

Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Primary Care First Component of the Primary Care First 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 and Medicaid Innovation (Innovation Center) of certain innovative payment and service delivery models. In accordance with section 1115A(b) of the Act, the Innovation Center is testing the Primary Care First Model (Model), a payment model that seeks to support the delivery of advanced primary care. The Model has two components: the Primary Care First Component (PCF Component of the Model) and the Seriously Ill Patient Component. Pursuant to section 1115A(d)(1) of the Act, this Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Primary Care First Component of the Primary Care First Model (Notice) establishes two waivers applicable to arrangements entered into by specified individuals and entities participating in the PCF Component of the Model.

This Notice has two parts. Part I sets forth the waivers established for the PCF Component of the Model and the conditions that must be met to qualify for each waiver. The waivers protect certain in-kind incentives and Cost Sharing Support arrangements. 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 requirements of the two waivers set forth in Part I, as well as general limitations. The waivers established by this Notice apply only to the PCF Component of the Model and are not applicable to the Seriously Ill Patient Component of the Model.

I. The Waiver and Applicable Requirements

Terms defined in the Participation Agreement that are used in this Notice have the meanings set forth in the Participation Agreement, as amended from time to time. These terms include, but are not limited to, the following: Cost Sharing Support, Face-to-Face Visit, Implementation Period, Model Performance Period, Participation Agreement, PCF Beneficiary, PCF Component, PCF Practice, PCF Practitioner.

A. In-Kind Incentive 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 the furnishing of in-kind items or services, provided all of the following conditions are met:

1. The PCF Practice has entered into a Participation Agreement with the Centers for Medicare & Medicaid Services (CMS) for the PCF Component of the Model.
2. The item or service is in-kind and is furnished by the PCF Practice or its PCF Practitioners to a PCF Beneficiary during the Model Performance Period (“In-Kind Incentive”).

3. There is a direct connection between the In-Kind Incentive and the medical care of the PCF Beneficiary.
4. The In-Kind Incentive:
 - i. Is a preventive care item or service; or
 - ii. Advances a clinical goal for the PCF Beneficiary, including: (a) adherence to a treatment regime; (b) adherence to a drug regime; (c) adherence to a follow-up care plan; or (d) management of a chronic disease or condition.
5. The offer or provision of an In-Kind Incentive is not tied to the receipt of items or services reimbursable by a Federal health care program outside of the PCF Component of the Model.
6. The In-Kind Incentive is not a Medicare-covered item or service for the PCF Beneficiary on the date the In-Kind Incentive is furnished to that PCF Beneficiary.
7. The cost of providing the In-Kind Incentive is not shifted to any Federal health care program.
8. The availability of an In-Kind Incentive is not advertised or promoted. Notwithstanding the foregoing, the PCF Practice may inform a PCF Beneficiary, at the time such PCF Beneficiary could reasonably benefit, that an In-Kind Incentive may be available.
9. The PCF Practice must make available to OIG, upon request, materials and records sufficient to establish whether the In-Kind Incentives were distributed in a manner that meets the conditions of this waiver.
10. The Participation Agreement does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the date of this Notice, and end on the earlier of: (i) the expiration of the Model Performance Period, including any renewals thereof; or (ii) the date on which the Participation Agreement has been terminated.

A PCF Beneficiary may keep items received under this waiver and may receive the remainder of any service covered by this waiver, provided: (i) all of the preceding waiver conditions are met; and (ii) the item was received, or the service was initiated, on the earlier of the expiration date of the Model Performance Period (and any renewals thereof) or the termination date of the Participation Agreement.

B. Cost Sharing Support 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 the provision of Cost Sharing Support, provided all of the following conditions are met:

1. The PCF Practice has entered into a Participation Agreement with CMS for the PCF Component of the Model.
2. The Cost Sharing Support is furnished by the PCF Practice to a PCF Beneficiary for one or more Face-to-Face Visits during the Model Performance Period.
3. The PCF Practice has developed, and CMS has not rejected, an implementation plan for the provision of Cost Sharing Support to PCF Beneficiaries.
4. The PCF Beneficiary receiving Cost Sharing Support meets the following minimum eligibility criteria:
 - i. The PCF Beneficiary does not have a Medigap supplemental plan that covers all of the relevant cost sharing amount for Face-to-Face Visits; and
 - ii. The PCF Beneficiary is experiencing financial hardship; or
 - iii. The PCF Beneficiary has a high disease burden, and in the reasonable medical opinion of a PCF Practitioner, one or more medically necessary Face-to-Face Visits may avoid hospitalization of the PCF Beneficiary or otherwise facilitate a reduction in Medicare expenditures for the PCF Beneficiary; or
 - iv. The PCF Beneficiary has been recently hospitalized or visited the emergency department.
5. The offer or provision of Cost Sharing Support is not tied to the receipt of items or services reimbursable by a Federal health care program outside of the PCF Component of the Model.
6. The cost of providing the Cost Sharing Support is not shifted to any Federal health care program.
7. The availability of Cost Sharing Support is not advertised or promoted. Notwithstanding the foregoing, the PCF Practice may inform a PCF Beneficiary, at the time such PCF Beneficiary could reasonably benefit, that Cost Sharing Support may be available.
8. The PCF Practice must make available to OIG, upon request, materials and records sufficient to establish that its provision of Cost Sharing Support met the conditions of this waiver.
9. The Participation Agreement does not provide that this waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver will start on the first day of the Model Performance Period and end on the earlier of the: (i) expiration of the Model Performance Period, including any renewals thereof; or (ii) the termination date of the Participation Agreement.

II. Explanation of Waiver Requirements

The In-Kind Incentive and Cost Sharing Support waivers set forth in this Notice have been developed in consultation with the Innovation Center, which is administering and testing the PCF Component of the Model. In accordance with Section 1115A(d)(1) of the Act, the Secretary has determined that these waivers are necessary to carry out the testing of the PCF Component of the Model. The design and intent of these waivers is to mitigate risks of fraud and abuse.

Arrangements must meet all the conditions of the applicable waiver in this Notice to receive waiver protection. The waivers do not waive any requirement or prohibition set forth in the Participation Agreement; they waive only the Federal anti-kickback statute and the Beneficiary Inducements CMP with respect to an arrangement permitted by both the Participation Agreement and either the In-Kind Incentive waiver or Cost Sharing Support waiver.

Each waiver incorporates a number of Participation Agreement requirements related to the provision of In-Kind Incentives or Cost Sharing Support, as applicable. We will interpret these waiver conditions in a manner consistent with how CMS interprets the corresponding Participation Agreement requirement.

Nothing in this Notice prevents PCF Practices or PCF Practitioners from providing, or structuring arrangements to provide, other items or services to PCF Beneficiaries if they can do so in a manner that complies with existing law and, as applicable, the Participation Agreement.

A. In-Kind Incentive Waiver

This waiver protects the provision of In-Kind Incentives, *i.e.*, in-kind items or services furnished by a PCF Practice or its PCF Practitioners to PCF Beneficiaries during the Model Performance Period. In-Kind Incentives may not be provided during the Implementation Period. Moreover, In-Kind Incentives may not be cash or cash equivalents, such as a debit card or check.

The waiver requires that there be a direct connection between the In-Kind Incentive provided to the PCF Beneficiary and the medical care of the PCF Beneficiary. In addition, to receive waiver protection, the In-Kind Incentive must be a preventive care item or service, or must advance one or more clinical goals for the PCF Beneficiary. Such clinical goals may include, but are not limited to, adherence to a treatment regime, adherence to a drug regime, adherence to a followup care plan, or management of a chronic disease or condition.

The waiver further requires that the offer or provision of an In-Kind Incentive is not: (i) tied to the receipt of items or services reimbursable by a Federal health care program outside of the PCF Component of the Model; or (ii) advertised or promoted; however, a PCF Practice may inform a PCF Beneficiary, at the time such PCF Beneficiary could reasonably benefit, that an In-Kind Incentive may be available, *e.g.*, during a Face-to-Face Visit, in an effort to promote greater medication adherence. We note that the scope of “items or services reimbursable by a Federal health care program” could include, for example, items or services reimbursable by Medicare, Medicaid, a CMS demonstration program, or another Innovation Center model.

A Medicare-covered item or service (if the item or service is covered by Medicare on the date furnished to the PCF Beneficiary) would not qualify as an In-Kind Incentive. In addition, the parties to the PCF Component of the Model may not shift the cost of furnishing an In-Kind Incentive to a Federal health care program. In tandem, these waiver requirements are intended to result in the PCF Practice assuming responsibility for all costs related to the provision of In-Kind Incentives.

The PCF Practice must make available to OIG, upon request, all materials and records sufficient to establish whether the In-Kind Incentives were distributed in a manner that meets the conditions of this waiver. We expect the PCF Practice to maintain sufficient materials and records to demonstrate compliance with the waiver conditions and are not setting particular requirements regarding the manner and form of these materials and records to allow the PCF Practice flexibility in demonstrating waiver compliance to OIG and CMS.

Where all the conditions of the In-Kind Incentive waiver are met, the waiver will start on the first day of the Model Performance Period and end on the earlier of the: (i) expiration of the Model Performance Period, including any renewals thereof; or (ii) the termination date of the Participation Agreement. While this waiver does not include a “tail” period, we have included provisions to ensure continuity of care for PCF Beneficiaries who may be receiving an In-Kind Incentive upon the expiration of the Model Performance Period or termination of the Participation Agreement, as may be applicable.

B. Cost Sharing Support Waiver

This waiver protects the provision of Cost Sharing Support from a PCF Practice to certain PCF Beneficiaries. Cost Sharing Support, as defined in the Participation Agreement, constitutes reduced or eliminated cost sharing for medically necessary Face-to-Face Visits¹ furnished by the PCF Practice under the PCF Component of the Model. Cost Sharing Support may only be furnished by a PCF Practice to a PCF Beneficiary during the Model Performance Period. Cost Sharing Support may not be provided during the Implementation Period.

For a PCF Practice to receive protection under the Cost Sharing Support waiver, it must meet specified threshold requirements, in particular, development of a Cost Sharing Support implementation plan that CMS has not rejected. As set forth in the Participation Agreement, a Cost Sharing Support implementation plan will be “deemed” approved by CMS so long as CMS does not reject the PCF Practice’s plan in the 30 days following receipt. The Participation Agreement permits CMS to reject an implementation plan after it has been deemed approved, but such rejection would not be effective retroactively. Thus, if CMS rejects an implementation plan after it has been deemed approved, this waiver will not protect any Cost Sharing Support furnished by the PCF Practice after the effective date of the implementation plan rejection.

¹ This waiver does not address cost sharing obligations for all items and services furnished under the Model; rather, it applies only to Cost Sharing Support for Face-to-Face visits, as defined by the Participation Agreement. Cost sharing assistance for other items and services is not covered by this waiver, even if those items and services are furnished under the Model.

Any PCF Beneficiary receiving Cost Sharing Support must meet a minimum set of eligibility criteria, as set forth in both this waiver and the Participation Agreement. Specifically, a PCF Beneficiary must not have a Medigap supplemental plan that covers all of the relevant cost sharing amount for Face-to-Face Visits and the PCF Beneficiary must have a: (i) financial hardship; (ii) high disease burden, for which, in the reasonable medical opinion of a PCF Practitioner, medically necessary Face-to-Face Visits may avoid future hospitalizations or otherwise facilitate a reduction in Medicare expenditures for the PCF Beneficiary; or (iii) recent hospitalization or visit to the emergency department.

The waiver further provides that the cost of providing the Cost Sharing Support may not be shifted to any Federal health care program. The term “Federal health care program” could include, for example, items or services reimbursable by Medicare, Medicaid, a CMS demonstration program, or another Innovation Center model. It is our intent that this prohibition would, as a practical matter, result in the PCF Practice assuming responsibility for all costs related to provision of Cost Sharing Support.

Moreover, the offer or provision of the Cost Sharing Support may not be tied to the receipt of items or services reimbursable by a Federal health care program outside of the PCF Component of the Model. In addition, the offer or provision of Cost Sharing Support may not be advertised or promoted. However, a PCF Practice may inform a PCF Beneficiary about the Cost Sharing Support benefit at the time such PCF Beneficiary could reasonably benefit from receipt of Cost Sharing Support, *e.g.*, during a Face-to-Face Visit at which time the PCF Practitioner becomes aware that the PCF Beneficiary is experiencing financial hardship.

The PCF Practice must make available to OIG, upon request, all materials and records sufficient to establish whether Cost Sharing Support was furnished in a manner that meets the conditions of this waiver. We expect the PCF Practice to maintain sufficient materials and records to demonstrate compliance with the waiver conditions, and are not setting particular requirements regarding the manner and form of these materials and records that must be maintained to allow the PCF Practice flexibility in demonstrating waiver compliance to OIG and CMS.

Where all the conditions of the Cost Sharing Support waiver are met, the waiver will start on the first day of the Model Performance Period and end on the earlier of the: (i) expiration of the Model Performance Period; or (ii) the termination date of the Participation Agreement.

III. General Limitations

- The waivers set forth in Part I of this Notice apply to the provision of In-Kind Incentives or Cost Sharing Support that squarely meet all the conditions pertaining in the applicable waiver. If the In-Kind Incentives or Cost Sharing Support do not meet all the applicable waiver conditions, they do not qualify for waiver protection.
- The waivers do not provide retrospective protection; the provision of In-Kind Incentives or Cost Sharing Support 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 covered by the waivers set forth in Part I of this Notice.
- 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 the waivers set forth in Part I of this Notice 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), and 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 Participation Agreement.
- We reserve the right to reconsider the waivers set forth in Part I of this Notice and, where the public interest requires, to modify or terminate the waiver(s) on a prospective basis with respect to some or all entities and individuals specified in the waiver(s). The modification, suspension, or termination of part or all of the waiver(s) 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: 12/16/2020

/s/ Christi A. Grimm

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