Notice of Waivers of Certain Fraud and Abuse Laws in Connection With the Bundled Payments for Care Improvement (BPCI) Model 1

September 13, 2012

Section 1115A(d)(l) of the Social Security Act (the Act) 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 & Medicaid Innovation of certain innovative payment and service delivery models, including the Bundled Payments for Care Improvement Model 1 (the BPCI Model 1). This Notice of Waivers (Notice) is issued pursuant to this authority. This Notice is composed of two parts: I. Explanation of Waiver Requirements and II. Waiver Scope and Conditions.

I. Explanation of Waiver Requirements

The waiver in this Notice applies to Incentive Payments that squarely meet all the conditions set forth in Part II. 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. 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 section 1877 of the Act (the Physician Self-Referral Law),[1] sections 1128A(b)(1) and (2) of the Act (the Gainsharing Civil Monetary Penalty (CMP)),[2] and section 1128B(b) of the Act (the Federal anti-kickback statute).[3]

For consistency, this Notice employs the same terminology used in the BPCI Model 1 agreement entered into by the Model 1 Awardee and the Centers for Medicare & Medicaid Services (CMS) (the Participation Agreement). The following terms have the same meanings as in the Participation Agreement: Administrative Services, BPCI Entity, Care Redesign Under BCPI Model 1, Enrolled Practitioners, Gainsharing Arrangement, Incentive Payment, Internal Hospital Cost Savings, Hospital, Medically Necessary, Model 1 Awardee, and Performance Year.

This waiver protects certain financial relationships that arise when Incentive Payments are distributed by or among a Model 1 Awardee, a Hospital, an Enrolled Practitioner, or a BPCI Entity. To be protected by the waiver, the Incentive Payments must meet the requirements of the Participation Agreement and the conditions of this Notice. This waiver does not protect any other payments made to or by the Model 1 Awardee, a Hospital, BPCI Entity, Enrolled Practitioner, or any other person or entity.

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[1] 42 U.S.C. § 1395nn.
[2] 42 U.S.C. §§ 1320a-7a(b)(l) and (2).
[3] 42 U.S.C. § 1320a-7b(b).

This waiver requires that the Model 1 Awardee have a Participation Agreement with CMS, not be terminated from its Participation Agreement, and be in compliance with specific sections of the Participation Agreement noted in the waiver text in Part II. The design of the waiver is premised on an expectation that the requirements of the Participation Agreement will, in the first instance, mitigate risks of fraud and abuse. The waiver adds additional safeguards. The intent of the waiver is to ensure that protected Incentive Payments are consistent with the BPCI Model 1, are subject to safeguards designed to mitigate the risk of fraud and abuse, and can readily be audited and monitored.

The waiver applies to Incentive Payments derived from the Internal Hospital Cost Savings generated by the Model 1 Awardee's approved Gainsharing Arrangement during the Performance Years of the Participation Agreement. Internal Hospital Cost Savings must be verifiable and measurable in accordance with the Participation Agreement. The waiver does not apply to the distribution of funds from any other source or to the distribution of funds generated by mechanisms other than the approved gainsharing methodology set forth in the Gainsharing Arrangement. The waiver does not protect any financial arrangements, other than Incentive Payments, such as personal services or management contracts, health information technology or other infrastructure arrangements, staffing arrangements, or others. All such arrangements must comply with the fraud and abuse laws and, depending on their structure, may qualify under existing safe harbors or exceptions.

Under the BPCI Model 1, Incentive Payments may be made only to an Enrolled Practitioner or to a BPCI Entity. Incentive Payments made to BPCI Entities must be passed through in their entirety to an Enrolled Practitioner, except that a BPCI Entity may retain a portion of an Incentive Payment solely for Administrative Services that the BPCI Entity performs. The conditions of this waiver reflect these requirements. Accordingly, the waiver protects Incentive Payments received by an Enrolled Practitioner; this would include Incentive Payments made directly or indirectly to the Enrolled Practitioner by a Model 1 Awardee, as well as Incentive Payments received by a BPCI Entity and passed through to an Enrolled Practitioner. The waiver also protects Incentive Payments received and retained by a BPCI Entity solely for Administrative Services that the BPCI Entity performs (see section IV.A.5 of the Participation Agreement); the waiver does not protect any other Incentive Payment amounts retained by a BPCI Entity (i.e., amounts that are not passed through to an Enrolled Practitioner). The waiver includes a requirement that all retained amounts protected by the waiver be solely for Administrative Services. Under the Participation Agreement, Administrative Services must be directly related to the administration of the Gainsharing Arrangement. Thus, parties seeking to use the waiver must be able to demonstrate through reasonable means that the Administrative Services for which the Incentive Payment is retained are directly related to the administration of the Gainsharing Arrangement. While fair market value is not required under the waiver, an Incentive Payment retained by a BPCI Entity that is fair

market value for Administrative Services performed by the BPCI Entity would presumptively meet the requirement that the retained Incentive Payment is solely for Administrative Services.

Under the terms of the waiver, protected Incentive Payments must be in the form of a check, electronic funds transfer, or another traceable cash transaction. The purpose of this condition is to make clear that payments in the form of in-kind goods or services are not protected, even if they are of comparable value to an Incentive Payment calculated and otherwise due under the Participation Agreement. For example, a payment made to an Enrolled Practitioner in the form of free or reduced-price equipment, staff, or space would not be protected.

The waiver contains a further safeguard in connection with Incentive Payments made indirectly or passed through to an Enrolled Practitioner or a BPCI Entity. Incentive Payments are subject to certain conditions, limitations, and restrictions under the Participation Agreement. To qualify for waiver protection, no additional conditions, limitations, or restrictions can be appended explicitly or implicitly to the Incentive Payment. In other words, by way of example only, a BPCI Entity that receives an Incentive Payment from a Model 1 Awardee and is passing the Incentive Payment through to an Enrolled Practitioner may not condition the Enrolled Practitioner's receipt of the Incentive Payment on the Enrolled Practitioner's satisfaction of any additional conditions or criteria, such as expected future business or referral volumes.

This waiver requires an audit trail of contemporaneous documentation that identifies key information related to the Incentive Payment for which waiver protection is sought. This waiver does not require documentation to be maintained in any particular form. For waiver purposes, it may be in paper or electronic format. The documentation should possess sufficient clarity that the Government or another third party reviewing the documentation would be able to ascertain key information. The documentation requirements in the waiver do not supersede, and may be in addition to, any documentation requirements in the Participation Agreement. All required documentation must be retained for at least 10 years following the date of the last Incentive Payment made under the Participation Agreement and must be made available to the Secretary upon request.

The waiver does not protect payments made to reduce or limit Medically Necessary services. Arrangements that incentivize the provision of alternate and appropriate Medically Necessary care consistent with the Care Redesign Under BCPI Model 1 (such as the use of alternative evidence-based protocols for Medically Necessary care) can be protected by this waiver if all other waiver conditions are satisfied. Knowing payments by a hospital to induce a physician to reduce or limit Medically Necessary care without providing acceptable alternative Medically Necessary care (for example, payments to discharge patients without regard to appropriate care transitions or payments to use a drug or device known to be clinically less effective) would not qualify for the 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 under the Participation Agreement.

The waiver set forth in this Notice will apply to any Incentive Payment that meets the conditions described above. We expect the waiver to be interpreted in a reasonable manner. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required in order to be covered by this waiver.

We reserve the right to reconsider the waivers and to suspend, modify, or terminate the waivers on a prospective basis for any reason consistent with the public interest and with respect to all participants in BPCI Model 1 or with respect to specific participants. Suspension, modification, or termination of the waiver does not require advance notice and is effective upon notice to the Model 1 Awardee of such suspension, modification, or termination. 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.

II. Waiver Scope and Conditions

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and section 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute), are waived with respect to an Incentive Payment made pursuant to a Participation Agreement, provided all of the following conditions are met:

1. The Model 1 Awardee makes the Incentive Payment pursuant to the terms of its Participation Agreement to an Enrolled Practitioner and/or BPCI Entity that is participating in the BPCI Model 1 pursuant to the Participation Agreement.

2. The Incentive Payment is received by (a) an Enrolled Practitioner; or (b) a BPCI Entity that passes through the entire Incentive Payment, except that the BPCI Entity may retain a portion of such Incentive Payment if that portion is solely for the Administrative Services the BPCI Entity performs.

3. The Model 1 Awardee's Participation Agreement is not terminated, and the Model 1 Awardee is in compliance with sections IV.A.2, IV.A.3, IV.A.4, IV.A.5, IV.A.6, IV.C, IV.F, IV.G, VII.B, and IX.A of its Participation Agreement and has not engaged in the conduct described in section VII.A(1)(b).

4. The Hospital for which the Internal Hospital Cost Savings are calculated is participating in the BPCI Model 1 pursuant to the Participation Agreement, and the Internal Hospital Cost Savings that form the basis of the Incentive Payment accrue during the Performance Years.

5. The Incentive Payment is distributed by check, electronic funds transfer, or another traceable cash transaction.

6. If the Incentive Payment is made indirectly through a BCPI Entity to another BCPI Entity or to an Enrolled Practitioner, the BPCI Entity or Entities through which the Incentive Payment is made must not add conditions, limitations, or restrictions, explicitly or implicitly, to receipt of the Incentive Payment.

7. The operation of the Gainsharing Arrangement and the Incentive Payment are documented by the Model 1 Awardee (or through documentation readily available to the Model 1 Awardee). The documentation must identify at least the following information:

    a. the parties to the Gainsharing Arrangement and any Enrolled Practitioner or BCPI Entity that receives an Incentive Payment pursuant to the Participation Agreement;

    b. the methodology and formula for accruing and calculating the Internal Hospital Cost Savings;

    c. the actual calculation of Internal Hospital Cost Savings;

    d. the methodology for calculating, allocating, and distributing the Incentive Payment to the Enrolled Practitioner and/or BPCI Entity;

    e. the actual calculation of the Incentive Payment;

    f. all Incentive Payments made for each Performance Year, including the identity of the party making the Incentive Payment and the date, amount, and recipient of each Incentive Payment;

    g. in the case of an Incentive Payment made indirectly to an Enrolled Practitioner or a BPCI Entity, the identity of all BPCI Entities through which the Incentive Payment is made; the date and amount of the Incentive Payment to the Enrolled Practitioner or to another BPCI Entity; and verification that the Incentive Payment was passed through in its entirety, except to the extent a BPCI Entity retains a portion of the Incentive Payment that is solely for Administrative Services it performs; and

h. in the case of an Incentive Payment retained by a BPCI Entity that is solely for Administrative Services it performs, the identity of the BPCI Entity performing the Administrative Services, the date and amount of the Incentive Payment retained, and a description of the Administrative Services.

All such documentation must be contemporaneous, retained for at least 10 years following the last Incentive Payment made pursuant to the Participation Agreement, and made available to the Secretary upon request.

8. The Incentive Payment is not made knowingly to induce an Enrolled Practitioner or BPCI Entity to reduce or limit Medically Necessary items or services to patients.

9. The Participation Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

Authority: Section 1115A(d)(l) of the Act.

As to section 1877(a) of the Social Security Act:

Dated: [9/13/12]

/Marilyn Tavenner/

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

As to sections 1128A(b)(1) and (2), and sections 1128B(b)(1) and (2) of the Social Security Act:

Dated: [9/13/12]

/Daniel R. Levinson/

Daniel R. Levinson,

Inspector General,

Department of Health and Human Services.