

**Notice of Waivers of Certain Fraud and Abuse Laws  
in Connection With the Vermont Medicare ACO Initiative Within the  
Vermont All-Payer ACO Model  
December 20, 2018**

Section 1115A(d)(1) of the Social Security Act (Act) authorizes the Secretary to waive certain fraud and abuse laws as may be necessary solely for purposes of carrying out testing by the Center for Medicare and Medicaid Innovation (Innovation Center) of certain innovative payment and service delivery models. The Innovation Center is testing the Vermont All-Payer Accountable Care Organization Model (Model) under section 1115A(b) of the Act, and is implementing the Vermont Medicare ACO Initiative (Initiative) within this Model.

Pursuant to section 1115A(d)(1), this Notice of Waivers of Certain Fraud and Abuse Laws in Connection With the Vermont Medicare ACO Initiative (Notice) establishes waivers applicable to arrangements entered into by individuals and entities participating in the Initiative.

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

**I. The Waivers and Applicable Requirements**

Terms defined in the Participation Agreement that are used in this Notice have the meanings set forth in the Participation Agreement, as amended from time to time. These terms include but are not limited to, the following: ACO, ACO Activities, AIPBP, AIPBP Fee Reduction, AIPBP Payment Arrangement, Beneficiary, Covered Services, Effective Date, Initiative Beneficiary, Initiative Participant, Other Monies Owed, Preferred Provider, Shared Losses, and Shared Savings have the meanings set forth in the Participation Agreement.

**A. Participation 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 any arrangement between the ACO, one or more of its Initiative Participants, or a combination thereof, provided all of the following conditions are met:

1. The ACO has entered into a Participation Agreement.
2. The ACO meets the requirements set forth in section III of the Participation Agreement concerning its governance, leadership, and management.
3. The 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 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 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 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 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 ACO, provided all of the following conditions are met:

1. The ACO has entered into a Participation Agreement.
2. The Shared Savings are earned by the ACO pursuant to the Initiative.
3. The Shared Savings are earned by the 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 ACO, its Initiative Participants, or individuals and entities that were its Initiative Participants during the year in which the Shared Savings were earned by the ACO, so long as the Initiative Participants, or former Initiative Participants, were not terminated pursuant to section XVIII.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 ACO and its Initiative Participants or Preferred Providers that implicates the physician self-referral law, provided that all of the following conditions are met:

1. The ACO has entered into a 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), 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 ACO or its Initiative Participants to Beneficiaries if all of the following conditions are met:

1. The ACO has entered into a 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.
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 followup care plan.
    - iv. Management of a chronic disease or condition.
5. The ACO, Initiative Participants, and Preferred Providers must make available to OIG, upon request, materials and records sufficient to establish whether the items and services were distributed in a manner that meets the conditions of this waiver.
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.

#### **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 ACO has entered into a Participation Agreement.
2. The ACO has entered into an AIPBP Payment Arrangement with the AIPBP-participating Initiative Participant or Preferred Provider that establishes how the 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 make available to OIG and CMS, upon request, materials and records sufficient to establish whether the payments made under the AIPBP Payment Arrangement were distributed in a manner that meets the conditions of this waiver.
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 Waiver Requirements**

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

We note that several of the waiver conditions incorporate requirements that appear in the Participation Agreement. We intend to interpret such waiver conditions in a manner consistent with how CMS interprets the corresponding program requirement. Arrangements entered into as part of the Initiative within the Model must meet all of the conditions of the applicable waiver in this Notice to receive waiver protection. We expect individuals and entities to maintain sufficient materials and records to demonstrate compliance with the waiver

conditions. Except for the Participation Waiver, we are not setting particular parameters regarding the nature of the documentation necessary to demonstrate waiver compliance to OIG and CMS.

Many of the arrangements of the type that we intend to protect under this Notice may already exist if they were entered into as part of the Next Generation ACO Model. These pre-existing arrangements would have been eligible for waivers provided by earlier notices of waivers: the Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model, dated December 9, 2015, and the Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model, dated December 29, 2016 (collectively, “Next Generation ACO Model Notices”).<sup>1</sup>

We do not intend to disrupt waiver protection for arrangements that satisfy the conditions set forth in the Next Generation ACO Model Notices. With respect to arrangements protected by the Next Generation ACO Model Notices’ Shared Savings Distribution Waiver, the Compliance with the Physician Self-referral Law Waiver, the Waiver for Patient Engagement Incentives, and the AIPBP Payment Arrangement Waiver, respectively, we intend for waiver protection to transition seamlessly into waiver protection under the applicable waiver as set forth in this Notice. The Participation Waiver, however, requires authorization of the governing body and documentation, including the basis for the determination that the arrangement is reasonably related to ACO Activities. To ensure that the ACO’s governing body has sufficient time to review such arrangements and make any necessary updates to reflect participation in the Initiative rather than the Next Generation ACO Model, any ongoing arrangement entered into on or before December 31, 2018, that qualified for waiver protection under the Next Generation ACO Model Notices’ Participation Waiver will receive waiver protection under this Notice until the earlier of (1) the date the ACO’s governing body authorizes the arrangement in compliance with this Notice, or (2) June 30, 2019.

## **Commentary Applicable to Specific Waivers**

### **A. Participation Waiver**

The Participation Waiver is intended to protect a wide variety of arrangements entered into by the ACO and Initiative Participants that are reasonably related to ACO Activities. These arrangements need not be solely among these entities; arrangements entered into by the ACO or Initiative 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 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 Model. Broadly speaking, ACO Activities are activities that

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<sup>1</sup> Copies of the Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model, dated December 9, 2015, and the Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model, dated December 29, 2016, can be found at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

promote accountability for the quality, cost, and overall care for a population of Initiative 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 ACO. See section II of the Participation Agreement. An arrangement need only 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 an ACO and an Initiative Participant or Preferred Provider for payment or recoupment of Shared Losses or Other Monies Owed, that relates to participation in ACO Activities, could be protected by the Participation Waiver if all waiver conditions are met. In contrast, not every arrangement connected to the 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 an Initiative Participant) would not be reasonably related to ACO Activities.

A key role of the governing body under the 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 to 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 the 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. The ACO governing body has available a variety of methods for making such a determination, provided that it meets all the requirements of the waiver. We believe and expect that members of the 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.<sup>2</sup> 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, as well as the public and regulators, who may have an interest in knowing about the ACO’s arrangements. Third, we believe that

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<sup>2</sup> 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 OIG website at: <http://oig.hhs.gov/compliance/accountable-care-organizations/files/Additional-MSSP-Waiver-Guidance.pdf>.

transparency creates incentives for ACOs and members of the governing body to exercise due diligence when establishing arrangements to ensure compliance with Model and waiver requirements.

Because some AIPBP Payment Arrangements—under which the ACO assumes full responsibility for reimbursing providers and suppliers for Covered Services (i.e., providing direct patient care)—may not align with the design of the 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 AIPBP Payment Arrangements; other arrangements among those participating in AIPBP, such as arrangements under which the ACO provides care coordination infrastructure or staffing, would continue to need to be protected under the 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 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.

## **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 ACO to its Initiative Participants and between and among Initiative Participants in any form or manner. This waiver for Shared Savings distributions within the ACO is premised, in part, on recognition that an award of Shared Savings necessarily reflects the collective achievement by the ACO and Initiative Participants (which, among other things, share responsibility for governance and accountability) under the model of the quality, efficiency, and cost-reduction goals of the Initiative. 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 ACO may not occur until after expiration of the 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. We are not persuaded that a specific waiver is necessary for such payments to carry out the Initiative. 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 Participation Waiver if all conditions of the waiver are met. The

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 laws.

### **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 Initiative 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 the Innovation Center of certain innovative payment and service delivery models, such as the Initiative. 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, 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 ACO, Initiative 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, 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 Waiver for Patient Engagement Incentives protects only items and services provided by the ACO or an Initiative 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 ACO or Initiative Participant. Nothing in this Notice prevents the ACO or Initiative 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.

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.

One condition of the waiver provides that the ACO, Initiative Participants, and Preferred Providers must make available to OIG, upon request, materials and records sufficient to establish whether the items and services were distributed in a manner that meets the conditions of this waiver. This condition is intended to be flexible enough for Initiative Participants and Preferred Providers to reasonably determine the types of records and materials that would demonstrate how the items and services were distributed.

#### **E. AIPBP Payment Arrangement Waiver**

The AIPBP Payment Arrangement Waiver protects certain payment arrangements between an ACO and its Initiative Participants or Preferred Providers for the provision of Covered Services to Initiative Beneficiaries. This waiver is available only to the ACO participating in AIPBP and only for payments made by the ACO to its Initiative 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 J 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 an Initiative Participant or Preferred Provider to continue offering Covered

Services to Initiative Beneficiaries, with a 100% reduction in fee-for-service payments from CMS for those services. Initiative Participants or Preferred Providers instead would receive reimbursement for Covered Services from the ACO (which would receive payments from CMS as set out in the Participation Agreement). Under the Participation Agreement, the 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 the ACO pays its Initiative Participants or Preferred Providers 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, the ACO could not offer an Initiative Participant who is a surgeon a higher rate on surgeries performed on Initiative Beneficiaries in exchange for referrals of Beneficiaries who are not part of the model.

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

One condition of the waiver provides that the parties to an AIPBP Payment Arrangement must make available to OIG and CMS, upon request, materials and records sufficient to establish whether the payments made under the AIPBP Payment Arrangement were distributed in a manner that meets the conditions of this waiver. This condition is intended to be flexible enough for the parties to an AIPBP Payment Arrangement to reasonably determine the types of records and materials that would demonstrate how AIPBP Payments were distributed.

### **General Limitations**

- The waivers set forth in Part I of this Notice apply to arrangements or beneficiary engagement incentives that squarely meet all of the conditions pertaining to that particular waiver. If an arrangement or beneficiary engagement incentive does not meet all of the waiver conditions, it does not qualify for waiver protection. Individuals and entities must make materials and records sufficient to establish waiver compliance available to OIG and CMS, as applicable, upon request.
- Waivers do not provide retrospective protection. An arrangement or beneficiary engagement incentive must meet all of the waiver conditions during the period for which waiver protection is sought.

- Apart from meeting applicable waiver conditions, no special action (such as submission of a separate application for a waiver) is required by parties to be covered by these waivers.
- A waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) does not implicate the specific fraud and abuse law; (2) implicates the law, but fits within an existing exception or safe harbor; 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 Federal physician self-referral law (section 1877 of the Act), the Federal anti-kickback statute (sections 1128B(b)(1) and (2) of the Act), the beneficiary inducements CMP (section 1128A(a)(5) of the Act), or any other applicable law.
- Nothing in this Notice affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the Internal Revenue Code or other applicable Federal or State laws and regulations, including, but not limited to, any anti-fraud laws, other than those specified above. Nothing in this Notice changes any Medicare program reimbursement or coverage rule or alters any obligations under the Participation Agreement.
- We reserve the right to reconsider any waiver and, when the public interest requires, to modify or terminate a waiver on a prospective basis with respect to an ACO and some or all Initiative Participants, Preferred Providers, and Beneficiaries. The modification, suspension, or termination of part or all of the waiver does not require advance notice. We anticipate, however, that the circumstances under which no advance notice would be provided would be limited to egregious conduct that poses an imminent risk of harm to programs or patients.

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

**Dated:** [December 20, 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 19, 2018]

/Daniel R. Levinson/

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