

**Notice of Amended Waivers of Certain
Fraud and Abuse Laws in Connection With the
Bundled Payments for Care Improvement Advanced Model
January 1, 2020**

Introduction

This Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Bundled Payments for Care Improvement Advanced Model (Notice) is being issued in connection with certain programmatic changes being made by the Center for Medicare and Medicaid Innovation (Innovation Center) to the Bundled Payments for Care Improvement Advanced Model (BPCI Advanced Model), beginning January 1, 2020. Accordingly, beginning January 1, 2020, this Notice supersedes the Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Bundled Payments for Care Improvement Advanced Model dated May 25, 2018 (2018 Notice). This Notice includes all of the waivers in the 2018 Notice without substantive changes or limitations, except that this Notice modifies the Internal Cost Savings Contribution Waiver and the NPRA Shared Payment and Shared Repayment Amount Waiver to remove certain restrictions on the contribution and distribution of Internal Cost Savings that previously existed in the BPCI Advanced Model.

Background

Section 1115A(d)(1) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain fraud and abuse laws as may be necessary solely for the purpose of carrying out testing by the Innovation Center of certain innovative payment and service delivery models. The Innovation Center is testing the BPCI Advanced Model under section 1115A(b) of the Act. Pursuant to section 1115A(d)(1), this Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Bundled Payments for Care Improvement Advanced Model (Notice) establishes waivers that protect specified arrangements entered into pursuant to the BPCI Advanced Model.

This Notice is composed of two parts. Part I sets forth the four waivers established for the BPCI Advanced Model and the specific conditions that must be met to qualify for each waiver. The four waivers protect specific financial arrangements or beneficiary incentives that are part of the BPCI Advanced Model and described in the Bundled Payments for Care Improvement Advanced Participation Agreement, as amended from time to time (Participation Agreement), and in the applicable waiver. Each waiver protects only arrangements that meet all of the listed conditions and applies only with respect to the specific laws cited in the waiver. Part II consists of commentary explaining the waiver requirements set forth in Part I as well as general limitations.

I. The Waivers and Applicable Requirements

As used in this Notice:

Acute Care Hospital, Administrative Services, Agreement Performance Period, BPCI Advanced Activities, BPCI Advanced Beneficiary, BPCI Advanced Entity, BPCI Advanced Savings Pool,

Agreement Performance Period, Care Redesign, Clinical Episode, Downstream Episode Initiator, Financial Arrangement, Financial Arrangement List, Internal Cost Savings, Net Payment Reconciliation Amount (NPRA), Non-Convener Participant, NPRA Shared Payment, NPRA Sharing Arrangement, NPRA Sharing Group Practice Practitioner, NPRA Sharing Partner, Participant Profile, Participating Practitioner, Partner Distribution Arrangement, Partner Distribution Payment, Performance Period, PGP NPRA Sharing Partner, Reconciliation Report, Repayment Amount, and Shared Repayment Amount have the meanings set forth in the Participation Agreement.

Program Integrity Determination means a determination by the Centers for Medicare & Medicaid Services (CMS) that the Participant, a Downstream Episode Initiator, a Participating Practitioner, an NPRA Sharing Partner, an NPRA Sharing Group Practice Practitioner, the BPCI Advanced Entity, or another individual or entity performing functions or services related to BPCI Advanced Activities (1) has taken any action that threatens the health and safety of a beneficiary or other patient; (2) has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the BPCI Advanced Model; (3) is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency, including without limitation revocation of Medicare billing privileges, termination of Medicare provider agreement or supplier approval, Medicare or Medicaid program exclusion, or debarment; or (4) is subject to investigation or action by the U.S. Department of Health and Human Services (HHS) (including the HHS Office of Inspector General (OIG) and CMS) or the U.S. Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

Federal Health Care Program means: (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or (2) any State health care program, as defined in section 1128(h) of the Act.

A. Internal Cost Savings Contribution Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to Internal Cost Savings contributions by NPRA Sharing Partners and, if applicable, Non-Convener Participants to the BPCI Advanced Savings Pool, provided all of the following conditions are met:

1. The Participant has entered into a Participation Agreement.
2. The Participant has entered into an NPRA Sharing Arrangement with the NPRA Sharing Partner, and the specific methodology for accruing and calculating Internal Cost Savings contributions are specified in writing.

3. The Internal Cost Savings contributions paid pursuant to the NPRA Sharing Arrangement are not offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the BPCI Advanced Model.
4. Internal Cost Savings contributions must be made solely and directly to the BPCI Advanced Savings Pool.
5. The NPRA Sharing Partner's and, if applicable, Non-Convener Participant's Internal Cost Savings contributions do not exceed the measurable, actual, and verifiable cost savings realized by the NPRA Sharing Partner and, if applicable, Non-Convener Participant resulting from Care Redesign undertaken by the NPRA Sharing Partner and, if applicable, Non-Convener Participant in connection with furnishing items and services to BPCI Advanced Beneficiaries within Clinical Episodes for which the Participant is accountable pursuant to the Participant's Participant Profile.
6. No NPRA Sharing Partner may contribute Internal Cost Savings to the BPCI Advanced Savings Pool for a Performance Period unless: (i) the NPRA Sharing Partner is identified on the Financial Arrangement List during the applicable Performance Period and (ii) the NPRA Sharing Partner engaged in BPCI Advanced Activities during the applicable Performance Period.
7. No Internal Cost Savings may be contributed to the BPCI Advanced Savings Pool by the Participant for a Performance Period unless the Participant is a Non-Convener Participant and the Internal Cost Savings are realized from Care Redesign undertaken in Model Year 3 or a subsequent Model Year.
8. The Participant must make available to OIG and CMS, upon request, all materials and records sufficient to establish whether the Internal Cost Savings contributions were contributed in a manner that meets the conditions of this waiver.

For arrangements that meet all of the preceding conditions, the waiver period will start on the date of this Notice and end 6 months after the effective date of termination of the Participation Agreement, unless CMS terminates the Participation Agreement as a result of a Program Integrity Determination, in which case the Internal Cost Savings Contribution Waiver will end on the effective date of termination of the Participation Agreement.

B. NPRA Shared Payment and Shared Repayment Amount Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to NPRA Shared Payments made from the BPCI Advanced Savings Pool to an NPRA Sharing Partner and Shared Repayment Amounts paid by an NPRA Sharing Partner into the BPCI Advanced Savings Pool, provided all of the following conditions are met:

1. The Participant has entered into a Participation Agreement.
2. The Participant has entered into an NPRA Sharing Arrangement with the NPRA Sharing Partner, and the financial or economic terms of any NPRA Shared Payments or Shared Repayment Amounts are specified in writing.
3. The remuneration set forth in and paid pursuant to the NPRA Sharing Arrangement is not offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the BPCI Advanced Model.
4. NPRA Shared Payments must be derived solely and directly from the BPCI Advanced Savings Pool.
5. Shared Repayment Amounts must be made solely and directly to the BPCI Advanced Savings Pool.
6. No NPRA Shared Payments may be made from the BPCI Advanced Savings Pool to an NPRA Sharing Partner, unless: (i) the recipient NPRA Sharing Partner is identified on the Financial Arrangement List during the applicable Performance Period, (ii) the recipient NPRA Sharing Partner engaged in BPCI Advanced Activities during the applicable Performance Period, and (iii) the recipient NPRA Sharing Partner has achieved the quality performance targets necessary to receive the NPRA Shared Payments, as specified in the NPRA Sharing Arrangement.
7. No Shared Repayment Amount may be made from an NPRA Sharing Partner to the BPCI Advanced Savings Pool unless: (i) the Participant owes CMS a Repayment Amount, as set forth in a final Reconciliation Report; (ii) the NPRA Sharing Partner is identified on the Financial Arrangement List during the applicable Performance Period; and (iii) the NPRA Sharing Partner engaged in BPCI Advanced Activities during the applicable Performance Period.
8. Neither the NPRA Shared Payment nor the Shared Repayment Amount may be a loan, and the NPRA Shared Payment must not be an advance payment of an expected or potential NPRA Shared Payment.
9. The Participant must make available to OIG and CMS, upon request, all materials and records sufficient to establish whether the NPRA Shared Payment or Shared Repayment Amount was distributed in a manner that meets the conditions of this waiver.

For arrangements that meet all of the preceding conditions, the waiver period will start on the date of this Notice and end 6 months after the effective date of termination of the Participation Agreement, unless CMS terminates the Participation Agreement as a result of a Program Integrity Determination, in which case the NPRA Shared Payment and Shared Repayment Amount Waiver will end on the effective date of termination of the Participation Agreement.

C. Partner Distribution Payment and Shared Repayment Amount Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Federal physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to a Partner Distribution Payment from a PGP NPRA Sharing Partner to an NPRA Sharing Group Practice Practitioner and a payment made by an NPRA Sharing Group Practice Practitioner to a PGP NPRA Sharing Partner of an apportioned Shared Repayment Amount, provided all of the following conditions are met:

1. The Participant has entered into a Participation Agreement.
2. The PGP NPRA Sharing Partner has entered into a Partner Distribution Arrangement with the NPRA Sharing Group Practice Practitioner, and the financial or economic terms of any Partner Distribution Payments or Shared Repayment Amounts are specified in writing.
3. The remuneration set forth in and paid pursuant to the Partner Distribution Arrangement is not offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the BPCI Advanced Model.
4. All Partner Distribution Payments must be derived solely from NPRA Shared Payments received by the PGP NPRA Sharing Partner directly from the BPCI Advanced Savings Pool.
5. Any apportioned Shared Repayment Amounts received by the NPRA Sharing Partner must be directed solely to the BPCI Advanced Savings Pool.
6. No Partner Distribution Payments may be made by the PGP NPRA Sharing Partner to its NPRA Sharing Group Practice Practitioner unless: (i) the recipient NPRA Sharing Group Practice Practitioner is identified on the Financial Arrangement List during the applicable Performance Period; (ii) the NPRA Shared Payment the PGP NPRA Sharing Partner received satisfied the conditions of the NPRA Shared Payment and Shared Repayment Amount Waiver or otherwise complied with the Federal anti-kickback statute and the Federal physician self-referral law; (iii) the recipient NPRA Sharing Group Practice Practitioner engaged in BPCI Advanced Activities during the applicable Performance Period; and (iv) the recipient NPRA Sharing Group Practice Practitioner has achieved the quality performance targets necessary to receive the Partner Distribution Payments, as specified in the Partner Distribution Arrangement.
7. No Shared Repayment Amount may be apportioned by a PGP NPRA Sharing Partner to an NPRA Sharing Group Practice Practitioner unless: (i) the PGP NPRA Sharing Partner owes the Participant a Repayment Amount, as set forth in a final Reconciliation Report; (ii) the NPRA Sharing Group Practice Practitioner is

identified on the Financial Arrangement List during the applicable Performance Period; and (iii) the NPRA Sharing Group Practice Practitioner was engaged in BPCI Advanced Activities during the applicable Performance Period.

8. Neither the Partner Distribution Payment nor the Shared Repayment Amount may be a loan, and the Partner Distribution Payment must not be an advance payment of an expected or potential Partner Distribution Payment.
9. The PGP NPRA Sharing Partner must make available to OIG and CMS, upon request, all materials and records sufficient to establish whether the Partner Distribution Payment was distributed in a manner that meets the conditions of this waiver.

For arrangements that meet all of the preceding conditions, the waiver period will start on the date of this Notice and end 6 months after the effective date of termination of the Participation Agreement, unless CMS terminates the Participation Agreement as a result of a Program Integrity Determination, in which case the Partner Distribution Payment and Shared Repayment Amount Waiver will end on the effective date of termination of the Participation Agreement.

D. Waiver for Beneficiary Engagement Incentives Provided to BPCI Advanced Beneficiaries (BEI Waiver)

Pursuant to section 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (relating to the Beneficiary Inducements Civil Monetary Penalty (CMP)) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to in-kind items and services provided to a BPCI Advanced Beneficiary if all of the following conditions are met:

1. The item or service is furnished directly to the BPCI Advanced Beneficiary during a Clinical Episode by the Participant, a Participating Practitioner, Downstream Episode Initiator, NPRA Sharing Partner, or NPRA Sharing Group Practice Practitioner.
2. There is a reasonable connection between the item and service and medical care provided to the BPCI Advanced Beneficiary.
3. The items or services:
 - a. are preventive care items or services, or
 - b. advance one or more of the following clinical goals:
 - i. adherence to a treatment regime,
 - ii. adherence to a drug regime,
 - iii. adherence to a follow-up care plan, or
 - iv. management of a chronic disease or condition.

4. The item or service is not tied to the receipt of items or services reimbursable by Federal Health Care Programs outside of the BPCI Advanced Model.
5. The Participant, Participating Practitioner, Downstream Episode Initiator, NPRA Sharing Partner, or NPRA Sharing Group Practice Practitioner that furnished the item or service to the BPCI Advanced Beneficiary must make available to OIG, upon request, all materials and records sufficient to establish whether the items and services were distributed in a manner that meets the conditions of this waiver.

For arrangements that meet all of the preceding conditions, the waiver period will start on the date of this Notice and end upon completion of the last Clinical Episode initiated during the Agreement Performance Period.

A BPCI Advanced Beneficiary may keep items received, or, for any items loaned, complete the term for which the item was loaned, under this waiver and may receive the remainder of any service covered by this waiver if the service was initiated during a Clinical Episode.

II. Explanation of Waiver Requirements

The waivers are intended to allow Participants, NPRA Sharing Partners, NPRA Sharing Group Practice Practitioners, Participating Practitioners, and Downstream Episode Initiators flexibility to negotiate and enter into certain arrangements or furnish beneficiary engagement incentives under the BPCI Advanced Model without risking sanctions under the Federal anti-kickback statute, the Beneficiary Inducements CMP, or the Federal physician self-referral law. The waivers set forth in this Notice have been developed in consultation with the Innovation Center, which is administering and testing the BPCI Advanced Model. In accordance with Section 1115A(d)(1) of the Act, the Secretary has determined that these waivers are necessary to carry out testing of the BPCI Advanced Model. The Participation Agreement includes requirements that are designed to mitigate risks of fraud and abuse. The objective of the waiver conditions is to ensure that protected arrangements and beneficiary engagement incentives are consistent with the quality, care coordination, and cost-reduction goals of the BPCI Advanced Model; are subject to safeguards designed to mitigate the risk of fraud and abuse; and can be readily monitored and audited.

Commentary Applicable to Specific Waivers

A. Internal Cost Savings Contribution Waiver

Under the BPCI Advanced Model, a Participant may elect to enter into a NPRA Sharing Arrangement with an NPRA Sharing Partner that permits the NPRA Sharing Partner and, if applicable, the Non-Convener Participant to contribute Internal Cost Savings to the BPCI Advanced Savings Pool as permitted by the Participation Agreement. This waiver allows the relevant parties flexibility to negotiate and enter into such arrangements without risking sanctions under the Federal anti-kickback statute or the Federal physician self-referral law.

We note that beginning January 1, 2020, the Participation Agreement permits: (1) Non-Convener Participants to contribute Internal Cost Savings to the BPCI Advanced Savings Pool

if Internal Cost Savings are realized from Care Redesign undertaken in Model Year 3 (2020) or a subsequent Model Year; and (2) NPRA Sharing Partners to contribute Internal Cost Savings to the BPCI Advanced Savings Pool for a Performance Period regardless of whether the Participant received an NPRA payment from CMS, as set forth in a final Reconciliation Report. This Internal Cost Savings Contribution Waiver has been amended to align with these programmatic changes.

The Participation Agreement sets forth certain requirements that must be met when the Participant enters into an NPRA Sharing Arrangement that permits Internal Cost Savings contributions from the NPRA Sharing Partner and, if applicable, Non-Convener Participant. This Internal Cost Savings Contribution Waiver sets forth certain requirements that must be met to qualify for waiver protection. For example, the waiver prohibits contributions that are offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the BPCI Advanced Model. Under the prohibition, the amount of Internal Cost Savings that an NPRA Sharing Partner and, if applicable, Non-Convener Participant contributes to the BPCI Advanced Savings Pool under an NPRA Sharing Arrangement cannot be a payment that is in any way related to, or in exchange for, any items and services outside the model. For example, a Participant could not require an NPRA Sharing Partner that does not make frequent referrals to a Participant to contribute a higher percentage of Internal Cost Savings to the BPCI Advanced Savings Pool than an NPRA Sharing Partner that is a source of frequent referrals. We note that the Participation Agreement includes various other requirements that help guard against fraud and abuse (for example, requiring that Internal Cost Savings contributions be administered, received, and apportioned in accordance with generally accepted accounting principles). If the waiver requirements are satisfied by an NPRA Sharing Partner but not by the Non-Convener Participant, only the Internal Cost Savings contributed by the NPRA Sharing Partner would be protected by the Internal Cost Savings Contribution Waiver.

Because the NPRA Sharing Partner and, if applicable, Non-Convener Participant need a reasonable period of time to calculate Internal Cost Savings after they are earned, the waiver applies to Internal Cost Savings earned during the term of the Participation Agreement, even if subsequently contributed to the BPCI Advanced Savings Pool. If, however, CMS terminates the Participation Agreement as a result of a Program Integrity Determination, the Internal Cost Savings Contribution Waiver will end on the effective date of termination of the Participation Agreement.

B. NPRA Shared Payment and Shared Repayment Amount Waiver

Under the BPCI Advanced Model, the Participant may elect to enter into an NPRA Sharing Arrangement with an NPRA Sharing Partner, pursuant to which the Participant would make NPRA Shared Payments and receive Shared Repayment Amounts as permitted under the Participation Agreement. This waiver allows the relevant parties flexibility to negotiate and enter into payment arrangements without risking sanctions under the Federal anti-kickback statute or Federal physician self-referral law.

The Participation Agreement sets forth certain requirements that must be met when the Participant enters into an NPRA Sharing Arrangement. This NPRA Shared Payment and

Shared Repayment Amount Waiver sets forth certain requirements that must be met to qualify for waiver protection. For example, the waiver prohibits payments that are offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the BPCI Advanced Model. Under the prohibition, the amount the Participant pays an NPRA Sharing Partner, or an NPRA Sharing Partner pays a Participant, under an NPRA Sharing Arrangement cannot be a payment that is in any way related to, or in exchange for, any items and services outside the model. For example, a Participant that is an Acute Care Hospital could not offer a physician group practice that is an NPRA Sharing Partner more favorable terms in an NPRA Sharing Arrangement than another type of provider or supplier that is an NPRA Sharing Partner in exchange for referrals of Medicare beneficiaries who are not part of the model.

We have incorporated certain requirements included in the Participation Agreement as of the date of this Notice into the NPRA Shared Payment and Shared Repayment Amount Waiver as conditions of waiver protection, which includes certain requirements for payments flowing into or out of the BPCI Advanced Savings Pool. We note that, in accordance with the Participation Agreement, the BPCI Advanced Savings Pool may be maintained by the Participant or a BPCI Advanced Entity on the Participant's behalf. In the latter case, the BPCI Advanced Entity may retain funds distributed from the BPCI Advanced Savings Pool solely for Administrative Services actually performed by the BPCI Advanced Entity.

Because the Participant may (1) not receive the final Reconciliation Report from CMS that indicates whether CMS owes an NPRA payment to the Participant or the Participant owes a Repayment Amount to CMS until after the termination or expiration of the Participation Agreement; and (2) need a reasonable period of time to calculate Internal Cost Savings after they are earned, the waiver applies to NPRA Shared Payments and Shared Repayment Amounts owed as set forth in the final Reconciliation Report, even if distributed subsequently. If, however, CMS terminates the Participation Agreement as a result of a Program Integrity Determination, the NPRA Shared Payment and Shared Repayment Amount Waiver will end on the effective date of termination of the Participation Agreement.

We note that beginning January 1, 2020, the Participation Agreement permits NPRA Shared Payments to be made from the BPCI Advanced Savings Pool to an NPRA Sharing Partner regardless of whether the Participant received an NPRA payment from CMS, as set forth in a final Reconciliation Report. This NPRA Shared Payment and Shared Repayment Amount Waiver has been amended to reflect this change.

C. Partner Distribution Payment and Shared Repayment Amount Waiver

Under the BPCI Advanced Model, a PGP NPRA Sharing Partner may elect to enter into a Partner Distribution Arrangement with an NPRA Sharing Group Practice Practitioner as permitted under the Participation Agreement. This waiver allows the relevant parties flexibility to negotiate and enter into payment arrangements without risking sanctions under the Federal anti-kickback statute or the Federal physician self-referral law.

The Participation Agreement sets forth certain requirements that must be met when the PGP

NPRA Sharing Partner enters into a Partner Distribution Arrangement. This Partner Distribution Payment and Shared Repayment Amount Waiver sets forth certain requirements that must be met to qualify for waiver protection. For example, the waiver prohibits payments that are offered, paid, solicited, or received in return for, or to induce or reward, any referrals or other business generated outside of the BPCI Advanced Model. Under the prohibition, the amount a PGP NPRA Sharing Partner pays an NPRA Sharing Group Practice Practitioner, or an NPRA Sharing Group Practice Practitioner pays a PGP NPRA Sharing Partner under a Partner Distribution Arrangement, cannot be a payment that is in any way related to, or in exchange for, any items and services outside the model.

We have incorporated certain requirements included in the Participation Agreement as of the date of this Notice into the Payment Distribution Arrangement Waiver as conditions of waiver protection.

Because the PGP NPRA Sharing Partner may not receive notice from the Participant indicating whether the Participant owes an NPRA Shared Payment to the PGP NPRA Sharing Partner or the PGP NPRA Sharing Partner owes a Shared Repayment Amount to the Participant until after the termination or expiration of the Participation Agreement, the waiver applies to Partner Distribution Payments and Shared Repayment Amounts owed as set forth in the Partner Distribution Arrangement, even if distributed subsequently. If, however, CMS terminates the Participation Agreement as a result of a Program Integrity Determination, the Partner Distribution Payment and Shared Repayment Amount Waiver will end on the effective date of termination of the Participation Agreement.

D. Waiver for Beneficiary Incentives Provided to BPCI Advanced Beneficiaries (BEI Waiver)

Under the BPCI Advanced Model, a Participant may elect to furnish in-kind items and services to BPCI Advanced Beneficiaries during the Agreement Performance Period. Under the Participation Agreement, the incentives must be in-kind. Any particular item or service permitted by CMS as an in-kind beneficiary engagement incentive under the Participation Agreement would be covered by the BEI Waiver, provided all waiver conditions are met.

Waivers of cost-sharing amounts (for example, copayments and deductibles) are not protected by the waiver.¹

Under the Participation Agreement, there must be a reasonable connection between the items and services provided to the BPCI Advanced Beneficiary and the medical care provided to the BPCI Advanced Beneficiary. We have incorporated this “reasonable connection” requirement into our waiver as a condition of waiver protection.

In addition, to receive waiver protection, the items and services furnished must be preventive

¹ Any such practices must continue to comply with Federal fraud and abuse laws. For additional guidance, see, e.g., OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (August 2002).

care items or services or advance a clinical goal for the BPCI Advanced Beneficiary, including adherence to a treatment regime, adherence to a drug regimen, adherence to a follow-up care plan, or management of a chronic disease or condition.

Nothing in this Notice prevents the Participant, Participating Practitioners, Downstream Episode Initiators, NPRA Sharing Partners, or NPRA Sharing Group Practice Practitioners from providing, or structuring arrangements to provide other items or services to BPCI Advanced Beneficiaries if they can do so in a manner that complies with existing law and, as applicable, the Participation Agreement.

The Participant must make available to OIG, upon request, all materials and records sufficient to establish whether the items and services were distributed in a manner that meets the conditions of this waiver.

This waiver does not include a “tail” period after the Participation Agreement is terminated or expires. However, to ensure continuity of care for BPCI Advanced Beneficiaries who are in a Clinical Episode at the time the Participation Agreement is terminated or expires, the waiver will continue to apply until completion of the last Clinical Episode initiated during the Agreement Performance Period.

E. General Limitations

- The waivers set forth in Part I of this Notice apply to arrangements or beneficiary engagement incentives that squarely meet all of the conditions pertaining to that particular waiver. If an arrangement or beneficiary engagement incentive does not meet all of the waiver conditions, it does not qualify for waiver protection. Waivers do not provide retrospective protection; an arrangement or beneficiary engagement incentive must meet all of the waiver conditions during the period for which waiver protection is sought.
- Apart from meeting applicable waiver conditions, no special action (such as submission of a separate application for a waiver) is required by parties to be covered by these waivers.
- A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (i) does not implicate the specific fraud and abuse law; (ii) implicates the law but fits within an existing exception or safe harbor; or (iii) otherwise complies with the law. Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Federal physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (sections 1128B(b)(1) and (2) of the Act), the Beneficiary Inducements CMP (section 1128A(a)(5) of the Act), or any other applicable law.
- Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other applicable Federal or State laws and regulations, including, but not limited to, any anti-fraud laws,

other than those specified above. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the Participation Agreement.

- We reserve the right to reconsider any waiver and, where the public interest requires, to modify or terminate a waiver on a prospective basis with respect to some or all entities and individuals specified in the waivers. The modification, suspension, or termination of part or all of any waiver does not require advance notice. We anticipate, however, that the circumstances under which no advance notice would be provided would be limited to egregious conduct that poses an imminent risk of harm to programs or patients.

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

Dated: [December 13, 2019]

/Seema Verma/

Seema Verma
Administrator
Centers for Medicare & Medicaid Services

As to section 1128A(a)(5) and sections 1128B(b)(1) and (2) of the Social Security Act:

Dated: [December 13, 2019]

/Joanne M. Chiedi/

Joanne M. Chiedi
Acting Inspector General
Department of Health and Human Services