

Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model

December 12, 2018

Introduction

This Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model (Notice) is being issued in connection with certain programmatic changes being made by the Centers for Medicare & Medicaid Services (CMS) to the Next Generation Accountable Care Organization Model (the Next Generation ACO Model). As explained below, this new Notice supersedes the Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model dated December 29, 2016 (2016 Notice), which superseded the Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model dated December 9, 2015 (2015 Notice),¹ and is effective as of its date. This new Notice includes all of the waivers in the 2016 Notice without substantive changes or limitations, except for the following additions. This Notice modifies the Waiver for Patient Engagement Incentives to add protection for certain patient engagement incentives under two new Benefit Enhancements: gift card rewards provided to certain Beneficiaries to incentivize participation in a qualifying Chronic Disease Management Program and Cost Sharing Support provided to certain Beneficiaries for certain Part B services. This Notice includes explanatory commentary about these changes.

Background

Section 1115A(d)(1) of the Social Security Act (the Act) authorizes the Secretary to waive certain specified fraud and abuse laws as may be necessary solely for purposes of

¹ On December 29, 2016, the Office of Inspector General (OIG) and CMS jointly issued amended waivers for specified arrangements involving ACOs participating in the Next Generation ACO Model as a result of certain programmatic changes being made by the CMS to the Next Generation ACO Model. The original waiver notice was jointly issued by OIG and CMS on December 9, 2015. Copies of these waivers can be found at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

carrying out testing by the Center for Medicare & Medicaid Innovation (CMMI) of certain innovative payment and service delivery models, including the Next Generation ACO Model. This Notice is issued pursuant to this authority to establish waivers applicable to arrangements entered into by individuals and entities participating in the Next Generation ACO Model, subject to the conditions set forth in the waivers.

As used in this Notice, ACO, ACO Activities, AIPBP, AIPBP Fee Reduction, AIPBP Payment Arrangement, Alternative Payment Mechanism, Beneficiary, Benefit Enhancements, Chronic Disease Management Program, Chronic Disease Management Reward Benefit Enhancement, Cost Sharing Support, Cost Sharing Support Arrangement, Cost Sharing Support Benefit Enhancement, Cost Sharing Support Eligible Beneficiary, Covered Services, Effective Date, Eligible Service, Implementation Plan, Infrastructure Payments, Next Generation Beneficiary, Next Generation Participant, Other Monies Owed, PBP, PBP Fee Reduction, Performance Year, Preferred Provider, Reward Eligible Beneficiary, Shared Losses, Shared Savings, and Voluntary Alignment Form have the meanings set forth in the Participation Agreement, including Appendix N, Appendix O, and Appendix P.

A Next Generation ACO is an ACO that has entered into a Participation Agreement.

Participation Agreement refers to the Next Generation ACO Model Participation Agreement between the Next Generation ACO and CMS for the Next Generation ACO's participation in the Next Generation ACO Model, as amended from time to time.

I. The Waivers and Applicable Requirements

A. Next Generation ACO Participation Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the

physician self-referral law)² and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute)³ are waived with respect to any arrangement of the Next Generation ACO, one or more of its Next Generation Participants, or a combination thereof, provided that all of the following conditions are met:

1. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.
2. The Next Generation ACO meets the requirements set forth in section III of the Participation Agreement concerning its governance, leadership, and management.
3. The Next Generation ACO's governing body has made and duly authorized a *bona fide* determination, consistent with the governing body members' duty set forth in section III.B of the Participation Agreement, that the arrangement is reasonably related to ACO Activities.
4. Both the arrangement and its authorization by the governing body are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must identify at least the following:
 - a. A description of the arrangement, including all parties to the arrangement; date of the arrangement; purpose of the arrangement; items, services, facilities, and

² Section 1877 of the Act (42 U.S.C. 1395nn, the "physician self-referral law").

³ Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b), the "Federal anti-kickback statute").

goods covered by the arrangement (including nonmedical items, services, facilities, or goods); and financial or economic terms of the arrangement.

- b. The date and manner of the governing body's authorization of the arrangement. The documentation should include the basis for the determination by the Next Generation ACO's governing body that the arrangement is reasonably related to ACO Activities.
5. The description of the arrangement is publicly disclosed at a time and in a place and manner established by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.
6. The Participation Agreement does not provide that this Next Generation ACO Participation Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Participation Agreement and will end 6 months after the earlier of the expiration of the Participation Agreement, including any renewals thereof, or the date on which the Next Generation ACO has voluntarily terminated the Participation Agreement. However, if CMS terminates the Participation Agreement, the waiver period will end on the date of the termination notice.

B. Shared Savings Distribution 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 distributions or use of Shared Savings earned by the Next Generation ACO, provided that all of the following conditions are met:

1. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.

2. The Shared Savings are earned by the Next Generation ACO pursuant to the Next Generation ACO Model.
3. The Shared Savings are earned by the Next Generation ACO during the term of its Participation Agreement, even if the actual distribution or use of the Shared Savings occurs after the expiration of that agreement.
4. The Shared Savings are—
 - a. Distributed to or among the Next Generation ACO, its Next Generation Participants, or individuals and entities that were its Next Generation Participants during the year in which the Shared Savings were earned by the Next Generation ACO, so long as the Next Generation Participants, or former Next Generation Participants, were not terminated pursuant to section XIX.A.1 of the Participation Agreement; or
 - b. Used by recipients of the Shared Savings, including Preferred Providers or other individuals or entities, for ACO Activities.
5. The Participation Agreement does not provide that this Shared Savings Distribution Waiver is inapplicable.

C. Compliance with the Physician Self-referral Law Waiver

Pursuant to section 1115A(d)(1) of the Act, sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to any financial relationship between or among the Next Generation ACO and its Next Generation Participants or Preferred Providers that implicates the physician self-referral law, provided that all of the following conditions are met:

1. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.

2. The financial relationship is reasonably related to ACO Activities.
3. The financial relationship fully complies with an exception at 42 CFR 411.355 through 411.357.
4. The Participation Agreement does not provide that this Compliance with the Physician Self-referral Law Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the Effective Date of the Participation Agreement and will end on the earlier of the expiration of the term of the Participation Agreement, including any renewals thereof, or the date on which the Participation Agreement has been terminated.

D. Waiver for Patient Engagement Incentives

Pursuant to 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (relating to civil monetary penalties for beneficiary inducements),⁴ and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to the following three categories of incentives if the conditions in the applicable category are met: (1) in-kind incentives, (2) chronic disease management rewards, and (3) Cost Sharing Support.

Specifically:

1. In-kind incentives in the form of items and services provided by the Next Generation ACO or its Next Generation Participants to Beneficiaries if all of the following conditions are met:
 - a. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.

⁴ Section 1128A(a)(5) of the Act (42 U.S.C. 1320a-7a(a)(5), the “beneficiary inducements CMP”).

- b. There is a reasonable connection between the items or services and the medical care of the Beneficiary.
 - c. The items or services are in-kind.
 - d. 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 treatment regime.
 - 2. Adherence to a drug regime.
 - 3. Adherence to a follow-up care plan.
 - 4. Management of a chronic disease or condition.
 - e. The Next Generation ACO maintains the records for each in-kind item or service provided as required by the Participation Agreement in section V.H.2(b).
 - f. The Participation Agreement does not provide that this Waiver for Patient Engagement Incentives is inapplicable.
2. Chronic disease management rewards in the form of gift cards provided by the Next Generation ACO to Beneficiaries to incentivize participation in a qualifying Chronic Disease Management Program if all of the following conditions are met:
- a. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.
 - b. The Next Generation ACO has submitted to CMS its selection of the Chronic Disease Management Reward Benefit Enhancement and its Implementation Plan describing the Next Generation ACO's implementation of the Chronic Disease Management Reward Benefit Enhancement, and CMS has not rejected

the Next Generation ACO's selection of the Chronic Disease Management Reward Benefit Enhancement or the contents of the Next Generation ACO's Implementation Plan for the Performance Year.

- c. The Beneficiary receiving the gift card:
 - i. Was a Reward Eligible Beneficiary at the time he or she enrolled in, or otherwise began participating in, the Chronic Disease Management Program;
 - ii. Satisfies all criteria for obtaining the gift card as set forth in the Next Generation ACO's Implementation Plan; and
 - iii. Does not receive more than \$75 in aggregate value of gift cards from the Next Generation ACO during a Performance Year.
 - d. The gift card:
 - i. Is funded entirely, and provided to the Beneficiary directly, by the Next Generation ACO;
 - ii. Is programmed to prevent the purchase of alcohol and tobacco products; and
 - iii. Is not in the form of cash or monetary discounts or rebates, including reduced cost-sharing or reduced premiums.
 - iv. Cannot be redeemed for cash.
 - e. The Next Generation ACO maintains the records required by the Participation Agreement in section V.A. of Appendix O.
3. Cost Sharing Support provided by Next Generation Participants and Preferred Providers to Cost Sharing Support Eligible Beneficiaries, if all of the following conditions are met:

- a. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.
- b. The Next Generation ACO has submitted to CMS its selection of the Cost Sharing Support Benefit Enhancement and its Implementation Plan describing the Next Generation ACO's implementation of the Cost Sharing Support Benefit Enhancement, and CMS has not rejected the Next Generation ACO's selection of the Cost Sharing Support Benefit Enhancement or the contents of the Next Generation ACO's Implementation Plan for the Performance Year.
- c. The Next Generation ACO has entered into a Cost Sharing Support Arrangement with each participating Next Generation Participant and Preferred Provider.
- d. The Cost Sharing Support is provided in accordance with the ACO's Implementation Plan and the applicable Cost Sharing Support Arrangement.
- e. Payments made by the Next Generation ACO to Next Generation Participants and Preferred Providers to cover the cost of any cost sharing amounts not collected under this Cost Sharing Support Benefit Enhancement are financed entirely out of the Next Generation ACO's own funds.
- f. The Cost Sharing Support advances 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.
 - iv. Management of a chronic disease or condition.

- g. Participation in the Next Generation ACO by a Next Generation Participant or Preferred Provider is not conditioned on participation in the Cost Sharing Support Benefit Enhancement.
- h. The Next Generation ACO maintains the records required by the Participation Agreement in section V.A. of Appendix P.

For arrangements that meet all of the preceding conditions in section I.D.1, of this Notice for in-kind incentives, the waiver period will start on the Effective Date of the Participation Agreement and will end on the earlier of the expiration of the term of the Participation Agreement, including any renewals thereof, or the date on which the Participation Agreement has been terminated, provided that a Beneficiary may keep items received before the Participation Agreement expired or terminated, and receive the remainder of any service initiated before the Participation Agreement expired or terminated.

For arrangements that meet all of the preceding conditions in section I.D.2 of this Notice for chronic disease management rewards, the waiver period will start on the effective date of this Notice and will end on the earlier of the expiration of the term of the Participation Agreement, including any renewals thereof, or the date on which the Participation Agreement has been terminated, provided that a Beneficiary may keep the gift card(s) received before the Participation Agreement expired or terminated and receive any gift card reward earned for participating in a qualifying Chronic Disease Management Program even if some of the activities necessary to earn the reward were completed after the Participation Agreement expired or was terminated.

For arrangements that meet all of the preceding conditions in section I.D.3 of this Notice for Cost Sharing Support, the waiver period will start on the effective date of this Notice and will end on the earlier of the expiration of the term of the Participation Agreement,

including any renewals thereof, or the date on which the Participation Agreement has been terminated provided that a Cost Sharing Support Eligible Beneficiary may receive Cost Sharing Support for an Eligible Service that was rendered before the Participation Agreement expired or terminated.

E. AIPBP Payment Arrangement 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 an AIPBP Payment Arrangement, provided that all of the following conditions are met:

1. The Next Generation ACO has entered into a Participation Agreement and remains in good standing under its Participation Agreement.
2. The Next Generation ACO has entered into an AIPBP Payment Arrangement with the AIPBP-participating Next Generation Participant or Preferred Provider that establishes how the Next Generation ACO will make payments for Covered Services that are subject to the AIPBP Fee Reduction.
3. In establishing the terms of, implementing, and performing under, the AIPBP Payment Arrangement, neither party gives or receives remuneration in return for or to induce business other than Covered Services covered by the AIPBP Payment Arrangement.
4. The parties to an AIPBP Payment Arrangement must, upon request, provide the Government with access to records regarding the AIPBP Payment Arrangement (including records of any payments made or received under the arrangement) that are required to be maintained in accordance with Section XVIII.B of the Participation Agreement.

5. The Participation Agreement does not provide that this AIPBP Payment Arrangement Waiver is inapplicable.

For arrangements that meet all of the preceding conditions, the waiver period will start on the date of this Notice and will end 9 months following the earlier of the expiration of the Participation Agreement, including any renewals thereof; the effective date of termination of the Participation Agreement; or the date on which the AIPBP Payment Arrangement is terminated.

II. Explanation of Select Waiver Requirements

This Notice includes the following five waivers of specified fraud and abuse laws: Next Generation ACO Participation Waiver, Shared Savings Distribution Waiver, Compliance with the Physician Self-referral Law Waiver, Waiver for Patient Engagement Incentives, and AIPBP Payment Arrangement Waiver. As of the date of this Notice, this Notice supersedes the 2016 Notice. In this Notice, we are amending the waivers issued in the 2016 Notice to address two new Benefit Enhancements that CMS will permit Next Generation ACOs to select under the Next Generation ACO Model. The waivers in this Notice apply only with respect to ACOs that are participating in the Next Generation ACO Model and have no applicability to other programs or arrangements, even those that may bear some similarity to the arrangements described in this Notice.

Each waiver set forth in Part I of this Notice applies to arrangements that squarely meet all of the conditions pertaining to that particular waiver. An arrangement need only fit in one waiver in this Notice to be protected; parties seeking to ensure that an arrangement is covered by a waiver for a particular law may look to any waiver that applies to that law. An arrangement may meet the criteria of more than one 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; (2) implicates the law, but fits within an existing exception or safe harbor, as applicable; or (3) 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 physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), and the beneficiary inducements CMP (section 1128A(a)(5) of the Act). Failure to fit in a waiver is not, in and of itself, a violation of the laws. If an arrangement complies with existing law, it does not need to fit in a waiver.

The waivers in this Notice have been developed in consultation with CMMI, which is administering and testing the Next Generation ACO Model. 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, and the beneficiary inducements CMP may be waived “as may be necessary solely for purposes of carrying out the testing” of the Next Generation ACO Model. CMMI has determined that the arrangements covered by these waivers are necessary to carry out testing of the Next Generation ACO Model.⁵ OIG relies on the model design as outlined by CMS in the Participation Agreement and appendices in developing these waivers.

Each waiver protects only arrangements that meet all of the listed conditions. If an arrangement does not meet all of the waiver conditions, it does not qualify for waiver protection. Waivers do not provide retrospective protection: an arrangement must meet all of the waiver conditions during the period for which waiver protection is sought. We note, however, that this

⁵ This Notice does not waive the “gainsharing” CMP (section 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 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 made by hospitals to induce physicians to reduce or limit medically unnecessary services, no waiver of the gainsharing CMP is needed.

Notice does not change or limit the waivers issued in the 2016 Notice. Arrangements that were protected under a waiver in the 2016 Notice continue to be protected under this Notice, provided that they continue to meet the conditions of the applicable waiver in the 2016 Notice (which are now reflected in this Notice). If an arrangement met all of the conditions of a waiver in the 2016 Notice and continues to meet those conditions, there will be no additional actions needed, such as new governing body authority. For example, if a Next Generation ACO entered into an ongoing arrangement with a Next Generation Participant in 2017 that met all conditions of the Next Generation ACO Participation Waiver set forth in the 2016 Notice, that same arrangement would still be protected in 2019 without requiring new authorization from the governing body.

The design of the waivers is premised on the expectation that the requirements of the Participation Agreement will mitigate risks of fraud and abuse. Some waiver provisions incorporate the provisions of the Participation Agreement by reference. Readers are cautioned to consult the Participation Agreement, including its appendices, as necessary to ensure compliance with the Participation Agreement and, if desired, these waivers.

The waivers in this Notice apply uniformly to arrangements entered into by each Next Generation ACO and each Next Generation Participant or Preferred Provider, as applicable, that is participating in the Next Generation ACO Model. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required by parties to be covered by a waiver. Parties need not apply for an individualized waiver.

Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other Federal or State laws and regulations. Moreover, nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations that parties may have under their

Participation Agreements.

The waivers set forth in this Notice will apply to any arrangement that meets the conditions described above. We reserve the right to reconsider these waivers and, where the public interest requires, to modify or terminate the waivers on a prospective basis. The modification, suspension, or termination of part or all of the waivers 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. We reiterate, however, that arrangements protected under the 2016 Notice need no new action to continue to be protected under this Notice.

A. Next Generation ACO Participation Waiver

The Next Generation ACO Participation Waiver is intended to protect a wide variety of arrangements entered into by Next Generation ACOs and Next Generation Participants that are reasonably related to ACO Activities. These arrangements need not be solely among these entities; arrangements entered into by Next Generation ACOs or Next Generation Participants with Preferred Providers or other individuals or entities may qualify for protection so long as the arrangements comply with all requirements set forth in this waiver.

To qualify for the Next Generation ACO Participation Waiver, one requirement is that the governing body must make a *bona fide* determination that the arrangement at issue is reasonably related to ACO Activities. “ACO Activities” is defined in the Participation Agreement and, as used in this Notice, encompasses the “purposes” of the Next Generation ACO Model. Broadly speaking, ACO Activities are activities that promote accountability for the quality, cost, and overall care for a population of Next Generation Beneficiaries, including managing and coordinating care, encouraging investment in infrastructure and redesigned care processes for high-quality and efficient service delivery, or carrying out any other obligation or

duty of the Next Generation ACO. See section II of the Participation Agreement. An arrangement need only to be reasonably related to one ACO Activity. The definition provides a list of specific examples of activities that would be considered ACO Activities. This list is not exclusive. For example, an arrangement between a Next Generation ACO and a Next Generation Participant or Preferred Provider for payment or recoupment of Shared Losses or Other Monies Owed that relate to participation in ACO Activities could be protected by the Next Generation ACO Participation Waiver if all waiver conditions are met. In contrast, not every arrangement connected to a Next Generation ACO will be reasonably related to ACO Activities. For example, per-referral payments (e.g., expressly paying a specialist \$500 for every referral generated by the specialist or paying a nursing facility staff member \$100 for every patient transported to a hospital that is owned or controlled by a Next Generation Participant) would not be reasonably related to ACO Activities.

A key role of the governing body under the Next Generation ACO Participation Waiver is to evaluate and identify clearly whether arrangements are reasonably related to ACO Activities. Arrangements prohibited by the Participation Agreement cannot be reasonably related ACO Activities. By way of example only, arrangements whereby providers or suppliers offer or are required to pay a sum or fee to receive referrals or to be a Preferred Provider in the model (e.g., “pay-to-play” arrangements) or involving payments to induce providers or suppliers to stint on medically necessary care for Beneficiaries, would not be reasonably related to ACO Activities.

We do not believe that a Next Generation ACO’s governing body can make and authorize a *bona fide* determination that an arrangement is reasonably related to ACO Activities by “rubber stamping” its approval of an arrangement. We are not prescribing particular methods for this determination. Next Generation ACO governing bodies have available a variety of methods for

making such a determination, provided that they meet all the requirements of the waiver. We believe and expect that members of the Next Generation ACO governing body will employ a thoughtful, deliberative process for making a determination that an arrangement will be used for ACO Activities and will articulate clearly the basis for their determinations and authorizations. The waiver also includes requirements for documentation and record retention.

The waiver requires that a description of the arrangement be publicly disclosed at a time and in a place established by the Secretary. Compliance with this requirement may be met by following the guidance set forth in connection with the waivers for the Medicare Shared Savings Program (MSSP). See 80 Fed. Reg. 66726, 66735.⁶ This public transparency serves important goals. First, we are declining to protect hidden arrangements because secrecy is a common element of criminal or fraudulent conduct. Second, the requirement makes information about protected arrangements available to parties involved with the ACO who may have an interest in knowing about the ACO's arrangements, as well as the public and regulators. Third, we believe that transparency creates incentives for ACOs and members of the governing body to exercise due diligence when establishing arrangements to ensure compliance with Next Generation ACO Model and waiver requirements.

Because some AIPBP Payment Arrangements—under which Next Generation ACOs assume full responsibility for reimbursing providers and suppliers for Covered Services (i.e., providing direct patient care)—may not align with the design of the Next Generation ACO Participation Waiver, we promulgated a separate waiver for AIPBP Payment Arrangements that meet certain conditions, as described further below. This separate protection applies only to

⁶ Additional guidance referenced in the cited rule, which may be amended from time to time, is available on CMS's website at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Additional-MSSP-Waiver-Guidance.pdf>, and on the Office of Inspector General's website at: <http://oig.hhs.gov/compliance/accountable-care-organizations/files/Additional-MSSP-Waiver-Guidance.pdf>.

AIPBP Payment Arrangements; other arrangements among those participating in the AIPBP mechanism, such as arrangements under which the Next Generation ACO provides care coordination infrastructure or staffing, would continue to need to be protected under the Next Generation ACO Participation Waiver or other waivers, or comply with existing law.

Arrangements that combine both an AIPBP Payment Arrangement with other remunerative arrangements might need to use more than one waiver to cover the full arrangement. Nothing precludes an AIPBP Payment Arrangement from using the Next Generation ACO Participation Waiver if all conditions of that waiver are squarely met. We note that the definition of “ACO Activities” in the Participation Agreement includes “providing direct patient care” to the extent such care is provided “in a manner that reduces costs and improves quality.” This is likely to be a fact-specific determination.

We believe that payment arrangements under the PBP Alternative Payment Mechanism can continue to be structured to fit in the Next Generation ACO Participation Waiver or another available waiver, or to comply with existing law.

B. Shared Savings Distribution Waiver

The Shared Savings Distribution Waiver is intended to protect arrangements created by the distribution of Shared Savings, within an ACO, as well as arrangements created by the use of Shared Savings to pay outside parties, including Preferred Providers, for ACO Activities. The waiver permits Shared Savings to be distributed from the Next Generation ACO to its Next Generation Participants and between and among Next Generation Participants in any form or manner. This waiver for Shared Savings distributions within the Next Generation ACO is premised, in part, on recognition that an award of Shared Savings necessarily reflects the collective achievement by the Next Generation ACO and its Next Generation Participants (which, among other things, share responsibility for governance and accountability under the

model) of the quality, efficiency, and cost-reduction goals of the Next Generation ACO Model. These goals are consistent with interests protected by the fraud and abuse laws. The waiver also offers protection for ACOs to distribute Shared Savings in arrangements with outside parties, including Preferred Providers, provided the Shared Savings are used for ACO Activities.

Because the payment of Shared Savings from CMS to the Next Generation ACO may not occur until after expiration of the Next Generation ACO's Participation Agreement, the waiver applies to Shared Savings earned during the term of the Participation Agreement, even if distributed subsequently.

We are aware that ACOs may have questions regarding protection for the distribution of Shared Savings earned by the ACO under a comparable program sponsored by a commercial health plan. As with the MSSP, we are not including in this Notice specific waiver protection for such arrangements. We are not persuaded that a specific waiver is necessary for such payments to carry out the Next Generation ACO Model. Moreover, we believe that avenues exist to provide flexibility for ACOs participating in commercial plans. First, nothing precludes arrangements "downstream" of commercial plans (such as arrangements between hospitals and physicians) from qualifying for the Next Generation ACO Participation Waiver if all conditions of the waiver are met. The Next Generation ACO Participation Waiver does not turn on the source of the funds for the arrangement. Second, depending on the facts, commercial shared savings arrangements may qualify for protection under existing exceptions to the physician self-referral law and safe harbors under the Federal anti-kickback statute. Finally, no waiver or other protection is needed for private payer arrangements that do not implicate the fraud and abuse law.

C. Compliance with the Physician Self-referral Law Waiver

The Compliance with the Physician Self-referral Law Waiver waives the Federal anti-kickback statute for arrangements that implicate the physician self-referral law but fully comply with an exception to that law. Thus, arrangements that do not implicate the physician self-referral law (e.g., if there is no referring physician, or the arrangement does not involve a designated health service) would not be covered under this waiver.

Arrangements covered by this waiver remain subject to scrutiny—including monitoring, auditing, or other means—for compliance with the physician self-referral law. Importantly, we remind stakeholders that compliance with an exception to the physician self-referral law does not ordinarily operate to immunize conduct under the Federal anti-kickback statute, and arrangements that comply with the physician self-referral law are still subject to scrutiny under the Federal anti-kickback statute. We are departing from this general rule because we believe there are specific safeguards in the Next Generation ACO Model that minimize some typical fraud and abuse concerns, and we desire to reduce the burden on ACOs. Further, section 1115A(d)(1) of the Act authorizes the Secretary to waive the Federal anti-kickback statute, as necessary, to carry out testing by CMMI of certain innovative payment and service delivery models, such as the Next Generation ACO Model. We believe that exercising our discretion to waive the Federal anti-kickback statute for those arrangements that comply with an existing exception to the physician self-referral law will continue to facilitate the development of arrangements that present a low risk of fraud and abuse through continuing compliance with the requirements of the applicable physician self-referral law exception.

D. Waiver for Patient Engagement Incentives

The Waiver for Patient Engagement Incentives addresses the application of the beneficiary inducements CMP and the Federal anti-kickback statute to the provision of certain items and services to Beneficiaries for three types of patient engagement incentives, each of

which is subject to specified conditions. The Participation Agreement expressly prohibits inducements to Beneficiaries, including inducements to influence a Beneficiary's decision regarding completion of a Voluntary Alignment Form or a MyMedicare.gov designation, or except as set forth in section V.H.2, Appendix O, and Appendix P of the Participation Agreement, to induce Beneficiaries to receive, or continue to receive, items or services from the Next Generation ACO, Next Generation Participants, or Preferred Providers. This Waiver for Patient Engagement Incentives does not waive any requirements or prohibitions set forth in the Participation Agreement; it waives only the beneficiary inducements CMP and the Federal anti-kickback statute with respect to incentives permitted (or not prohibited) by the Participation Agreement. This waiver does not include a "tail" period after the Participation Agreement is terminated or expires. However, we have included provisions to ensure continuity of care for Beneficiaries who may be receiving items or services at the time the Participation Agreement is terminated or expires.

The three types of patient engagement incentives protected by the Waiver for Patient Engagement Incentives are:

1. In-kind Incentives:

This Notice continues to protect, without change, the in-kind incentives protected in the 2016 Notice. Under the Participation Agreement, the incentives must be in-kind. Gift cards, coupons, cash, or other cash equivalents are not covered by the in-kind incentives provision of the Waiver for Patient Engagement Incentives. Waivers of cost-sharing amounts (for example, copayments and deductibles) also are not protected by the in-kind incentives provision of the Waiver for Patient Engagement Incentives. The in-kind requirement means that the Beneficiary must receive the actual item or service and not funds to purchase the item or service. For example, Beneficiaries may not be given cash reimbursements for transportation

costs such as bus or taxi fare or gasoline, or public transportation fare cards or tokens.

Beneficiaries may be given, for example, prepaid vouchers redeemable solely for transportation services for them and any caregivers accompanying them.

The item or service also must be reasonably related to a Beneficiary's medical care and be either preventive care items or services or advance one or more specified clinical goals. For example, technology in the form of a device to monitor and transmit medical indications and symptoms could meet these requirements, but a device that solely plays games would not. Similarly, transportation to medical appointments or to pick up prescriptions could be protected, but transportation to entertainment or recreational events would not be.

The in-kind incentives provision of the Waiver for Patient Engagement Incentives protects only items and services provided by a Next Generation ACO or a Next Generation Participant directly to a Beneficiary or through an agent, which could include a Preferred Provider acting as an agent. The in-kind incentives provision of the Waiver for Patient Engagement Incentives does not, however, protect the provision of an item or service if a reasonable Beneficiary would perceive the item or service as being from the agent, rather than from the Next Generation ACO or Next Generation Participant or Preferred Provider. Nothing in this Notice prevents Next Generation ACOs or Next Generation Participants from providing, or structuring arrangements to provide, items or services to Beneficiaries if they can do so in a manner that complies with existing law.

With respect to the 3-Day SNF Rule Waiver Benefit Enhancement, Telehealth Expansion Benefit Enhancement, and Post-Discharge Home Visits Benefit Enhancement, as defined in the Participation Agreement, provided by a Next Generation Participant or Preferred Provider to Beneficiaries, we do not believe that protection under this Waiver for Patient Engagement Incentives is necessary. Those Benefit Enhancements are a means to offer certain covered

services to Beneficiaries with certain changes to the coverage requirements. The receipt by a Beneficiary of a Medicare-covered service does not implicate the beneficiary inducements CMP or the Federal anti-kickback statute with respect to the arrangement between the provider furnishing the covered service and the Beneficiary. We note that arrangements between or among Next Generation Participants, Preferred Providers, and others to furnish these three Benefit Enhancements must comply with fraud and abuse laws, and may qualify for protection under the Participation Waiver, if all waiver conditions are met. In contrast, the Chronic Disease Management Reward Benefit Enhancement and Cost Sharing Support Benefit Enhancement involve giving remuneration to Beneficiaries to induce them to seek care or reward them for seeking care. These incentives implicate both the beneficiary inducements CMP and the Federal anti-kickback statute. Therefore, this Notice adds two more sections to the Waiver for Patient Engagement Incentives.

2. Chronic Disease Management Reward

Under Appendix O of the Participation Agreement, the Chronic Disease Management Reward Benefit Enhancement allows the Next Generation ACO to provide a gift card reward to certain Beneficiaries to incentivize their participation in a qualifying Chronic Disease Management Program that focuses on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources for individuals with the chronic diseases targeted by the program. For instance, the qualifying Chronic Disease Management Program may involve getting the Beneficiary to use particular services or preventive screening benefits, adhere to prescribed treatment regimens, attend education or self-care management lessons, or meet nutritional goals.

This Waiver for Patient Engagement Incentives, as amended by this Notice, protects Chronic Disease Management Program rewards that meet the criteria set forth in the Chronic

Disease Management Reward Benefit Enhancement provision of the Waiver for Patient Engagement Incentives. One such criterion requires that a Beneficiary receiving a gift card must have been a Reward Eligible Beneficiary at the time he or she enrolled or otherwise began participating in the Chronic Disease Management Program. Another criterion of this amended Waiver for Patient Engagement Incentives requires that the reward take the form of a gift card that is not in the form of cash or monetary discounts or rebates, including reduced cost-sharing or reduced premiums, that is not redeemable for cash, and that is programmed to prevent the purchase of alcohol and tobacco products. By way of example only, a grocery store gift card that could be used on all grocery items, but not prescription cost-sharing, alcohol, or tobacco, could meet this criterion, but a gift card that allowed any remaining balance to be given in cash would not. This Waiver for Patient Engagement Incentives protects up to \$75 in the aggregate for all gift cards given to any Beneficiary in a Performance Year. In addition, the Next Generation ACO must fund the gift card entirely from its own funds and directly provide it to the Beneficiary; a gift card that is given to the Beneficiary by, for example, a Preferred Provider, would not meet this criterion.

3. Cost Sharing Support

Under Appendix P of the Participation Agreement, the Cost Sharing Support Benefit Enhancement allows the Next Generation ACO to enter into Cost Sharing Support Arrangements with Next Generation Participants and Preferred Providers to reduce or eliminate cost sharing for those categories of Part B services and Next Generation Beneficiaries identified by the ACO in the Cost Sharing Support Agreement and the Next Generation ACO's Implementation Plan.

This Waiver for Patient Engagement Incentives, as amended by this Notice, protects Cost Sharing Support that meets the criteria set forth in the Cost Sharing Support Benefit Enhancement provision of the Waiver for Patient Engagement Incentives, consistent with the

Cost Sharing Support Benefit Enhancement as established under the Next Generation ACO Model. For example, the Cost Sharing Support must advance one or more of the specified clinical goals, and a Next Generation Participant's or Preferred Provider's participation in the Next Generation ACO must not be conditioned on participation in the Cost Sharing Support Benefit Enhancement. In addition, the Participation Agreement requires all Cost Sharing Support to be provided in accordance with the Implementation Plan, which must set forth the categories of Eligible Services and the categories of Cost Sharing Support Eligible Beneficiaries. Therefore, this Waiver for Patient Engagement Incentives protects Cost Sharing Support only when provided to a Cost Sharing Support Eligible Beneficiary for an Eligible Service; the Waiver for Patient Engagement Incentives would not protect Cost Sharing Support provided for categories of services or to categories of Beneficiaries not identified in the Implementation Plan.

The Cost Sharing Support Benefit Enhancement provision of the Waiver for Patient Engagement Incentives applies only to remuneration in the form of Cost Sharing Support provided to Cost Sharing Support Eligible Beneficiaries; it does not apply to payments made by a Next Generation ACO to a Next Generation Participant or Preferred Provider to reimburse any cost sharing amounts not collected under the Cost Sharing Support Benefit Enhancement. Such arrangements would need to be protected under the Next Generation ACO Participation Waiver or otherwise comply with existing law. Whether an arrangement to reimburse cost sharing amounts not collected meets the requirements of the Next Generation ACO Participation Waiver or otherwise complies with existing law is a fact-specific determination. Nothing in this Notice prevents Next Generation ACOs, Next Generation Participants, or Preferred Providers from waiving cost sharing amounts in consideration of a particular beneficiary's financial hardship if they can do so in a manner that complies with existing law. See, e.g., section 1128A(i)(6)(A) of the Act; 42 C.F.R. § 1001.952(k); OIG, Special Advisory Bulletin: Offering Gifts and Other

Inducements to Beneficiaries (Aug. 2002); OIG, Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills (Feb. 2004); OIG, Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 65,372, 65,374 (1994).

E. AIPBP Payment Arrangement Waiver

The AIPBP Payment Arrangement Waiver protects certain payment arrangements between a Next Generation ACO and its Next Generation Participants or Preferred Providers for the provision of Covered Services to Next Generation Beneficiaries. This waiver is available only to Next Generation ACOs participating in AIPBP and only for payments made by a Next Generation ACO to its Next Generation Participants or Preferred Providers that have agreed to an AIPBP Fee Reduction pursuant to an AIPBP Payment Arrangement and that CMS has not prohibited from participating in AIPBP. Under Appendix N of the Participation Agreement, AIPBP Payment Arrangements must meet certain additional programmatic conditions, including a requirement that payments must be monetary payments negotiated in good faith and consistent with fair market value (which may be more or less than the Medicare payment amount for a given Medicare-reimbursable service). Participation in AIPBP requires a Next Generation Participant or Preferred Provider to continue offering Covered Services to Next Generation Beneficiaries, with a 100% reduction in fee-for-service payments from CMS for those services. Next Generation Participants or Preferred Providers instead would receive reimbursement for Covered Services from the Next Generation ACO (which would receive payments from CMS as set out in the Participation Agreement). Under the Participation Agreement, the Next Generation ACO has a certain amount of discretion in setting payment rates. This waiver allows the relevant parties flexibility to negotiate and enter into payment arrangements for Covered Services without risking sanctions under the Federal anti-kickback

statute or physician self-referral law. Arrangements for other items and services would not qualify for this particular waiver.

This AIPBP Payment Arrangement Waiver sets forth certain requirements that must be met to qualify for waiver protection. For example, the waiver does not protect arrangements that involve payment or acceptance of remuneration for referring or inducing business other than Covered Services covered by the AIPBP Payment Arrangement. This requirement should have the effect of protecting the model from being used as a vehicle to pay kickbacks for business generated outside the model. Under the requirement, the amount that a Next Generation ACO pays its Next Generation Participant or Preferred Provider under an AIPBP Payment Arrangement cannot be a payment that is in any way related to, or in exchange for, any services outside the model. For example, a Next Generation ACO could not offer a Next Generation Participant who is a surgeon a higher rate on surgeries performed on Next Generation Beneficiaries in exchange for referrals of Beneficiaries who are not part of the model.

This waiver applies only to a Next Generation ACO and its Next Generation Participants or Preferred Providers that have agreed to an AIPBP Fee Reduction pursuant to an AIPBP Payment Arrangement.

Authority: Section 1115A(d)(1) of the Act.

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

Dated: [December 12, 2018]

/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 12, 2018]

/Daniel R. Levinson/

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