBID PBP, in compliance with the Contract Addendum and Approved Proposal. Arrangements entered into as part of the Model must meet all the conditions of the applicable waiver in this Notice. 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 Cash or Monetary Rebates permitted by the Contract Addendum.

We note that several of the waiver conditions incorporate requirements that appear in the Contract Addendum. For example, under the Contract Addendum, the MA Organization cannot selectively market the Cash or Monetary Rebates to enrollees based on health status or risk profile or in a discriminatory manner.³ Additionally, the MA Organization

³ With regard to the anti-discrimination requirement, we note that the Contract Addendum states the MA Organization must provide and market the Cash or Monetary Rebates in accordance with the anti-discrimination provisions of Section 1852(b)(1) of the Act, 42 CFR § 422.110, all other applicable Federal and State anti-discrimination laws, Article 3 of the Contract Addendum, and the VBID Model Communications and Marketing Guidelines.

cannot use the Cash or Monetary Rebates to incentivize rationing of care or the avoidance of medically necessary care, or to encourage enrollment⁴ in the VBID PBP or any other plan offered by the MA Organization. We will interpret such waiver conditions in a manner consistent with how CMS interprets the corresponding model requirement.

We expect individuals and entities to maintain sufficient materials and records to demonstrate compliance with the waiver conditions. The MA Organization must make available to OIG, upon request, all materials and records sufficient to establish whether the Cash or Monetary Rebates were distributed in a manner that meets the conditions of this waiver. We are not setting particular parameters on 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 MA Organizations from providing, or structuring arrangements to provide, Cash or Monetary Rebates if they can do so in a manner that complies with existing law and, as applicable, the Contract Addendum.

This waiver does not include a “tail” period after the Contract Addendum is terminated or expires, so all Cash or Monetary Rebates must be distributed to the enrollees in the applicable VBID PBP before the Contract Addendum for the applicable year is terminated or expires.

General Limitations

- The waivers set forth in Part I of this Notice apply to the Cash and Monetary Rebates and the rewards and incentives offered pursuant to a Rewards and Incentives Program that squarely meet all the conditions in the waiver. If either does not meet all the applicable waiver conditions, it does not qualify for waiver protection.
- The waivers do not provide retrospective protection; the Cash or Monetary Rebates or rewards and incentives offered pursuant to a Rewards and Incentive Program must meet all the applicable 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

⁴ Notwithstanding the foregoing, marketing of the Cash and Monetary Rebates is permitted, as long as it complies with the terms of the Contract Addendum and the Approved Proposal.

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: August 18, 2020

/s/ Christi A. Grimm

Christi A. Grimm
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Office of Inspector General
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