

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

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 carrying out the testing by the Center for Medicare & Medicaid Innovation (CMMI) of certain innovative payment and service delivery models, including the Next Generation Accountable Care Organization Model (the Next Generation ACO Model). This Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model (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, Alternative Payment Mechanisms, Beneficiary, Benefit Enhancements, Effective Date, Infrastructure Payments, Next Generation Beneficiary, Next Generation Participant, Other Monies Owed, PBP, Performance Year, Preferred Provider, Shared Losses, Shared Savings, and Voluntary Alignment Form have the meanings set forth in the Participation Agreement.

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 the Centers for Medicare & Medicaid Services (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)¹ and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute)² 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 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; the purpose of the arrangement; the items, services, facilities, and goods covered by the arrangement (including nonmedical items,

¹ Section 1877 of the Act (42 U.S.C. 1395nn, the "Physician Self-referral Law").

² Section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b), the "Federal anti-kickback statute").

services, facilities, or goods); and the 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 following 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 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 that implicates the physician self-referral law, provided 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 section 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (relating to the Beneficiary Inducements CMP),³ and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided by the Next Generation ACO or its Next Generation Participants to Beneficiaries if 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. There is a reasonable connection between the items or services and the medical care of the Beneficiary.
3. The items or services are in-kind.

³ Section 1128A(a)(5) of the Act (42 U.S.C. 1320a-7a(a)(5)), the “Beneficiary Inducements CMP”).

4. The items or services-
 - a. Are preventive care items or services; or
 - b. Advance one or more of the following clinical goals:
 - i. Adherence to a treatment regime.
 - ii. Adherence to a drug regime.
 - iii. Adherence to a follow-up care plan.
 - iv. Management of a chronic disease or condition.
5. The Next Generation ACO maintains the records for each in-kind item or service provided required by the Participation Agreement in section V.H.2(b).
6. The Participation Agreement does not provide that this Waiver for Patient Engagement Incentives 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, 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.

II. Explanation of Select Waiver Requirements

This Notice includes the following four waivers of specified fraud and abuse laws: Next Generation ACO Participation Waiver, Shared Savings Distribution Waiver, Compliance with the Physician Self-referral Law Waiver, and Waiver for Patient Engagement Incentives. The Waivers in this Notice apply only with respect to ACOs that are participating in the Next

Generation ACO Model using payment mechanisms available for the first Performance Year, including normal Medicare fee-for-service payments, Infrastructure Payments, and PBPs. To the extent these payment mechanisms change, or other payment mechanisms are added in future Performance Years, these waivers may change or evolve with respect to those new elements. This Notice has 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. In some cases, 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 the testing of the Next Generation ACO Model.⁴

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.

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 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 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-

⁴ 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.

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 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.

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 Next Generation Beneficiaries, including managing and coordinating care for Next Generation Beneficiaries, 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, which 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 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 to them a variety of methods for making such a determination, provided they meet all of 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, 66735.⁵ 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 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.

⁵ 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>.

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 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 the authority 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. The Participation Agreement expressly prohibits inducements to patients, including inducements to influence a Beneficiary's decision regarding completion of a Voluntary Alignment Form, or except as set forth in section V.H.2 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.

Under the Participation Agreement, the incentives must be in-kind. Gift cards, coupons, cash, or other cash equivalents are not covered. Waivers of cost-sharing amounts (for

example, copayments and deductibles) also are not protected by the Waiver. 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 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 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. This waiver 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. 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 Benefit Enhancements, as defined in the Participation Agreement, provided by a Next Generation Participant or Preferred Provider to Beneficiaries, we do not believe protection under this Waiver is necessary. Benefit Enhancements are a means to offer

certain covered services to Beneficiaries with certain changes to the coverage requirements. The receipt by a Medicare 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 Benefit Enhancements must comply with the fraud and abuse laws, and may qualify for protection under the Participation Waiver, if all waiver conditions are met.

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.

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

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

Dated: [December 9, 2015]

/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 Social Security Act:

Dated: [December 9, 2015]

/Daniel R. Levinson/

Daniel R. Levinson

Inspector General

Department of Health and Human Services