

Notice of Waiver of Certain Fraud and Abuse Laws in Connection With Patient Engagement Arrangements in the Health Care Innovation Awards Round Two Demonstration Program

Section 1115A(d)(1) of the Social Security Act (SSA) authorizes the Secretary of Health and Human Services (Secretary) to waive certain specified fraud and abuse laws as may be necessary solely for purposes of carrying out the testing by the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare & Medicaid Services (CMS) of certain innovative payment and service delivery models. This Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Health Care Innovation Awards Round Two (Notice) is issued pursuant to this authority. The Health Care Innovation Awards Round Two (HCIA Round Two) is being tested under section 1115A(b) of the SSA.

This Notice is composed of two parts. Part I enumerates the specific conditions that must be met to qualify for the waiver for Patient Engagement Arrangements (as defined below) set forth in this Notice. Part I also defines terms used in the waiver conditions and throughout this Notice. Part II consists of background information and commentary explaining the waiver. The waiver established by this Notice applies only for the HCIA Round Two initiative and only in those cases where the applicable Notice of Award indicates that the authorization is section 3021 of the Patient Protection and Affordable Care Act (or section 1115A of the SSA). Awards made under other authorities are not covered by this Notice. Moreover, this waiver is not applicable to participants in, or arrangements for, any other Federal health care program or demonstration, nor is it applicable to any arrangements or activities outside the scope of the HCIA Round Two initiative, even if those arrangements or activities involve participants in the HCIA Round Two initiative.

I. Waiver for Patient Engagement Arrangements: Definitions and Conditions

A. Definitions

Cooperative Agreement Funds means the award funds provided to the Recipient pursuant to box 13 of the Notice of Award.

Funding Opportunity Announcement means the public document by which CMS made known its intention to award cooperative agreement funds for HCIA Round Two under funding opportunity number CMS-I CI -14-001, which, along with the Notice of Award, describes the funding opportunity, the award information, and the requirements for participation as a Recipient in HCIA Round Two.

HCIA Round Two means the initiative administered by CMMI that has the Funding Opportunity Title "Health Care Innovation Awards Round Two" and that is funded pursuant to Funding Opportunity Number CMS-I CI-14-001, issued May 15, 2013.

HCIA Round Two Award means the award of financial assistance to the Recipient pursuant to the Notice of Award for HCIA Round Two.

HCIA Round Two Beneficiary means a Medicare, Medicaid, or Children's Health Insurance Program beneficiary who receives items or services from a Recipient or Subrecipient that are provided using Cooperative Agreement Funds under HCIA Round Two.

HCIA Round Two Operational Plan or Operational Plan means the operational plan required to be submitted by the Recipient to CMS, as described in the "Funding Requirements" section of the HCIA Round Two Program Terms and Conditions and other HCIA Round Two program documents, including any revisions during the preaward or Cooperative Agreement Period as approved by CMS.

HCIA Round Two Program Terms and Conditions means the Program Terms and Conditions that are incorporated in the Notice of Award and describe additional requirements for participation as a Recipient in HCIA Round Two.

HCIA Round Two Standard Terms and Conditions means the Standard Terms and Conditions that are incorporated in the Notice of Award.

Notice of Award means the legal document issued to the Recipient to notify the Recipient that the Recipient has been selected to receive an award of Federal funds pursuant to HCIA Round Two and that Cooperative Agreement Funds may be requested from CMS.

Patient Engagement Arrangement means an arrangement involving solely the offer, transfer, or provision by a Recipient or Subrecipient to a HCIA Round Two Beneficiary of a good or service as part of the specific project for which the Recipient received the HCIA Round Two Award, as specified in the Operational Plan.

Project Period means the project period identified in box 6 of the Notice of Award.

Recipient means the entity receiving the HCIA Round Two Award, as identified in box 9a of the Notice of Award.

Subrecipient means an entity as defined in 45 CFR § 74.2 or a subgrantee as defined in 45 CFR § 92.3 that receives Cooperative Agreement Funds from a Recipient to be used pursuant to the terms of the HCIA Round Two Award.

Waiver Period means the period of time during which the waiver applies to the Recipient.

B. Conditions

Pursuant to section 1115A(d)(1) of the SSA, section 1128A(a)(5) of the SSA (the civil monetary penalty provision prohibiting inducements to beneficiaries (CMP))¹ and section 1128B(b) of the SSA (the Federal anti-kickback statute)² are waived with respect to goods or services offered, transferred, or provided to a HCIA Round Two Beneficiary through a Patient Engagement

¹ 42 U.S.C. § 1320a-7a(a)(5).

² 42 U.S.C. § 1320a-7b(b).

Arrangement if all of the following conditions are met at the time the good or service is offered, transferred, or provided:

1. The Recipient has received a Notice of Award of Cooperative Agreement Funds for HCIA Round Two, the Notice of Award indicates that the authorization for the award is section 3021 of the Patient Protection and Affordable Care Act or section 1115A of the SSA, the Recipient has drawn down or otherwise obtained Cooperative Agreement Funds as described in box 16 of the Notice of Award, and the Recipient is in compliance with the:
 - a. "Use of Funds" section of the HCIA Round Two Program Terms and Conditions and
 - b. Operational Plan approved by CMS.
2. The Recipient's Cooperative Agreement Funds have not been withheld, suspended, or voluntarily or involuntarily terminated or are not subject to any other enforcement action, nor has the Recipient's HCIA Round Two Award been terminated pursuant to:
 - a. the "Termination" sections of the HCIA Round Two Program Terms and Conditions,
 - b. the HCIA Round Two Standard Terms and Conditions, or
 - c. applicable regulations.
3. The good or service is offered, transferred, or provided to the HCIA Round Two Beneficiary during the Project Period.
4. The Patient Engagement Arrangement does not involve the offer, transfer, or payment to a HCIA Round Two Beneficiary of cash or instruments convertible to cash (such as checks, money orders, or debit cards) or the waiver of all or part of any cost-sharing amount. (However, gift cards that are not redeemable for cash or for items or services furnished by the Recipient or a Subrecipient are permitted for purposes of this waiver if all other waiver conditions are met.)
5. If the Patient Engagement Arrangement involves a Subrecipient:
 - a. the Subrecipient has an agreement with the Recipient pursuant to 45 CFR Part 74 or Part 92 that has not been terminated,
 - b. the Subrecipient is in full compliance with the "Use of Funds" section of the HCIA Round Two Program Terms and Conditions, and
 - c. the Recipient has expressly approved in writing, in advance, the Subrecipient's participation in the Patient Engagement Arrangement as part of the specific project for which the Recipient received the HCIA Round Two Award.
6. The Patient Engagement Arrangement is specifically described in the current Operational Plan approved by CMS.

7. The Patient Engagement Arrangement is funded entirely with Cooperative Agreement Funds, and such use of funds meets all requirements of the HCIA Round Two program, including all applicable requirements of the Funding Opportunity Announcement and Notice of Award.
8. Notwithstanding any other provision in this waiver, the use of Cooperative Agreement Funds for the Patient Engagement Arrangement is reported to the Department of Health and Human Services in accordance with all applicable reporting requirements and is documented in accordance with the record retention and access requirements set forth in 45 CFR Parts 74 and 92, as applicable.
9. There is a reasonable connection between the Patient Engagement Arrangement and medical care of the HCIA Round Two Beneficiary.
10. The Patient Engagement Arrangement involves goods or services that:
 - a. are preventive care goods or services; or
 - b. advance one or more of the following health care goals:
 1. adherence to a treatment regime,
 11. adherence to a drug regime,
 111. adherence to a care plan, or
 - 1v. management of a chronic disease or condition; or
 - c. further the quality and care improvement goals of the specific project for which the Recipient received the HCIA Round Two Award as described in the Operational Plan.
11. The Patient Engagement Arrangement is documented through contemporaneous documentation that is retained for at least 10 years following the earlier of the end of the Project Period or the termination of the HCIA Round Two Award and is made available to the Secretary upon request. The documentation must include at least the following for each Patient Engagement Arrangement:
 - a. a description of the good or service offered, transferred, or provided;
 - b. the value of the good or service;
 - c. the identity of the HCIA Round Two Beneficiary receiving the good or service;
 - d. the identity of the Recipient or Subrecipient that offered, transferred, or provided the good or service;
 - e. if a Subrecipient offered, transferred, or provided the good or service, the written approval of the Patient Engagement Arrangement by the Recipient;
 - f. the date or dates the good or service was transferred or provided; and

- g. evidence that the Patient Engagement Arrangement was designed to meet and/or met at least one of the goals enumerated in condition 10 of this waiver.
12. Neither the Notice of Award, as amended from time to time, nor any corrective action imposed on the Recipient by CMS pursuant to 42 CFR §§ 74.62 or 92.43 provides that this waiver is inapplicable.

For Patient Engagement Arrangements that meet all of the preceding conditions, the waiver period starts on the first day of the Project Period and will end on *the earlier of* (1) the date on which the Recipient's HCIA Round Two Award is terminated or (2) the end of the Project Period. Notwithstanding the preceding sentence, the HCIA Round Two Beneficiary may (1) keep goods received before the end of the waiver period (unless otherwise required to return them pursuant to the terms of the Patient Engagement Arrangement or Operational Plan), provided that all other conditions of this waiver and all applicable conditions of the Funding Opportunity Announcement and Notice of Award are met, and (2) receive the remainder of any service initiated before the end of the waiver period, provided that all other conditions of this waiver and all applicable conditions of the Funding Opportunity Announcement and Notice of Award are met.

II. Background and Commentary

A. General Commentary

The waiver set forth in this Notice describes the application of sections 1128A(a)(5) of the SSA (the CMP) and 1128B(b) of the SSA (the Federal anti-kickback statute) to Patient Engagement Arrangements offered by Recipients and Subrecipients in HCIA Round Two when all conditions of the waiver set forth in Part I of this Notice are satisfied. CMMI has identified the Patient Engagement Arrangements addressed by this waiver as necessary to test HCIA Round Two.

Apart from squarely meeting all waiver conditions set forth in Part I of this Notice, no special action is required to use this waiver (such as the submission of a separate application for a 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 or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. An arrangement that does not fit within the waiver has no special protection and must be evaluated on a case-by-case basis for compliance with the CMP and the Federal anti-kickback statute. Failure to fit in a waiver is not, in and of itself, a violation of law. The waiver set forth in this Notice does not protect any arrangements, or apply to any law, not specifically addressed in Part I. We expect this Notice to be interpreted in a reasonable manner. Compliance with the requirements of the HCIA Round Two Award is a critical component to mitigate the risks of fraud and abuse in HCIA Round Two. Moreover, it is incumbent on HCIA Round Two Recipients and Subrecipients to structure and operate Patient Engagement Arrangements in a manner that is consistent with the best interests of patients and the goals of HCIA Round Two. The waiver set forth in this Notice contains additional safeguards.

Our intention in this Notice is to incorporate safeguards that (1) foster beneficial innovation in patient engagement to improve quality and care outcomes; (2) enhance transparency and accountability; and (3) reduce the risk of harms often associated with beneficiary inducements, such as the provision of unnecessary services, or coercive or inappropriate steering of vulnerable beneficiaries. Given the potential for significant harm to Medicare and Medicaid programs and their beneficiaries resulting from improper beneficiary inducements, the Government must be judicious when waiving fraud and abuse authorities that provide important protections.

Nothing in this Notice affects the obligations of individuals or entities, including tax exempt organizations, to comply with the Internal Revenue Code, the Federal antitrust laws, 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 under HCIA Round Two. Nothing in this Notice changes, restricts, or limits any protections applicable to beneficiaries' freedom to choose any provider, practitioner, supplier, item, service, vendor, or treatment, including any applicable Medicare or Medicaid rule. Nothing in this Notice should be construed as endorsing or approving CMMI's evaluation or selection of HCIA Round Two Recipients, the HCIA Round Two program documents, or the goals or strategies of the specific projects for which CMS granted HCIA Round Two Awards.

Should indicia arise that the waiver in this Notice is not achieving its intended purposes, OIG will take appropriate action. OIG reserves the right to suspend, modify, or terminate the waiver described in this Notice, with respect to any or all Recipients or Subrecipients and any or all arrangements or activities, on a prospective basis, for any reason consistent with the public interest. Suspension, modification, or termination of the waiver does not require advance notice and is effective upon notice to the Recipient. 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.

B. Commentary Addressing Specific Waiver Requirements

This waiver protects Patient Engagement Arrangements offered by Recipients and Subrecipients to HCIA Round Two Beneficiaries, subject to the conditions enumerated in Part I of this Notice.³ The waiver applies to the Federal anti-kickback statute and the CMP, which prohibits inducements to Medicare and Medicaid beneficiaries, and includes certain safeguards designed to mitigate the risk of fraud and abuse. This waiver is intended to allow Recipients and Subrecipients to offer, transfer, and provide certain patient incentives permitted by, and consistent with, the Recipient's HCIA Round Two Award. The waiver applies if, at the time the incentive is offered, transferred, or provided to the beneficiary, all waiver conditions are satisfied.

For purposes of the waiver provided in this Notice, a Patient Engagement Arrangement must relate solely to activities funded by the HCIA Round Two Award and for this reason must be *solely* for the offer, transfer, or provision of a good or service from a Recipient or Subrecipient to a HCIA Round Two Beneficiary for the specific project funded by the HCIA Round Two Award. Protected arrangements must involve goods or services funded wholly with Cooperative

³ Certain terms used in this commentary are defined in Part I of this Notice.

Agreement Funds. This waiver protects only Patient Engagement Arrangements involving HCIA Round Two Beneficiaries participating in a specific project funded by a HCIA Round Two Award. It does not protect similar arrangements involving other beneficiaries. Arrangements not within the four corners of the specific project funded by the HCIA Round Two Award are not protected, even if they involve the same providers and patients and even if they relate to the same goals as the HCIA Round Two Award. Arrangements outside the waiver may qualify for other available legal protections, depending on their facts and circumstances.

The waiver applies only if the Recipient's Notice of Award indicates that the legal authority for the Award is section 3021 of the Patient Protection and Affordable Care Act (or section 1115A of the SSA, which is the codification of section 3021). This is the section pursuant to which the authority to waive the fraud and abuse laws derives. Patient Engagement Arrangements for HCIA Round Two Awards funded under other authorities, if any, are not eligible, as a matter of law, for the waiver described in this Notice.

Those offering Patient Engagement Arrangements must be Recipients or Subrecipients under a HCIA Round Two Award. Arrangements offered by others--even if offered to HCIA Round Two Beneficiaries--are not protected. If Subrecipients are offering the Patient Engagement Arrangement, the Recipient, as awardee of the grant funds, must be aware of and accountable for the Patient Engagement Arrangement. For this reason, the waiver requires the Recipient's written approval of Patient Engagement Arrangements undertaken by a Subrecipient. This approval must be provided in advance of implementation of the Patient Engagement Arrangement. This will help ensure that Patient Engagement Arrangements by Sub-Recipients are integral to the goals of HCIA Round Two and are in compliance with the HCIA Round Two Award.

To foster transparency and bright-line certainty regarding waiver coverage, we are requiring that each protected Patient Engagement Arrangement be described in a Recipient's Operational Plan approved by CMS. Section 6 of the Funding Opportunity Announcement requires Recipients to submit a detailed Operational Plan that describes the activities and budgets for each year of the model. The Funding Opportunity Announcement further provides that CMS may require additional submissions related to a Recipient's Operational Plan. We understand that such additional submissions shall include a list or catalogue describing each Recipient's grant-funded Patient Engagement Arrangements. Thus, we are not adding a new requirement for Recipients; rather, we are incorporating an existing program requirement as a condition of the waiver.

Protected remuneration under this waiver consists only of goods and services. Cash and instruments convertible to cash, such as checks, money orders, or debit cards, pose heightened risk of fraud or abuse and are not protected. Similarly, cost-sharing waivers are not protected. For purposes of this waiver, gift cards that are not redeemable for cash or for items or services furnished by the Recipient or a Subrecipient may be protected if the Patient Engagement Arrangement satisfies all waiver conditions. Any arrangements or agreements between vendors and Recipients or Subrecipients to furnish gift cards for a Patient Engagement Arrangement are not protected by the waiver. Vendors in this context would include, without limitation, manufacturers and equipment suppliers. Moreover, while the waiver could cover Patient Engagement Arrangements involving goods or services obtained by Recipients or Subrecipients for free or at a discount, neither the discount arrangement, nor any arrangement for the provision

of free goods and services to Recipients or Subrecipients, would be protected. Transportation furnished by a Recipient or Subrecipient may qualify for waiver protection as a noncash good or service, provided that the transportation is not furnished by giving cash or instruments convertible to cash to beneficiaries to pay or be reimbursed for transportation expenses and the arrangement otherwise squarely meets the waiver conditions.

The waiver does not apply if the Recipient's Cooperative Agreement Funds have been withheld, suspended, or voluntarily or involuntarily terminated or are subject to any other enforcement action or if the Recipient's HCIA Round Two Award has been terminated pursuant to the "Termination" sections of the HCIA Round Two Program Terms and Conditions, the HCIA Standard Terms and Conditions, or applicable regulations. The waiver also does not apply unless the Recipient has drawn down Cooperative Agreement Funds or otherwise obtains Cooperative Agreement Funds from the grant payment system; this is so because it is by these actions that the Recipient accepts the terms and conditions of the HCIA Round Two program, as set forth in box 16 of the Notice of Award.

To balance the health care improvement goals of patient engagement against the risk that incentives will be used to steer beneficiaries inappropriately, we are requiring, among other things, that there be a reasonable connection between the Patient Engagement Arrangement and the medical care of the HCIA Round Two Beneficiary. By way of example, the waiver might cover transportation to necessary medical appointments, but not transportation to a theater event, or the waiver might cover technology to ensure compliance with a care plan, but would not cover technology that is more valuable than what is reasonably necessary for the patient's medical care. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the patient's medical care. The HCIA Round Two Program Terms and Conditions "Use of Funds" section prohibits the use of Cooperative Agreement Funds for beneficiary inducements that are conditioned on patient referrals and/or that do not meet the quality and care improvement goals of the project described in the Recipient's Operational Plan. Accordingly, no such inducements would be protected by this waiver.

A protected Patient Engagement Arrangement must closely align with the clinical, quality, and care improvement goals of HCIA Round Two. The waiver design reflects this by requiring, among other things, that protected beneficiary incentives further the quality and care improvement goals of the specific project for which the Recipient received its HCIA Round Two Award. To provide additional bright-line certainty for waiver purposes, condition 10 of the waiver enumerates specific clinical care or treatment goals that can meet the condition. Notwithstanding this enumerated list for waiver purposes, nothing in this Notice supersedes the Recipient's obligation to comply with the requirements of the Notice of Award, including, but not limited to, the "Use of Funds" section of the HCIA Round Two Program Terms and Conditions and the Operational Plan.

The waiver provides that the Waiver Period will run from the beginning of the Project Period (which is indicated in box 6 of the Notice of Award) to the *earlier* of the date the HCIA Round Two Award is terminated or the end of the Project Period. (We are informed by CMS that the program documents use the terms "Project Period," "Cooperative Agreement Period," and "Period of Performance" interchangeably. For purposes of this Notice, we use the term "Project Period" as set forth in the Notice of Award.)

To ensure continuity of care for HCIA Round Two Beneficiaries, we are providing that if a HCIA Round Two Award terminates or expires, the beneficiary may keep any good received before the end of the Waiver Period, unless he or she would be required to return it pursuant to the terms of the Patient Engagement Arrangement or Operational Plan and provided that all other conditions of the waiver and all applicable conditions of the HCIA Round Two Award are met. The beneficiary may also receive the remainder of any service initiated before the end of the Waiver Period, provided that the service meets all waiver conditions (including the condition that the service be funded with Cooperative Agreement Funds) and all applicable conditions of the HCIA Round Two Award. By way of example, if a beneficiary is receiving free home visits pursuant to a chronic care management plan, the beneficiary could continue to receive the remainder of visits specifically included in the plan under the specific project funded by the now expired or terminated Award.

To promote accountability, this Notice requires the Recipient to maintain certain specified documentation. The documentation may be maintained in paper or electronic format and must possess at least the level of detail required by Part I of this Notice. The documentation requirements in this Notice do not supersede, and may be in addition to, any documentation requirements set forth in the HCIA Round Two program documents, other HCIA Round Two program requirements, or applicable program regulations. All documentation required by this Notice must be retained for at least 10 years following the earlier of the end of the Project Period or the termination of the HCIA Round Two Award and must be made available to the Secretary upon request.

Nothing in this waiver precludes Recipients or Subrecipients from offering patient engagement incentives to promote clinical care if the incentives fit in applicable safe harbors or exceptions or otherwise do not run afoul of the fraud and abuse laws.

JAN 20 2015

Dated: -----

/Daniel R. Levinson/

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