

Notice of Waivers of Certain Fraud and Abuse Laws in Connection With the
Bundled Payments for Care Improvement Model 2

July 26, 2013

Section 1115A(d)(1) 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 (CMMI) of certain innovative payment and service delivery models. This Notice of Waivers of Certain Fraud and Abuse Laws in Connection With the Bundled Payments for Care Improvement Model 2 (Notice) is issued pursuant to this authority. The Bundled Payments for Care Improvement Model 2 (BPCI Model 2) is being tested under section 1115A(b) of the Act.

This Notice is composed of two parts. Part I sets forth the specific conditions that must be met to qualify for a waiver. Each waiver protects only arrangements that meet all of the listed conditions. Part II consists of commentary explaining the waiver requirements of Part I. The waivers established by this Notice apply only for the Bundled Payments for Care Improvement Model 2 demonstration program. These waivers are not applicable to participants in, or arrangements for, any other Federal health care program or demonstration.

The waivers established by this Notice (and the commentary) employ some of the same terminology used in the Bundled Payments for Care Improvement Model 2 Agreement (BPCI Agreement) between the Centers for Medicare & Medicaid Services (CMS) and the Model 2 Awardee (as defined below) setting forth the Parties' respective duties and responsibilities under BPCI Model 2. Specifically, as specified in Part I, the following terms have the same meanings as in the BPCI Agreement: *Administrative Services, Model 2, BPCI Entity, BPCI Savings Pool¹, Care Redesign, Clinical Episode, Episode of Care, Effective Date, Effective Period, Episode Initiator, Episode-Integrated Provider, Excess Spending Amount, Gainsharer, Gainsharing Arrangement, Gainsharer Group Practice, Gainsharer Group Practice Practitioner, Gainsharing List, Gainsharing Payment, Implementation Protocol, Incentive Payment, Internal Cost Savings, Medically Necessary, Model 2 Awardee, Model 2 Beneficiary, Net Payment Reconciliation Amount (NPRA), Participant Agreement, Parties, and Performance Year.*

As further described in Part I, the waivers in this Notice apply to the following financial arrangements that are central to BPCI Model 2. These financial arrangements have been identified by CMMI as necessary to test BPCI Model 2. The financial arrangements are:

1. Contributions by Episode-Integrated Providers (EIPs) of Internal Cost Savings to the BPCI Savings Pool (the "Model 2 Savings Pool Contribution Waiver") (this waiver

¹ The term *BPCI Savings Pool*, as used in this Notice, includes any of the specific options for structuring a BPCI Savings Pool described in the Implementation Protocol.

pertains only to the Physician Self-Referral Law², the Federal anti-kickback statute³, and the Gainsharing Civil Monetary Penalty (CMP) Law⁴);

2. Incentive Payments distributed from the BPCI Savings Pool (the “Model 2 Incentive Payments Waiver”) (this waiver pertains only to the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP);
3. Gainsharing Payments made by Gainsharer Group Practices to Gainsharer Group Practice Practitioners (the “Model 2 Group Practice Gainsharing Waiver”) (this waiver pertains only to the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP); and
4. In-kind patient engagement incentives provided by a Model 2 Awardee, EIP, or Gainsharer to a Model 2 Beneficiary (the “Model 2 Patient Engagement Incentive Waiver”) (this waiver pertains only to the Federal anti-kickback statute and the Beneficiary Inducements CMP⁵).

Part I: Model 2 Waivers: Definitions and Conditions

A. Definitions

BPCI Agreement means the Bundled Payments for Care Improvement Model 2 Agreement between CMS and the Model 2 Awardee (as defined below) setting forth the Parties’ respective duties and responsibilities under BPCI Model 2.⁶

BPCI Model 2 means the Bundled Payment for Care Improvement Model 2 referred to as *Model 2* in the BPCI Agreement.

EIP-Gainsharer Agreement means the written gainsharing agreement between the EIP and the Gainsharer that meets the requirements of sections II.N, III.A.1.c.i, III.B, III.C, III.D, and III.E of the BPCI Agreement.

The following terms have the same meanings as in the BPCI Agreement: *Administrative Services, Model 2, BPCI Entity, BPCI Savings Pool, Care Redesign, Clinical Episode, Episode of Care, Effective Date, Effective Period, Episode Initiator, Episode-Integrated Provider, Gainsharer, Gainsharing Arrangement, Gainsharer Group Practice, Gainsharer Group Practice Practitioner, Gainsharing List, Gainsharing Payment, Implementation Protocol, Incentive*

² 42 U.S.C. § 1395nn.

³ 42 U.S.C. § 1320a-7b(b).

⁴ 42 U.S.C. § 1320a-7a(b)(1) and (2).

⁵ 42 U.S.C. § 1320a-7a(a)(5).

⁶We use the term *BPCI Agreement* in this Notice for clarity. It has the same meaning as the defined term *Agreement* in the BPCI Agreement itself.

Payment, Internal Cost Savings, Medically Necessary, Model 2 Awardee, Model 2 Beneficiary, Net Payment Reconciliation Amount, Participant Agreement, Parties, and Performance Year.

The term *BPCI Savings Pool*, as used in this Notice, includes any of the specific options for structuring a BPCI Savings Pool described in the Implementation Protocol.

B. Conditions

1. Model 2 Savings Pool Contribution Waiver

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 contributions of Internal Cost Savings to the BPCI Savings Pool, provided all of the following conditions are met:

- a) The EIP is participating in BPCI Model 2 pursuant to the BPCI Agreement.
- b) The contribution is made by the EIP pursuant to the terms of the BPCI Agreement including the Implementation Protocol.
- c) The Internal Cost Savings contributed to the BPCI Savings Pool are realized by the EIP and result from Care Redesign undertaken by the EIP in connection with providing items and services to Model 2 Beneficiaries within specific Episodes of Care.
- d) The contribution consists solely of Internal Cost Savings.
- e) The Model 2 Awardee's BPCI Agreement is not terminated, the Model 2 Awardee is in compliance with sections I.B.2(a), III.A-G, III.H.2(a), and III.I.1, 2, 4, 5, VI.E, and VIII.A of its BPCI Agreement and has not engaged in the conduct described in section VI.B.4(b), and the EIP making the contribution to the BPCI Savings Pool is in compliance with these sections where applicable to the EIP.
- f) The contribution of Internal Cost Savings is made by electronic funds transfer to the Model 2 Awardee for deposit or transfer into a BPCI Savings Pool to which the EIP is assigned pursuant to section III.B of the Implementation Protocol and is transferred or deposited in its entirety to the BPCI Savings Pool.
- g) The contribution is documented by the Model 2 Awardee (or through documentation readily available to the Model 2 Awardee). The documentation must identify at least the following information:
 - i. the BPCI Savings Pool to which the contribution was made, pursuant to the Implementation Protocol;

- ii. the EIP making the contribution;
- iii. the amount, date, recipient, and form of payment of the contribution, and verification that the entire amount of the contribution was transferred to or deposited into the BPCI Savings Pool;
- iv. the methodology and accounting formula for accruing, realizing, and calculating the Internal Cost Savings; and
- v. the actual calculation of Internal Cost Savings included in the contribution.

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

- h) The EIP making the contribution to the BPCI Savings Pool does not do so knowingly to induce the reduction or limitation of Medically Necessary items or services to patients.
- i) The BPCI Agreement, as amended from time to time, does not provide that this Model 2 Savings Pool Contribution Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated, (2) the expiration date of the last Performance Year plus 6 months, or (3) 6 years plus 6 months from the Effective Date of the BPCI Agreement.

2. Model 2 Incentive Payments Waiver

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 from the BPCI Savings Pool pursuant to the BPCI Agreement, provided all of the following conditions are met:

- a) The Incentive Payment meets the requirements of sections II.Q, III.B, III.C, and III.E.1(b)(ii) of the BPCI Agreement.
- b) The Model 2 Awardee's BPCI Agreement is not terminated pursuant to section VI.B of the BPCI Agreement, the Model 2 Awardee is in compliance with sections I.B.2(a), III.A-G, III.H.2(a), III.I.1, 2, 4, 5, VI.C, D, and F, and VIII.A of its BPCI Agreement and has not engaged in the conduct described in section VI.B.4(b), and the recipient of the Incentive Payment is in compliance with these sections where applicable to the recipient.

- c) The BPCI Savings Pool from which the Incentive Payment is made (whether directly or indirectly) meets the requirements of sections II.F and III.B.4 of the BPCI Agreement and section III.B of the Implementation Protocol.
- d) The Incentive Payment is derived solely from a BPCI Savings Pool to which the recipient is assigned pursuant to section III.B of the Implementation Protocol and includes no additional funds or payment amounts.
- e) The Incentive Payment is distributed by electronic funds transfer.
- f) If the recipient of the Incentive Payment is a BPCI Entity, the BPCI Entity passes through the entire Incentive Payment to an EIP or other BPCI Entity, except that the BPCI Entity may retain a portion of such Incentive Payment if that portion is solely for the Administrative Services actually furnished by the BPCI Entity.
- g) The party making the Incentive Payment (whether directly or indirectly) does not add conditions, limitations, or restrictions to receipt of the Incentive Payment.
- h) The Incentive Payment, the operation of the Gainsharing Arrangement, and, if applicable, the EIP-Gainsharer Agreement, are documented by the Model 2 Awardee (or through documentation readily available to the Model 2 Awardee). The documentation must identify at least the following information:
 - i. the parties to the Gainsharing Arrangement and, if applicable, the EIP-Gainsharer Agreement, and any Awardee, EIP, BPCI Entity, or Gainsharer receiving an Incentive Payment pursuant to the BPCI Agreement;
 - ii. the total positive Net Payment Reconciliation Amount received by the Model 2 Awardee, the date such amount was received, the amount of the Net Payment Reconciliation Amount contributed by the Model 2 Awardee to the BPCI Savings Pool, and the date(s) such amount was contributed to the BPCI Savings Pool;
 - iii. the methodology and accounting formula for accruing, realizing, and calculating the Internal Cost Savings that are contributed to the BPCI Savings Pool from which the Incentive Payment is made;
 - iv. the actual calculation of Internal Cost Savings contributed to the BPCI Savings Pool from which the Incentive Payment is made, the identification of the BPCI Savings Pool pursuant to section III.B of the Implementation Protocol, the identity of each EIP contributing such Internal Cost Savings, the amount of each contribution by each EIP, and the date of each contribution;

- v. the methodology and accounting formula for calculating, allocating, and distributing the Incentive Payment to each Model 2 Awardee, EIP, Gainsharer, and/or BPCI Entity;
- vi. the actual calculation of the Incentive Payment;
- vii. all Incentive Payments, including the identity of the party making the Incentive Payment and the date, amount, and recipient of each Incentive Payment (regardless of whether the recipient receives the Incentive Payment directly or indirectly);
- viii. in the case of an Incentive Payment made indirectly to an EIP 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 EIP or to another BPCI Entity; and verification that the Incentive Payment, if received by a BPCI Entity, was passed through in its entirety, except for any portion of the Incentive Payment that is solely for Administrative Services the BPCI Entity actually furnished; and
- ix. in the case of an Incentive Payment retained by a BPCI Entity solely for Administrative Services that it actually furnished, 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, and made available to the Secretary upon request.

- i) The party making the Incentive Payment (whether directly or indirectly) does not do so knowingly to induce the recipient to reduce or limit Medically Necessary items or services to patients.
- j) The BPCI Agreement, as amended from time to time, does not provide that this Model 2 Incentive Payments Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated pursuant to section VI.B of the BPCI Agreement, (2) the end of the Effective Period, or (3) 6 years plus 6 months from the Effective Date of the BPCI Agreement.

3. Model 2 Group Practice Gainsharing Waiver

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 a Gainsharing Payment made by a Gainsharer Group Practice to a Gainsharer Group Practice Practitioner, as described in section II.N of the BPCI Agreement, provided all of the following conditions are met:

- a) The Incentive Payment from which the Gainsharing Payment derives satisfies the requirements of the Model 2 Incentive Payments Waiver in Part I section B.2 of this Notice.
- b) The Gainsharing Payment derives solely from the Incentive Payment and is made to the Gainsharing Group Practice Practitioner solely for Care Redesign Activities performed after the Effective Date.
- c) The Model 2 Awardee's BPCI Agreement is not terminated pursuant to section VI.B of the BPCI Agreement, the Model 2 Awardee is in compliance with sections I.B.2(a), II.N, III.A-G, III.H.2(a), III.I.1, 2, 4, 5, VI.C, D, and F, and VIII.A of its BPCI Agreement and has not engaged in the conduct described in section VI.B.4(b), and the Gainsharer Group Practice and Gainsharer Group Practice Practitioners are in compliance with these sections where applicable to them.
- d) The Gainsharing Payment is made by electronic funds transfer.
- e) The Gainsharing Payment is documented by the Model 2 Awardee (or through documentation readily available to the Model 2 Awardee). The documentation must identify at least the following information:
 - i. the identity of the Gainsharer Group Practice and the Gainsharer Group Practice Practitioner receiving the Gainsharing Payment and the date and amount of the payment;
 - ii. the written agreement between the Gainsharer Group Practice and the Gainsharer Group Practice Practitioner described in section II.N of the BPCI Agreement and the associated EIP-Gainsharer Agreement;
 - iii. the methodology and accounting formula for calculating, allocating, and distributing the Gainsharing Payment and the actual calculation of the Gainsharing Payment;
 - iv. the Incentive Payment from which the Gainsharing Payment is derived; and
 - v. the Care Redesign activities for which the Gainsharing Payment is made.

All such documentation must be contemporaneous, retained for at least 10 years following the later of the last Incentive Payment or the last Gainsharing Payment, and made available to the Secretary upon request.

- f) The Gainsharer Group Practice making the Gainsharing Payment does not do so knowingly to induce the reduction or limitation of Medically Necessary items or services to patients.
- g) The BPCI Agreement, as amended from time to time, does not provide that this Model 2 Group Practice Gainsharing Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated pursuant to section VI.B of the BPCI Agreement, (2) the end of the Effective Period, or (3) 6 years plus 6 months from the Effective Date of the BPCI Agreement.

4. Model 2 Patient Engagement Incentive Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (relating to the Beneficiary Inducements CMP) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided by a Model 2 Awardee, EIP, or Gainsharer to a Model 2 Beneficiary for free or below fair market value if all of the following conditions are met:

- a) The items or services are provided by a Model 2 Awardee, EIP, or Gainsharer to a Model 2 Beneficiary during an Episode of Care, pursuant to the terms of the BPCI Agreement, including the Implementation Protocol.
- b) The Model 2 Awardee, EIP, or Gainsharer is in compliance with the requirements of section IV of the Implementation Protocol governing Beneficiary Incentives.
- c) The Model 2 Awardee's BPCI Agreement is not terminated, the Model 2 Awardee is in compliance with sections I.B.2(a), III.A-G, III.H.2(a), III.I.1, 2, 4, 5, VI.E, and VIII.A of its BPCI Agreement and has not engaged in the conduct described in section VI.B.4(b), and the EIP or Gainsharer, if applicable, is in compliance with these sections where applicable to them.
- d) There is a reasonable connection between the items and services and medical care provided to the Model 2 Beneficiary during the Episode of Care.
- e) The items or services are in-kind;
- f) The items or services –
 - i. are preventive care items or services or
 - ii. advance one or more of the following clinical goals:
 - 1. adherence to a drug regime,

2. adherence to a follow-up care plan, or
3. management of a chronic disease or condition.

g) The BPCI Agreement, as amended from time to time, does not provide that this Model 2 Patient Engagement Incentive Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated, (2) the expiration date of the last Performance Year, or (3) 6 years from the Effective Date of the BPCI Agreement, provided that the Model 2 Beneficiary may keep items received before the end of the waiver period (unless otherwise required to return them pursuant to the Implementation Protocol) and receive the remainder of any service initiated before the end of the waiver period.

Part II: Explanation of Waiver Requirements

Each waiver set forth in Part I of this Notice applies to arrangements that squarely meet all the conditions pertaining to that particular 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. 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 Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing and Beneficiary Inducements CMPs. Failure to fit in a waiver is not, in and of itself, a violation of the laws.

The waivers described in this Notice require that the Model 2 Awardee have a BPCI Agreement with CMS and the Model 2 Awardee is, and other relevant parties are, in compliance with sections of the BPCI Agreement specified in the waiver. A goal of these waivers is to ensure that protected financial arrangements are consistent with BPCI Model 2, are subject to safeguards designed to mitigate the risk of fraud and abuse, and can readily be audited and monitored. The design of the waivers is premised on an expectation that the requirements of the BPCI Agreement will, in the first instance, mitigate risks of fraud and abuse. The waivers established by this Notice are intended to balance the need for flexibility to test new models that aim to improve quality of care and lower costs with protections for beneficiaries and the Medicare program against risk of harms, including, by way of example only, overutilization and inappropriate patient steering, as well as underutilization or stinting. Additionally, there is a concern that remuneration related to BPCI Model 2 could be misused to induce or reward referrals of items and services for beneficiaries not covered by a BPCI Model 2 Episode of Care.

The waivers set forth in this Notice do not protect financial arrangements unless the arrangements are specifically addressed in Part I. All financial arrangements not specifically addressed in Part I must comply with the fraud and abuse laws. The waivers in this Notice have been developed in consultation with CMMI, which is administering and testing BPCI Model 2. Section 1115A(d)(1) of the Act specifies the legal standard that has guided development of these

waivers. Under this standard, the Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing CMP, and the Beneficiary Inducements CMP may be waived “as may be necessary solely for purposes of carrying out the testing” of BPCI Model 2. Following a Model 2 Awardee’s execution of its BPCI Agreement, the Model 2 Awardee is required to submit an Implementation Protocol to CMMI describing, *inter alia*, the Model 2 Awardee’s planned Care Redesign activities, which may include financial arrangements between or among actual or potential referral sources. We expect that Model 2 Awardees will identify financial arrangements as part of their Care Redesign that would either be covered by a waiver in Part I or otherwise comply with existing law. As BPCI Model 2 develops, we will continue to consult, as necessary, with CMMI regarding waivers.

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 BPCI Agreement or any other agreement. We expect the waivers 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 these waivers.

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 2 or with respect to specific participants. Suspension, modification, or termination of the waivers does not require advance notice and is effective upon notice to the Model 2 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.

1. Model 2 Savings Pool Contribution Waiver

Under the terms of the BPCI Agreement, the BPCI Savings Pool is administered by the Model 2 Awardee and is comprised of two possible funding streams: EIP contributions of Internal Cost Savings (including contributions by the Model 2 Awardee when it is an EIP) and Model 2 Awardee contributions of positive NPRA.⁷ This waiver protects the financial arrangements that arise from the first stream – EIP contributions of Internal Cost Savings.⁸ The BPCI Savings Pool

⁷The BPCI Agreement, through the Implementation Protocol, offers Awardees several options for structuring BPCI Savings Pools. It is our understanding that many Awardees will administer a single BPCI Savings Pool. For ease of reference and consistent with the BPCI Agreement, we refer to “BPCI Savings Pool” in the singular throughout this Notice. However, if an Awardee uses an option that allows it to administer multiple BPCI Savings Pools, each BPCI Savings Pool must meet all requirements described in the applicable waiver.

⁸No waiver protection is needed for contributions of NPRA, because the BPCI Agreement provides that the Model 2 Awardee receives any positive NPRA directly from CMS and thereafter contributes a portion of such funds to the BPCI Savings Pool that the Awardee itself administers. By contrast, contributions of Internal Cost Savings are transferred from EIPs to the

is the sole source of funds for Incentive Payments. As specified at section III.B.4 of the BPCI Agreement, the BPCI Savings Pool may not include, or be used to distribute, any amounts that are not Internal Cost Savings as defined in the BPCI Agreement.

Consistent with the BPCI Agreement, the BPCI Savings Pool must be administered in accordance with Generally Accepted Accounting Principles (GAAP) and may not be comingled with other Model 2 Awardee accounts or funds. *See e.g.*, section III.B.4 of the BPCI Agreement. Each contribution to the BPCI Savings Pool must reflect actual Internal Cost Savings achieved by the contributing EIP through implementation of Care Redesign. *See e.g.*, sections II.R, III.A.1(c)(i) and III.B.4 of the BPCI Agreement. Internal Cost Savings must be measurable, actual, and verifiable cost savings realized by an EIP resulting from Care Redesign undertaken by the EIP in connection with providing items and services to Model 2 Beneficiaries within specific Episodes of Care; Internal Cost Savings does not include cost savings realized by any individual or entity that is not an EIP. *See e.g.*, section II.R of the BPCI Agreement. These requirements, among others, serve to ensure that the contributions made to the BPCI Savings Pool are integral to the Gainsharing Arrangements that are at the center of BPCI Model 2 and that the BPCI Savings Pool is not used as a conduit for other payments from the Model 2 Awardee to EIPs or others. These requirements also aid in monitoring and verifying the accuracy of Incentive Payments.

The waiver applies to the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP. For purposes of this waiver and the Model 2 Incentive Payments Waiver, Internal Cost Savings contributed to the BPCI Savings Pool by an EIP must be realized by the EIP during a Performance Year of the BPCI Agreement. This timeframe reflects the requirements of the BPCI Agreement, which specifies that Internal Cost Savings must result from Care Redesign undertaken in connection with services provided to Model 2 Beneficiaries within specific Episodes of Care; a Model 2 Beneficiary is a Medicare fee-for-service beneficiary who receives inpatient hospital care for a Clinical Episode during a Performance Year. *See* section II.U of the BPCI Agreement.

To be protected by the Savings Pool Contribution Waiver, the contributing EIP must be participating in BPCI Model 2 pursuant to the BPCI Agreement, and the contributions of Internal Cost Savings to the BPCI Savings Pool must meet the requirements of the BPCI Agreement and the conditions of this Notice. This waiver does not protect any other contributions or payments, including contributions or payments by EIPs of other amounts or from other funding streams. An EIP may not knowingly make contributions in any fashion (such as by appending additional conditions) to induce a reduction or limitation of Medically Necessary care for patients. As discussed in more detail below, in Part II section 2 of this Notice, incentives to provide alternate and appropriate Medically Necessary care would not be precluded if all other waiver conditions are satisfied.

Under the terms of this waiver, protected contributions must be in the form of an electronic funds transfer to the Model 2 Awardee for deposit or transfer into the BPCI Savings Pool to which the

Model 2 Awardee; these parties may have actual or potential referral relationships and thus the funds transfer could, depending on the circumstances, implicate the fraud and abuse laws.

EIP is assigned pursuant to section III.B of the Implementation Protocol, and, consistent with the BPCI Agreement, must be transferred or deposited in its entirety to the BPCI Savings Pool. This condition ensures that an EIP only receives Incentive Payments from a BPCI Savings Pool for which it has the potential to contribute Internal Cost Savings based on its care for Model 2 Beneficiaries. This condition also increases transparency so that the contributions may be more readily subject to monitoring and verification.

This waiver requires an audit trail of contemporaneous documentation that identifies key information related to the Internal Cost Savings contributions 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 provided it is a viewable 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 this waiver do not supersede, and may be in addition to, any documentation requirements in the BPCI Agreement. All required documentation must be retained for at least 10 years following the date of the last Internal Cost Savings contribution made pursuant to the BPCI Agreement, and must be made available to the Secretary upon request.

For arrangements that meet all of the prescribed conditions in Part I, the waiver period for the Model 2 Savings Pool Contribution Waiver will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated, (2) the expiration date of the last Performance Year plus 6 months, or (3) 6 years plus 6 months from the Effective Date of the BPCI Agreement. These timeframes are intended to align with the terms of the BPCI Agreement, including a reasonable period that would accommodate amendment of the BPCI Agreement to include additional Clinical Episodes after the first Performance Year.

2. Model 2 Incentive Payments Waiver

This waiver applies to the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP to the financial arrangement created when an Incentive Payment is made by the Model 2 Awardee from the BPCI Savings Pool, as described in the BPCI Agreement. As described in greater detail above, there are only two permissible funding streams for the BPCI Savings Pool: EIP Contributions of Internal Cost Savings and Awardee contributions of positive NPRA. This Incentive Payments Waiver protects only Incentive Payments as defined in the BPCI Agreement and only if the Incentive Payment fully complies with all applicable requirements of the BPCI Agreement. An Incentive Payment is defined as: (i) a payment made directly or indirectly from the BPCI Savings Pool to an Awardee or EIP pursuant to a Gainsharing Arrangement set forth in a Participant Agreement, (ii) a payment of a portion of BPCI Savings (as defined in section II.F of the BPCI Agreement) from an EIP to a Gainsharer, pursuant to a written gainsharing agreement between the EIP and the Gainsharer, or (iii) a payment made directly or indirectly from the BPCI Savings Pool to a BPCI

Entity for Administrative Services actually furnished by the BPCI Entity pursuant to a Gainsharing Arrangement.^{9 10}

To be protected by this waiver, the Incentive Payments must meet the requirements of the BPCI Agreement – including, but not limited to, all requirements related to the calculation and distribution of payments, delivery of care, and achievement of quality and performance targets – as well as the conditions of this Notice. This waiver does not protect any other payments made by a Model 2 Awardee, an EIP, a BPCI Entity, or any other person or entity. This waiver only applies to Incentive Payments. Therefore, it does not apply to the payment of funds from any source other than the BPCI Savings Pool or to the payment of funds generated by mechanisms other than the approved gainsharing methodology, as set forth in the BPCI Agreement.

The Model 2 Incentive Payments Waiver does not apply to payments from the BPCI Savings Pool received and retained by a BPCI Entity, except for payments that are solely for Administrative Services that the BPCI Entity actually furnished that are directly related to the administration of a Gainsharing Arrangement. Any other BPCI Savings amounts received by a BPCI Entity must be passed through to other BPCI Entities or EIPs, pursuant to the BPCI Agreement. Parties seeking to use the Model 2 Incentive Payments Waiver to protect payments made to and retained by BPCI Entities must be able to demonstrate through reasonable means that the Administrative Services for which the Incentive Payment is retained by the BPCI Entity are directly related to the administration of the Gainsharing Arrangement. Although fair market value is not required under the waiver for the limited purposes of this 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 this waiver, a protected Incentive Payment must be in the form of an electronic funds transfer. This requirement increases transparency so that payments may be more readily subject to monitoring and verification; in addition, this condition makes clear that payments in the form of in-kind goods or services are not protected. For example, a payment made by a Model 2 Awardee or BPCI Entity to an EIP in the form of free or reduced-price equipment, staff, or space would not be protected. More generally, this waiver does not protect financial arrangements other than Incentive Payments, such as personal services or management contracts, health information technology or other infrastructure arrangements, staffing arrangements, or others, even if the arrangements are of comparable value to the Incentive Payments that would otherwise be paid. All such arrangements must comply with the fraud and

⁹ We note that the definition of *Incentive Payment* specifies that an Incentive Payment between an EIP and a Gainsharer consists of a portion of the *BPCI Savings*. For purposes of the Model 2 Incentive Payments Waiver and this Notice, we use the term *BPCI Savings Pool* because BPCI Savings Pool is defined as a collection of funds that consists solely of BPCI Savings. Further, Section III.C.6 of the Agreement states that Incentive Payments must be derived solely from the BPCI Savings contained in the BPCI Savings Pool. Therefore, an Incentive Payment from an EIP to a Gainsharer necessarily must derive from the BPCI Savings Pool.

¹⁰ Indirect payments to an EIP pursuant to a Gainsharing Arrangement may be made only through one or more BPCI Entities, as specified at section III.C.8 of the BPCI Agreement.

abuse laws; depending on their structure, such arrangements may qualify under existing safe harbors or exceptions or otherwise not violate the law.

Incentive Payments are subject to certain conditions, limitations, and restrictions under the BPCI Agreement. As an additional safeguard, this waiver precludes protection for Incentive Payments if the party making the Incentive Payment imposes additional conditions, limitations, or restrictions on receipt of the Incentive Payment, such as tying the Incentive Payment to expected referrals from the recipient of the payment.¹¹ Therefore, to qualify for waiver protection, no additional conditions, limitations, or restrictions, other than those permitted or required by the BPCI Agreement can be appended explicitly or implicitly to an Incentive Payment. In other words, by way of example, a BPCI Entity that receives an Incentive Payment from a Model 2 Awardee and passes a portion of the Incentive Payment through to an EIP may not condition the EIP's receipt of the passed through Incentive Payment on the EIP's satisfaction of any additional conditions or criteria related to expected or future referral volumes from the EIP to the BPCI Entity. Similarly, an EIP making an Incentive Payment to a Gainsharer may not condition the payment on the Gainsharer's expected or future referrals to the EIP.

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 provided it is a viewable 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 this waiver do not supersede, and may be in addition to, any documentation requirements in the BPCI Agreement. All required documentation must be retained for at least 10 years following the date of the last Incentive Payment, and must be made available to the Secretary upon request.

This waiver does not protect payments knowingly made to reduce or limit Medically Necessary items or services. Arrangements that incentivize the provision of alternate and appropriate Medically Necessary care (*i.e.*, items and services or a combination thereof) consistent with the Care Redesign (such as the use of alternative evidence-based protocols for Medically Necessary items and services) can be protected by this waiver if all other waiver conditions are satisfied. However, knowing payments by a hospital to induce a physician to reduce or limit Medically Necessary items and services without providing acceptable, alternative Medically Necessary items and services would not qualify for this waiver. 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 be protected.

¹¹ The BPCI Agreement prohibits Awardees, EIPs, BPCI Entities, and Gainsharers from conditioning the opportunity to receive Incentive Payments on referrals and prohibits methodologies for calculating Incentive Payments that directly account for the volume or value of referrals. See section III of the BPCI Agreement. The additional safeguard described here offers additional assurance that Incentive Payments will not be used to effectuate referral payments.

For Incentive Payments that meet all of the prescribed conditions in Part I, the waiver period for the Model 2 Incentive Payments Waiver will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated pursuant to section VI.B of the BPCI Agreement, (2) the end of the Effective Period, or (3) 6 years plus 6 months from the Effective Date of the BPCI Agreement. These timeframes are intended to align with the terms of the BPCI Agreement, including a reasonable period that would accommodate amendment of the BPCI Agreement to include additional Clinical Episodes after the first Performance Year pursuant to the BPCI Agreement. These timeframes are designed to include protection for Incentive Payments that may be made after termination by the Awardee or by mutual consent under sections VI.A or VI.C of the BPCI Agreement, provided all requirements of the BPCI Agreement are met and all outstanding NPRA and Excess Spending Amounts owed to CMS for Episodes of Care that occurred prior to the effective date of termination have been settled to CMS's satisfaction.

3. Model 2 Group Practice Gainsharing Waiver

Section II.N of the BPCI Agreement provides that a Gainsharer Group Practice may make Gainsharing Payments to a Gainsharer Group Practice Practitioner solely for Care Redesign activities performed by the Gainsharer Group Practice Practitioner provided that the Gainsharing Payment derives from an Incentive Payment received by the Gainsharer Group Practice. In addition, the EIP that is making the Incentive Payment to the Gainsharer from which the Gainsharing Payment will be made has a written agreement (for purposes of this Notice, the "EIP-Gainsharer Agreement") with the Gainsharer that obligates the Gainsharer to comply with all applicable terms and conditions of the BPCI Agreement. The Gainsharer Group Practice must have a written agreement with the Gainsharer Group Practice Practitioner for the Gainsharing Payments. Moreover, the BPCI Agreement specifies that Gainsharer Group Practice Practitioners must comply with all applicable terms and conditions of the BPCI Agreement, including those applicable to Gainsharers.

The Model 2 Group Practice Gainsharing Waiver addresses the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP to these Gainsharing Payments. The waiver protects Gainsharing Payments if the payment is derived solely from Incentive Payments received by the Gainsharer Group Practice; the Incentive Payment from which the Gainsharing Payment derives fully complies with the Model 2 Incentive Payments Waiver at Part I section B.2 of this Notice; the Gainsharing Payment is made solely for Care Redesign activities performed by the Gainsharer Group Practice Practitioner; and certain other conditions set forth in the waiver in Part I are satisfied. The Model 2 Group Practice Gainsharing Waiver covers only those Gainsharing Payments permitted under, and made in accordance with, the BPCI Agreement. The waiver does not protect any payments that are not part of BPCI Model 2.

The waiver does not apply if Gainsharing Payments are knowingly made to reduce or limit Medically Necessary care. We note that here, as with the other waivers, we are not limiting the restriction on payments to reduce or limit Medically Necessary care to hospital care. As noted above in Part II section 2, incentives for alternate and appropriate Medically Necessary care are not precluded if all other waiver conditions are satisfied.

This waiver requires an audit trail of contemporaneous documentation that identifies key information related to the Gainsharing 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 provided it is a viewable 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 this waiver do not supersede, and may be in addition to, any documentation requirements in the BPCI Agreement. All required documentation must be retained for at least 10 years following the date of the last Incentive Payment or the last Gainsharing Payment, and must be made available to the Secretary upon request.

For arrangements that meet all of the prescribed conditions in Part I, the waiver period for the Model 2 Group Practice Gainsharing Waiver will start on the Effective Date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated pursuant to section VI.B of the BPCI Agreement, (2) the end of the Effective Period, or (3) 6 years plus 6 months from the Effective Date of the BPCI Agreement. These timeframes are intended to align with the terms of the BPCI Agreement, including a reasonable period that would accommodate amendment of the BPCI Agreement to include additional Clinical Episodes after the first Performance Year pursuant to the BPCI Agreement. These timeframes are designed to include protection for Gainsharing Payments that may be made after termination by the Awardee or by mutual consent under sections VI.A or VI.C of the BPCI Agreement, provided all requirements of the BPCI Agreement are met and all outstanding NPRA and Excess Spending Amounts owed to CMS for Episodes of Care that occurred prior to the effective date of termination have been settled to CMS's satisfaction.

4. Model 2 Patient Engagement Incentive Waiver

This waiver protects arrangements involving the provision of in-kind patient engagement incentives by a Model 2 Awardee, EIP, or Gainsharer to a Model 2 Beneficiary for free or below fair market value, subject to conditions enumerated in Part I. The incentive must be provided to the Model 2 Beneficiary during an Episode of Care. This waiver is intended to allow Model 2 Awardees, EIPs, and Gainsharers to offer preventive care items or services¹² and other in-kind items or services permitted under the BPCI Agreement. *See the Implementation Protocol at Attachment B.* Such items and services must advance clinical goals related to the Episode of Care and engage Model 2 Beneficiaries in better managing their own health care. Particular goals of BPCI Model 2, as articulated in the BPCI Agreement, include adherence to drug regimes, adherence to follow up care plans, and management of chronic diseases and conditions. This waiver applies to the Federal anti-kickback statute and Beneficiary Inducements CMP, and includes certain safeguards designed to mitigate the risk of fraud and abuse.

¹² This waiver would apply to items and services that may not be covered by the exception to the Beneficiary Inducements CMP for incentives given to individuals to promote the delivery of preventive care. Section 1128A(i)(6)(D) of the Act. This exception to the Beneficiary Inducements CMP does not apply for purposes of the Federal anti-kickback statute.

In order to balance the goal of patient engagement against the risk that a Model 2 Awardee, EIP, or Gainsharer could use extravagant incentives to steer Model 2 Beneficiaries, we are requiring, among other things, a reasonable connection between the incentives and medical care provided to the Model 2 Beneficiary during the Episode of Care. By way of example, the waiver might cover post-surgical monitoring equipment for surgery patients, but not theatre tickets, which would bear no reasonable connection to the patient's medical care. Similarly, the waiver might cover post-surgical monitoring equipment, but not technology that is more valuable to the beneficiary than what is reasonably necessary for the patient's post-surgical care. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the medical care of the patient. The Incentive Payments must relate to medical care during the Model 2 Beneficiary's Episode of Care. Among other things, this safeguard precludes waiver protection for incentives unrelated to the Episode of Care that might serve to induce beneficiaries inappropriately to receive other medical care not part of the Episode of Care. Additionally, we note that section III.H.2(b) of the BPCI Agreement prohibits Model 2 Awardees, EIPs, and Gainsharers from providing gifts or other remuneration to Model 2 Beneficiaries as inducements for receiving items or services from an Awardee, an Episode Initiator, an EIP, a Gainsharer, a BPCI Entity, or any Third Party Provider, unless otherwise specified in the Implementation Protocol.

All program requirements set forth in the BPCI Agreement, including the Implementation Protocol, governing beneficiary incentives must be met for this waiver to apply. For example, the Implementation Protocol requires that all items and services provided to Model 2 Beneficiaries be approved in writing by the Model 2 Awardee and that the Model 2 Awardee maintain a list of all items exceeding \$10 in value (per service) and the identity of each associated recipient. Further, the Implementation Protocol provides that items or services involving technology provided to Model 2 Beneficiaries may not exceed \$1,000 in value for any one beneficiary in any one Episode of Care, and items of technology exceeding \$50 must remain the property of the Awardee, EIP, or Gainsharer and be retrieved from the Model 2 Beneficiary at the end of the Episode of Care.

This waiver does not protect cash or cash equivalent incentives provided to Model 2 Beneficiaries, such as the waiver of cost-sharing amounts (*i.e.*, copayments and deductibles)¹³; nor does it protect the provision of free or below-cost items or services or coupons provided to Model 2 Beneficiaries by manufacturers or other vendors. We believe these kinds of incentives are prone to greater abuse. This waiver would cover Model 2 Awardees, EIPs, and Gainsharers that give Model 2 Beneficiaries items or services that the Model 2 Awardee, EIP, or Gainsharer received from manufacturers at discounted rates. However, the waiver would not cover the discount arrangement (or any arrangement for free items and services) between the manufacturer and the Model 2 Awardee, EIP, or Gainsharer.

¹³ Such waivers may be covered by existing safe harbors to the Federal anti-kickback statute and exceptions to the Beneficiary Inducements CMP under some circumstances; long-standing guidance makes clear that a provider may waive a Medicare cost-sharing amount based on a good faith, individualized assessment that the beneficiary is in financial need, provided that the waiver is neither routine, nor offered as part of an advertisement or solicitation.

To ensure continuity of care for Model 2 Beneficiaries, if a BPCI Agreement terminates or expires or the waiver period otherwise ends before the end of a Model 2 Beneficiary's Episode of Care, we are providing that the beneficiary may keep any item received during the Episode of Care (unless the BPCI Agreement requires that the item be returned) and may continue to receive any service initiated during the Episode of Care, provided that the item or service complied with the terms of the waiver when initially furnished to the Model 2 Beneficiary and, if a service is involved, the service was in progress when the BPCI Agreement terminated or expired or the waiver period otherwise ended. By way of example, a post-surgical Model 2 Beneficiary receiving free home visits to coordinate in-home care during the recovery period could continue to receive the remainder of planned home visits. Nothing precludes Model 2 Awardees, EIPs, Gainsharers, or others from offering patient engagement incentives to promote clinical care if the incentives fit in an applicable safe harbor or exception, or do not otherwise violate the Federal anti-kickback statute or Beneficiary Inducements CMP. For example, such arrangements may fit in the exception to the Beneficiary Inducements CMP for incentives given to individuals to promote the delivery of preventive care at section 1128A(i)(6)(D) of the Act; 42 CFR 1003.101.

For arrangements that meet all of the prescribed conditions in Part I, the waiver period for the Model 2 Patient Engagement Incentive Waiver will start on the effective date of the BPCI Agreement and will end on *the earlier of* (1) the date on which the BPCI Agreement has been terminated, (2) the expiration date of the last Performance Year, or (3) 6 years from the effective date of the BPCI Agreement. For purposes of the Model 2 Patient Engagement Incentive Waiver, the waiver period does not include additional 6 month "tails" because patient engagement incentives can only be offered during an Episode of Care. We have included provisions to ensure continuity of care for beneficiaries who may be receiving patient engagement incentives during an Episode of Care in the event that the BPCI Agreement terminates or expires, or the waiver period otherwise ends during the Episode of Care.

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

Dated: [July 26, 2013]

/Marilyn Tavenner/

Marilyn Tavenner,
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: [July 26, 2013]

/Daniel R. Levinson/

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