Notice of Waivers of Certain Fraud and Abuse Laws
in Connection with the Oncology Care Model

April 28, 2016

Section 1115A(d)(1) of the Social Security Act (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 testing by the Center for Medicare & Medicaid Innovation (Innovation Center) of certain innovative payment and service delivery models. This Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Oncology Care Model (Notice) is issued under this authority. The Innovation Center is testing the Oncology Care Model (OCM) under section 1115A(b) of the Act. The Secretary has determined that the waivers in this Notice are necessary to carry out the testing of OCM. The waivers established by this Notice apply only to OCM and are not applicable outside of OCM.

This Notice is composed of two parts. Part I sets forth the four waivers established for OCM 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 OCM and described in the Oncology Care Model Participation Agreement between the Centers for Medicare & Medicaid Services (CMS) and the Practice (Participation Agreement).[1] Each waiver protects only arrangements or beneficiary incentives that meet all of the listed conditions. Each waiver applies only with respect to the specific laws cited in the waiver. Part II consists of commentary explaining the waiver requirements in Part I.

The first waiver (Pooling Waiver) applies to certain financial arrangements that arise when certain performance-based payments and certain recoupment payments are made under Pooling Arrangements described in the Participation Agreement. The second waiver (Care Partner Waiver) applies to the distribution of certain performance-based payments by a Practice to its Care Partners and the payment of certain recoupment payments by Care Partners to the Practice under PBP Sharing Arrangements, as described in the Participation Agreement. The third waiver (Group Practice Distributions Waiver) protects certain financial arrangements between a physician group practice (PGP) that is a Care Partner (PGP Care Partner) and the group practice's members (PGP Members). Lastly, this Notice contains a waiver that protects certain beneficiary incentives (BI Waiver) in the form of in-kind items or services provided to OCM Beneficiaries to promote preventive care and advance certain clinical goals of OCM.

Part I: OCM Waivers and Applicable Requirements

Terms defined in the Participation Agreement that are used in this Notice have the meaning set forth in the Participation Agreement. These terms include, but are not limited to, the following: Cancer, Care Partner, Episode, Final Performance Period, Medically Necessary, OCM Activities, OCM Beneficiary, Partner Distribution Arrangement, Partner Distribution Payment, PBP, PBP Shared Payment, PBP Sharing Agreement, PBP Sharing Arrangement, PGP, PGP Care Partner, PGP Member, Pool, Pooled Non-Payee, Pooled OCM Participant, Pooled Payee, Pooling Agreement, Pooling Arrangement, Pool PBP Payment, Pool Recoupment Payment, Practice, Practice Redesign Activities, Reconciliation, and Shared Recoupment Payment.

1. Waiver for Distribution of Pool PBP Payments and Payment of Pool Recoupment Payments (Pooling Waiver)

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the 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 the distribution of Pool PBP Payments and the payment of Pool Recoupment Payments under a Pooling Arrangement, provided all of the following conditions are met:

[1] As explained below, this Notice uses certain defined terms that also appear in the Participation Agreement.

a. The Pooling Arrangement has been approved by CMS and complies with the following requirements of the Participation Agreement:
   - (VII)(D)(3) (Pooling Arrangement entered into prior to providing care);[2]
   - (VII)(D)(5) (Pooled Non-Payee has implemented all Practice Redesign Activities);
   - (VII)(D)(6) (conditions for Pooled Non-Payee's liability for Pool Recoupment Payment, if any);
   - (VII)(D)(7) (opportunity to make or receive Pool PBP Payments or Pool Recoupment Payments not conditioned on the volume or value of referrals);
   - (VII)(D)(8)(a) and (b) (Pool PBP Payments derived solely from PBP, and they are not loans);
   - (VII)(D)(9) (Pool Recoupment Payments comply with timeframes, and they are not loans);
   - (VII)(D)(11) (no inducement to reduce or limit Medically Necessary services);
   - (VII)(D)(12) (no restriction on decisions in the best interests of patients);
   - (VII)(D)(14) (methodology for determining payments does not directly account for the volume or value of referrals or business otherwise generated);
   - (VII)(D)(15) (Pool PBP Payments and Pool Recoupment Payments not based on the volume or value of referrals of Federal health care program patients who are not OCM Beneficiaries);
   - (VII)(D)(18) (receipt or amount of payments not a condition of doing business with the Pooled Non-Payee);
   - (VII)(D)(19) (Pool Recoupment Payment made solely to repay a portion of OCM Recoupment owed by the Pooled Payee); and
   - (IX)(F) (beneficiary choice).

b. The Pool PBP Payment is not made to a Pooled Non-Payee if CMS has notified the Pooled Payee that the Pooled Non-Payee is subject to any action for noncompliance with the fraud and abuse laws or for the provision of substandard care to OCM Beneficiaries or other integrity problems.

c. The Pooling Arrangement is set forth in a Pooling Agreement that specifies the methodology for determining the Pool PBP Payments and Pool Recoupment Payments.

d. The Pooling Agreement must be executed by the parties in advance of any distribution of Pool PBP Payments or any payment of Pool Recoupment Payments.

e. The Pooled Payee and the Pooled Non-Payee paying or receiving the Pool PBP Payments or the Pool Recoupment Payments must maintain documentation of the Pooling Agreement and the payment or receipt of Pool PBP Payments or Pool Recoupment Payments; retain such documentation for at least 10 years following the last Pool PBP Payment or Pool Recoupment Payment (as applicable); and make such documentation available to the Secretary upon request. All documentation must be contemporaneous with the correlating event (e.g., documentation of payment of a Pool PBP Payment must be contemporaneous with the distribution of such payment).

f. The Pooled Payee and the Pooled Non-Payee do not impose any conditions, limitations, or restrictions on the Pooling Arrangement other than those required or permitted by the Participation Agreement or this waiver.

[2] For the convenience of readers, these waivers include parenthetical, summary descriptions of certain provisions of the Participation Agreement. These parenthetical summaries do not purport to interpret the Participation Agreement and are not substitutes for reading and complying with the provisions as set forth in the Participation Agreement.

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

For the distribution of Pool PBP Payments to a Pooled Non-Payee that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Pooled Non-Payee's Participation Agreement and will end 24 months following the last day of the Pooled Non-Payee's Final Performance Period, except that if CMS terminates the Participation Agreement of the Pooled Non-Payee pursuant to section XXII(C)(1)(d) and CMS determines pursuant to section XXII(C)(2) that no payment of PBP is warranted after termination, the waiver period will end on the effective date of termination of the Participation Agreement.

For the payment of Pool Recoupment Payments by a Pooled Non-Payee that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Pooled Non-Payee's Participation Agreement.

2. Waiver for Distribution of PBP Shared Payments and Payment of Shared Recoupment Payments (Care Partner Waiver)

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the 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 the distribution of PBP Shared Payments from a Practice to a Care Partner and the payment of Shared Recoupment Payments from a Care Partner to a Practice under a PBP Sharing Arrangement, provided all of the following conditions are met:

a. The PBP Sharing Arrangement complies with the following requirements in the Participation Agreement:
    - XII(B)(3) (voluntary participation in PBP Sharing Arrangement);
    - XII(B)(4) (PBP Sharing Arrangement entered into prior to providing care);
    - XII(B)(5) (requirements for Care Partner to receive PBP Shared Payment);
    - XII(B)(6) (conditions for Care Partner's liability for Shared Recoupment Payment, if any);
    - XII(B)(7) (opportunity to make or receive PBP Shared Payments or Shared Recoupment Payments not conditioned on the volume or value of referrals);
    - XII(B)(8)(a) and (b) (PBP Shared Payments derived solely from PBP or Pool PBP Payments, and they are not loans);
    - XII(B)(9) (Shared Recoupment Payments comply with timeframes, and they are not loans);
    - XII(B)(10) (no PBP Shared Payments if CMS notifies the Practice of certain noncompliance, substandard care, or integrity problems of a Care Partner);
    - XII(B)(12) (no inducement to reduce or limit Medically Necessary services);
    - XII(B)(13) (no restriction on decisions in the best interests of patients);
    - XII(B)(15) (methodology for determining PBP Shared Payments substantially based on criteria related to quality of care and the provision of OCM Activities);
    - XII(B)(16) (methodology for determining Shared Recoupment Payments does not directly account for the volume or value of referrals or business otherwise generated);
    - XII(B)(17) (PBP Shared Payments and Shared Recoupment Payments not based on the volume or value of referrals of Federal health care program patients who are not OCM Beneficiaries);
    - XII(B)(21) (Shared Recoupment Payments made solely to repay a portion of OCM Recoupment or Pool Recoupment Payment owed by the Practice); and
    - IX(F) (beneficiary choice).

b. If the Practice is a Pooled Non-Payee, the PBP Shared Payment must be derived solely from a Pool PBP Payment that meets the conditions of the Pooling Waiver.
c. The PBP Sharing Arrangement is set forth in a PBP Sharing Agreement that specifies the methodology for determining the PBP Shared Payments and Shared Recoupment Payments.
d. The PBP Sharing Agreement must be executed by the parties in advance of any distribution of PBP Shared Payments or the payment of any Shared Recoupment Payments.
e. The Practice and the Care Partner must maintain documentation of the PBP Sharing Agreement and the payment or receipt of PBP Shared Payments or Shared Recoupment Payments; retain such documentation for at least 10 years following the last PBP Shared Payment or Shared Recoupment Payment (as applicable); and make such documentation available to the Secretary upon request. All documentation must be contemporaneous with the correlating event (e.g., documentation of payment of a PBP Shared Payment must be contemporaneous with the distribution of such payment).
f. The Practice and the Care Partner do not impose any conditions, limitations, or restrictions on the PBP Sharing Arrangement other than those required or permitted by the Participation Agreement or this waiver.
g. The Participation Agreement, as amended from time to time, does not provide that this waiver is inapplicable.

For the distribution of PBP Shared Payments to a Care Partner from the Practice that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Participation Agreement of the Practice distributing the PBP Shared Payment to the Care Partner and will end 24 months following the last day of the Practice's Final Performance Period, except that if CMS terminates the Participation Agreement of the Practice pursuant to section XXII(C)(1)(d) and CMS determines pursuant to section XXII(C)(2) that no payment of PBP is warranted after termination, the waiver period will end on the effective date of termination of the Participation Agreement.

For the payment by a Care Partner to the Practice of Shared Recoupment Payments that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Practice's Participation Agreement.

3. Waiver for Group Practice Distributions (Group Practice Distributions Waiver)

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the 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 the distribution of Partner Distribution Payments from a PGP Care Partner to its PGP Members under a Partner Distribution Arrangement, provided all of the following conditions are met:

a. The Partner Distribution Arrangement complies with the following requirements in the Participation Agreement:
    - XIII(B)(2) (voluntary participation in Partner Distribution Arrangement);
    - XIII(B)(4)(a) and (b) (Partner Distribution Payments derived solely from PBP Shared Payments, and they are not loans);
    - XIII(B)(5) (Partner Distribution Arrangement entered into prior to providing care);
    - XIII(B)(6) (no restriction on decisions in the best interests of patients);
    - XIII(B)(7) (no Partner Distribution Payments if CMS notifies the Practice of certain noncompliance, substandard care, or integrity problems of a PGP Member);

- XIII(B)(8) (opportunity to make or receive Partner Distribution Payments not conditioned on the volume or value of referrals);
- XIII(B)(9) (methodology for determining Partner Distribution Payments complies with applicable law or substantially based on criteria related to quality of care and the provision of OCM Activities);
- XIII(B)(10) (Partner Distribution Payments not based on the volume or value of referrals of Federal health care program patients who are not OCM Beneficiaries);
- XIII(B)(11) (PGP Member must engage in OCM Activities);
- XIII(B)(12) (PBP Shared Payment shared only with PGP Members of PGP Care Partner);
- XIII(B)(16) (no inducement to reduce or limit Medically Necessary services); and
- IX(F) (beneficiary choice).

b. The PGP Care Partner derives the Partner Distribution Payments solely from PBP Shared Payments distributed by the Practice to the PGP Care Partner pursuant to a PBP Sharing Arrangement. Such distribution from the Practice to the PGP Care Partner must satisfy the conditions of the Care Partner Waiver or otherwise comply with the Federal anti-kickback statute and the physician self-referral law.

c. The Partner Distribution Arrangement is set forth in a written agreement that specifies the methodology for determining the Partner Distribution Payments and is executed by the parties in advance of any distribution.

d. The PGP Care Partner must maintain documentation of the written agreement setting forth the Partner Distribution Arrangement and the payment or receipt of Partner Distribution Payments; retain such documentation for at least 10 years following the last Partner Distribution Payment; and make such documentation available to the Secretary upon request. All documentation must be contemporaneous with the correlating event (e.g., documentation of payment of a Partner Distribution Payment must be contemporaneous with the distribution of such payment).

e. The PGP Care Partner does not impose any conditions, limitations, or restrictions on the Partner Distribution Arrangement other than those required or permitted by the Participation Agreement or this waiver.

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

For the distribution of Partner Distribution Payments to a PGP Member by a PGP Care Partner that meet all of the preceding conditions, the waiver period will start on the Effective Date of the PBP Sharing Agreement of the PGP Care Partner distributing the Partner Distribution Payment and will end 24 months following the last day of the Final Performance Period for the Practice that made the PBP Shared Payment to the PGP Care Partner.

4. Waiver for Beneficiary Incentives Provided to OCM Beneficiaries (BI 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) law) 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 to an OCM Beneficiary if all of the following conditions are met:

a. The item or service is provided to an OCM Beneficiary by the Practice or by an OCM Practitioner (other than an OCM Practitioner who is an independent contractor).

b. The item or service is in-kind.

c. The item or service is provided during the OCM Beneficiary's Episode.

d. The item or service is reasonably connected to the medical care provided to the OCM Beneficiary during the Episode and
    - is for preventive care, or
    - advances at least one of the following clinical goals by engaging the OCM Beneficiary in better managing his or her own health:
        1. OCM Beneficiary adherence to drug regimens related to Cancer;
        2. OCM Beneficiary adherence to a care plan related to Cancer; or
        3. Management of a Cancer diagnosis.

e. The item or service is not tied to the receipt of items or services outside the Episode.

f. All requirements of section IX(G)(3) of the Participation Agreement (documentation of beneficiary incentives) are met.

g. All requirements of sections IX(C) and (F) of the Participation Agreement (beneficiary notifications and beneficiary choice) are met.

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

For items and services that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Practice's Participation Agreement and will end six months following the last day on which the Practice could have initiated an Episode. Following termination of the waiver period, an OCM Beneficiary may keep items received under this waiver (other than those items covered under section IX(G)(4)(c) of the Participation Agreement) and may get the remainder of any service covered by this waiver if it was initiated during the Episode.

Part II: Explanation of Waiver Requirements

A. Commentary Applicable to All Waivers in This Notice

The waivers in this Notice have been developed in consultation with the Innovation Center, which is administering and testing OCM. 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 (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), and the CMP (section 1128A(a)(5) of the Act) may be waived "as may be necessary solely for purposes of carrying out the testing" of OCM. The Secretary has determined that these waivers are necessary to carry out the testing of OCM.[3]

Each waiver set forth in Part I of this Notice applies to arrangements or beneficiary incentives that squarely meet all of the conditions pertaining to that particular waiver. A waiver of a specific fraud and abuse law is not needed for an arrangement or a beneficiary incentive to the extent it (1) does not implicate the specific fraud and abuse law(s); (2) implicates the law(s) but fits within an existing exception or safe harbor, as applicable; or (3) otherwise complies with the law(s). Arrangements or beneficiary incentives 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 CMP. Failure to fit in a waiver is not in and of itself a violation of the law(s).

The waivers in this Notice apply uniformly to arrangements entered into by each Care Partner, PGP Member, Pooled Non-Payee, Pooled Payee, or Practice, as applicable, participating in OCM. Apart from

[3] This Notice does not waive the "gainsharing" CMP (sections 1128A(b)(1) and (2) of the Act). Section 512 of the Medicare Access and CHIP Reauthorization Act of 2015, 114 P.L. 10, revised the statute so that it prohibits hospitals from knowingly making payments, directly or indirectly, to induce physicians "to reduce or limit *medically necessary* services" provided to Medicare or Medicaid beneficiaries. 114 P.L. 10, *512, 129 Stat. 87 (emphasis added). Because the statute no longer prohibits payments knowingly made by hospitals to induce physicians to reduce or limit medically unnecessary services, no waiver of the gainsharing CMP is needed.

meeting the waiver conditions, no special action (such as the submission of a separate application for a waiver) is required for an arrangement or beneficiary incentive to be covered by these waivers. This Notice has no applicability to other programs or arrangements, even those that may bear some similarity to the arrangements described in this Notice.

The design of the waivers is premised on the expectation that the requirements in the Participation Agreement will mitigate risks of fraud and abuse. The goal of the waiver conditions is to ensure that protected arrangements and beneficiary incentives are consistent with the quality, care coordination, and cost-reduction goals of OCM; are subject to safeguards designed to mitigate the risk of fraud and abuse (including, for example, risks of harms such as overutilization, underutilization, increased cost, and inappropriate patient steering); and can be readily monitored and audited. The waivers include conditions that reference selected requirements of the Participation Agreement that further this goal. Our intent in referencing specific Participation Agreement requirements is to tie the waivers closely to the model being tested and create as much consistency between model requirements and waiver requirements as possible to ease the compliance burden on parties navigating participation in OCM. While compliance with each referenced requirement is necessary for waiver protection, such waiver protection is not conditioned on meeting every other requirement set forth in the Participation Agreement. Notwithstanding, parties are expected to comply fully with the requirements of the Participation Agreement in order to participate in OCM and are subject to applicable remedial action and termination by CMS if they do not.

Each waiver protects only arrangements or beneficiary incentives that meet *all* of the listed conditions. If an arrangement or beneficiary 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 incentive must meet all waiver conditions during the period for which waiver protection is sought. It is the responsibility of the Practice, Care Partner, PGP Member, Pooled Non-Payee, or Pooled Payee to ensure that the arrangement or beneficiary incentive meets all of the waiver conditions.

Apart from the specific financial arrangements indicated in each waiver, no other arrangements are protected by the waivers provided in Part I of the Notice. For example, arrangements for the provision of items or services between the Pooled Payee and the Pooled Non-Payee or between a Practice and a Care Partner are not covered by these waivers, even if the items or services contribute to OCM Activities, Practice Redesign Activities, Episode spending, or quality performance within an Episode. The waivers do not protect arrangements with persons or entities other than those specified in the waivers, including any arrangements in which PBP is shared with other persons or entities. Moreover, the Pooling Waiver, the Care Partner Waiver, and the Group Practice Distributions Waiver do not protect other financial arrangements, whether direct or indirect, 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 payments protected under the respective waivers. Such other payments and arrangements would need to comply with existing law and may qualify for protection under existing exceptions or safe harbors.

To qualify for waiver protection, no additional conditions, limitations, or restrictions, other than those permitted or required by the Participation Agreement or the Pooling Waiver, Care Partner Waiver, or Group Practice Distributions Waiver, may be added to the Pooling Arrangement, PBP Sharing Arrangement, or Partner Distribution Arrangement, respectively. For example, in the context of the Pooling Waiver, a Pooled Payee that makes a Pool PBP Payment to a Pooled Non-Payee may not condition receipt of that Pool PBP Payment on the Pooled Non-Payee's satisfaction of any additional conditions or criteria related to the number of expected or future referrals from the Pooled Non-Payee to the Pooled Payee. Similarly, a Pooled Non-Payee may not condition a Pool Recoupment Payment to a Pooled Payee on the number of the Pooled Payee's expected or future referrals to the Pooled Non-Payee. These examples for the Pooling Waiver apply equally to the Care Partner Waiver and the Group Practice Distributions Waiver, though the parties and the types of payments protected by the relevant waiver may

differ. For all of these waivers, the parties may add general contractual provisions to the applicable arrangement, such as notification requirements or severability clauses.

The waivers are designed to preclude protection in instances where there is a significant risk of program or patient harm. No waiver protects payments that induce reductions in the amount or quality of Medically Necessary care. Further, the Pooling Waiver, the Care Partner Waiver, and the Group Practice Distributions Waiver each provide that there is no waiver protection if CMS has notified the party making the payment that the recipient of the Pool PBP Payment, PBP Shared Payment, or Partner Distribution Payment, respectively, is subject to any action for noncompliance with the fraud and abuse laws or the provision of substandard care to OCM Beneficiaries, or other integrity problems. For purposes of the Pooling Waiver, we note that the Participation Agreement also provides CMS with the authority to cease payments if CMS determines that there has been noncompliance with section VII of the Participation Agreement. The Pooling Waiver will continue in effect even if CMS makes such a notification to the Pooled Payee of a Pooled Non-Payee's noncompliance with the Participation Agreement, provided all other conditions of the waiver are satisfied.

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. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the Participation Agreement.

We reserve the right to reconsider the waivers and to modify, suspend, or terminate the waivers on a prospective basis for any reason consistent with the public interest and with respect to some or all Care Partners, PGP Members, Pooled Non-Payees, Pooled Payees, and Practices. The modification, suspension, or termination of part or all of the waivers does not require advance notice, but we anticipate 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. Each waiver provides that it is not applicable if the Participation Agreement is amended to provide that the waiver is inapplicable. This term permits the Innovation Center to preclude protection under the waiver as part of an amendment to the Participation Agreement.

B. Commentary Applicable to Specific Waivers

1. Waiver for Distribution of Pool PBP Payments and Payment of Pool Recoupment Payments (Pooling Waiver)

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Part II.A of this Notice.

The Waiver for Distribution of Pool PBP Payments and Payment of Pool Recoupment Payments (Pooling Waiver) waives section 1877(a) of the Act (relating to the physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) as these statutes may apply to the distribution of Pool PBP Payments and the payment of Pool Recoupment Payments between the Pooled Payee and a Pooled Non-Payee. These arrangements, described more fully in section VII of the Participation Agreement, are the mechanisms whereby (i) Practices that are pooled for purposes of participating in OCM receive a share of PBP (i.e., performance-based payments from CMS under OCM), and (ii) Practices that are pooled repay certain recoupment payments owed to CMS. In the Participation Agreement, the Practice that receives the PBP from CMS is known as the Pooled Payee; the Pooled Payee distributes the PBP through Pool PBP Payments to other Practices in the Pool, known as Pooled Non-Payees (and also known as Pooled OCM Participants).

As explained above, certain specified requirements in the Participation Agreement have been referenced as conditions to this waiver. These requirements include, for example, ensuring that the opportunity to

make or receive Pool PBP Payments or Pool Recoupment Payments is not conditioned on referrals; that the methodology for calculating the amount of Pool PBP Payments and Pool Recoupment Payments does not directly account for the volume or value of referrals or business otherwise generated; that providers retain their ability to make decisions in the best interests of their patients; and that OCM Beneficiaries retain their freedom of choice of providers. Collectively, these provisions serve as safeguards against potentially abusive practices that are not consistent with OCM.

The Pooling Waiver protects only Pool PBP Payments from a Pooled Payee to a Pooled Non-Payee and Pool Recoupment Payments from a Pooled Non-Payee to a Pooled Payee. The Pooling Waiver does not protect arrangements with other persons or entities, including any arrangements in which Pooled Payees or Pooled Non-Payees share their Pool PBP Payments (or their liability for recoupment) with other persons or entities (including another practice in a Pool). We note that some "downstream" arrangements may be protected by other waivers in this Notice, such as the Care Partner Waiver.

The Pooling Arrangement must be set forth in a Pooling Agreement that specifies the methodology for determining the payments for which waiver protection is sought. Documentation of the Pooling Agreement and payments made and received must be maintained by both the Pooled Payee and the Pooled Non-Payee, must be retained for 10 years, and must be made available to the Secretary upon request. As a best practice, the parties should document the identity of the parties making and receiving the payments, the nature of the payments, and the date and amount of each payment. All documentation must be contemporaneous with the correlating event. By way of example, documentation of the Pooling Agreement must be contemporaneous with the establishment of the Pooling Agreement. This waiver requires that the Pooling Agreement be executed in advance of any distribution of payments from the Pooled Payee to the Pooled Non-Payee or the payment of any Pool Recoupment Payment from the Pooled Non-Payee to the Pooled Payee.

For distributions of Pool PBP Payments that meet all of the prescribed conditions of the Pooling Waiver, the waiver period will start on the Effective Date of the Pooled Non-Payee's Participation Agreement and will end 24 months following the last day of the Pooled Non-Payee's Final Performance Period, except in certain circumstances in which CMS terminates the Participation Agreement of the Pooled Non-Payee pursuant to section XXII(C)(1)(d). The 24-month period is intended to allow sufficient time under the waiver after the end of the Final Performance Period for certain post-participation operations, including Reconciliation and the calculation and distribution of Pool PBP Payments.

If CMS terminates the Pooled Non-Payee's Participation Agreement for one of the reasons set forth in section XXII(C)(1)(d), and CMS determines pursuant to section XXII(C)(2) that no payment of PBP is warranted after termination, the waiver period will end on the effective date of termination of the Pooled Non-Payee's Participation Agreement. In such circumstances, it would not be necessary for the waiver to continue. By way of example, if CMS terminates the Pooled Non-Payee's Participation Agreement because the Pooled Non-Payee submitted false data in connection with OCM, and CMS determines that payment of PBP is not warranted, the waiver period will end on the effective date of termination. However, if CMS terminates the Pooled Non-Payee's Participation Agreement because the Pooled Non-Payee failed to comply with a term of the Participation Agreement, and CMS makes a written determination that payment of PBP is warranted despite termination, the waiver will end 24 months after the last day of the Final Performance Period.

For the payment of Pool Recoupment Payments by a Pooled Non-Payee that meet all of the prescribed conditions of the Pooling Waiver, the waiver period will start on the Effective Date of the Pooled Non-Payee's Participation Agreement. The waiver period for payment of Pool Recoupment Payments continues without end to allow a Pooled Non-Payee to make a Pool Recoupment Payment at any time and remain protected by the waiver.

2. Waiver for Distribution of PBP Shared Payments and Payment of Shared Recoupment Payments (Care Partner Waiver)

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Part II.A of this Notice.

The Care Partner Waiver waives section 1877(a) of the Act (relating to the physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) for distributions of PBP Shared Payments from a Practice to a Care Partner and payment of Shared Recoupment Payments by a Care Partner to a Practice. The intent of this waiver is twofold. First, the waiver is intended to protect arrangements under which a Practice distributes to its Care Partners all or a portion of the PBP it receives from CMS or, in the case of a Pooled Non-Payee, all or a portion of the Pool PBP Payment it receives from the Pooled Payee. Second, this waiver is intended to protect arrangements under which a Care Partner repays a Practice a portion of the Practice's liability for an OCM Recoupment (or in the case of a Practice that is a Pooled Non-Payee, a Pool Recoupment Payment).

In order for PBP Shared Payments or Shared Recoupment Payments to be protected, all conditions of the waiver must be met. Certain conditions require the Care Partner, the Practice, the PBP Sharing Arrangement, and/or the PBP Sharing Agreement to meet requirements of the Participation Agreement that are referenced in the waiver. These requirements include, for example, ensuring that the opportunity to make or receive PBP Shared Payments or Shared Recoupment Payments is not conditioned on referrals; that PBP Shared Payments to Care Partners are calculated using a methodology that is substantially based on criteria related to quality of care and the provision of OCM Activities; that the methodology for calculating the amount of Shared Recoupment Payments shall not directly account for the volume or value of referrals or business otherwise generated; that providers retain their ability to make decisions in the best interests of their patients; and that OCM Beneficiaries retain their freedom of choice of providers. The waiver is designed to preclude protection for arrangements that are inconsistent with OCM and pose a risk to the Medicare program or beneficiaries.

In all cases, the PBP Shared Payments protected by this waiver must be derived from PBP paid by CMS under OCM. If the Practice is a Pooled Non-Payee, the PBP Shared Payment must be derived solely from a Pool PBP Payment that meets the conditions of the Pooling Waiver. This requirement helps to ensure that the protected arrangement does not include any additional arrangements or funds from other sources and is closely tied to OCM; any such arrangements would need to comply with all applicable laws.

As a condition of this waiver, the PBP Sharing Arrangement must be set forth in a PBP Sharing Agreement that specifies the methodology for determining the payments for which waiver protection is sought. Documentation of the PBP Sharing Agreement and payments made and received must be maintained by both the Practice and the Care Partner, must be retained for 10 years, and must be made available to the Secretary upon request. As a best practice, the parties should document the identity of the parties making and receiving the payments, and the date and amount of such payment. All documentation must be contemporaneous with the correlating event. By way of example, the documentation of the PBP Sharing Agreement must be contemporaneous with the establishment of the PBP Sharing Agreement. This waiver requires that the PBP Sharing Agreement be executed in advance of any distribution of payments from the Practice to the Care Partner or any payment of a Shared Recoupment Payment by a Care Partner to a Practice.

For the distribution of PBP Shared Payments to a Care Partner from the Practice that meet all of the prescribed conditions of the Care Partner Waiver, the waiver period will start on the Effective Date of the Participation Agreement of the Practice distributing the PBP Shared Payment to the Care Partner and will end 24 months following the last day of the Practice's Final Performance Period, except in certain circumstances in which CMS terminates the Participation Agreement of the Practice pursuant to section XXII(C)(1)(d). The 24-month period is intended to allow sufficient time under the waiver after the end of

the Final Performance Period for certain post-participation operations, including Reconciliation and the calculation and distribution of PBP Shared Payments.

If CMS terminates the Practice's Participation Agreement for one of the reasons set forth in section XXII(C)(1)(d), and CMS determines pursuant to section XXII(C)(2) that no payment of PBP is warranted after termination, the waiver period will end on the effective date of termination of the Participation Agreement. In such circumstances, it would not be necessary for the waiver to continue. By way of example, if CMS terminates the Practice's Participation Agreement because the Practice submitted false data in connection with OCM, and CMS determines that payment of PBP is not warranted, the waiver period will end on the effective date of termination. However, if CMS terminates the Practice's Participation Agreement because the Practice failed to comply with a term of the Participation Agreement, and CMS makes a written determination that payment of PBP is warranted despite termination, the waiver will end 24 months after the last day of the Final Performance Period.

For the payment of Shared Recoupment Payments that meet all of the prescribed conditions of the Care Partner Waiver, the waiver period will start on the Effective Date of the Participation Agreement for the Practice receiving the Shared Recoupment Payment from the Care Partner. The waiver period for payment of Shared Recoupment Payments continues without end to allow a Care Partner to make a Shared Recoupment Payment at any time and remain protected by the waiver.

3. Waiver for Group Practice Distributions (Group Practice Distributions Waiver)

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Part II.A of this Notice.

The Group Practice Distributions Waiver waives section 1877(a) of the Act (relating to the physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute). The intent of this waiver is to protect arrangements under which a Care Partner that is a PGP distributes to its members (defined in the Participation Agreement as "PGP Members" and limited to certain physicians and nonphysician practitioners who are owners and employees of the PGP) all or a portion of the PBP Shared Payment it has received from a Practice. The Partner Distribution Payment must be derived solely from a PBP Shared Payment received by the PGP Care Partner under OCM, and such PBP Shared Payment must comply with the Care Partner Waiver or otherwise comply with the Federal anti-kickback statute and the physician self-referral law.

As explained above, Partner Distribution Payments from a PGP Care Partner to a PGP Member are subject to all conditions in the waiver, which include full compliance with referenced portions of the Participation Agreement. These requirements include, for example, ensuring that the opportunity to make or receive Partner Distribution Payments not be conditioned on the volume or value of referrals; that the amount of any Partner Distribution Payment be calculated using a methodology that complies with applicable law or is substantially based on criteria related to quality of care and the provision of OCM Activities; that providers retain their ability to make decisions in the best interests of their patients; and that OCM Beneficiaries retain their freedom of choice of providers.

As a condition of this waiver, the Partner Distribution Arrangement must be set forth in a writing that specifies the methodology for determining the Partner Distribution Payment. Documentation of the writing setting forth the Partner Distribution Arrangement and payments made must be maintained by the PGP Care Partner, must be retained for 10 years, and must be made available to the Secretary upon request. As a best practice, the PGP Care Partner should document the identity of the parties making and receiving the payment and the date and amount of such payment. All documentation must be contemporaneous with the correlating event. By way of example, the documentation of the Partner Distribution Arrangement must be contemporaneous with the establishment of the Partner Distribution Arrangement. This waiver requires that the written agreement setting forth the Partner Distribution

Arrangement be executed in advance of any distribution of payments from the PGP Care Partner to the PGP Member.

For the distribution of a Partner Distribution Payment to a PGP Member by a PGP Care Partner that meet all of the prescribed conditions of the Group Practice Distributions Waiver, the waiver period will start on the Effective Date of the PBP Sharing Agreement of the PGP Care Partner distributing the Partner Distribution Payment and will end 24 months after the last day of the Final Performance Period for the Practice that made the PBP Shared Payment to the PGP Care Partner. This waiver period is intended to allow a PGP Care Partner to distribute Partner Distribution Payments if it receives a PBP Shared Payment after the end of the Final Performance Period for the Practice that made the PBP Shared Payment to the Care Partner.

4. Waiver for Beneficiary Incentives Provided to OCM Beneficiaries (BI Waiver)

The commentary on this waiver incorporates by reference the Commentary Applicable to All Waivers in Part II.A of this Notice.

The BI Waiver waives 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). The BI Waiver protects certain items or services provided to an OCM Beneficiary during an Episode that promote beneficiary engagement with managing his or her care. The BI Waiver includes certain safeguards designed to mitigate the risk of harm to patients and the program or misuse of the waiver. The BI Waiver is intended to protect beneficiary incentives generally described in section IX(G) of the Participation Agreement, provided the incentives meet all the conditions of this waiver. The waiver does not protect any items or services provided to an OCM Beneficiary outside of an Episode (except for the remainder of any services initiated during an Episode that occur after termination of the waiver period), or any items or services provided to other Federal health care program beneficiaries. The waiver also includes requirements for documentation and record retention that are consistent with requirements in the Participation Agreement.

Consistent with OCM, the BI Waiver protects only items and services provided by the Practice or by an OCM Practitioner (other than an OCM Practitioner who is an independent contractor). This requirement ensures that providers who furnish the beneficiary incentives are closely aligned with the Practice and are providing these items and services only to further the Practice's participation in OCM. Practices may engage subcontractors that are operating on behalf of the Practice and are not independently providing the beneficiary incentive. For example, a Practice could retain a transportation provider to provide transportation services to OCM Beneficiaries, provided all waiver conditions are met. Nothing in this Notice prevents Practices or others from providing items or services to beneficiaries if they can do so in a manner that complies with existing law.

The BI Waiver is intended to protect preventive care items and services offered and provided by Practices to OCM Beneficiaries, as well as items and services offered and provided by Practices to OCM Beneficiaries that advance at least one of three clinical Cancer-related goals set forth in the Participation Agreement. These goals are OCM Beneficiary adherence to drug regimens related to Cancer, OCM Beneficiary adherence to a care plan related to Cancer, and management of a Cancer diagnosis.

All items and services must be provided in-kind. Cash, debit cards, gift cards, and coupons are not covered by the BI Waiver. Waivers of cost-sharing amounts (for example, copayments and deductibles) are not protected by the waiver. The in-kind requirement means that the OCM Beneficiary must receive the actual item or service and not funds to purchase the item or service. For example, an OCM Beneficiary may not be given cash reimbursements for transportation costs such as bus or taxi fare or gasoline, or public transportation fare cards or tokens. OCM Beneficiaries may be given prepaid vouchers redeemable solely for transportation services for them and any caregivers accompanying them.

The item or service must be reasonably connected to the medical care provided to an OCM Beneficiary during an Episode. For example, technology in the form of a device to monitor and transmit medical indications and symptoms could be reasonably connected to medical care provided during an Episode, but a device that solely plays games would not be. Similarly, transportation provided by the Practice to attend medical appointments, to pick up prescriptions, or to participate in a nutrition counseling program could be protected, but transportation to entertainment or recreational events would not be.

For items or services that meet all of the prescribed conditions of the BI Waiver, the waiver period will start on the Effective Date of the Practice's Participation Agreement and will end six months following the last day on which the Practice could have initiated an Episode. The BI Waiver period ensures that items or services can be offered during an Episode. Following termination of the waiver period, however, an OCM Beneficiary may keep items received under this waiver (other than those items covered under section IX(G)(4)(c) of the Participation Agreement) and may get the remainder of any service covered by this waiver if it was initiated during the Episode. We have included this provision to ensure continuity of care for OCM Beneficiaries in the event the Practice's Performance Period ends or the Practice is terminated from the model during an Episode.

As to section 1877(a) of the Act:

Dated: [April 28, 2016]

/Andrew M. Slavitt/

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services

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

Dated: [April 28, 2016]

/Daniel R. Levinson/

Daniel R. Levinson

Inspector General

Department of Health and Human Services