

**Notice of Waiver of Certain Fraud and Abuse Laws
in Connection with the Pioneer ACO Model
December 8, 2011**

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 Pioneer Accountable Care Organization Model (the Pioneer ACO Model). This notice (Notice) is issued pursuant to this authority to establish waivers applicable to arrangements entered into by individuals and entities participating in the Pioneer ACO Model, subject to the conditions set forth in the waivers.

I. The Waivers and Applicable Requirements

As used in these waivers, Effective Date, Pioneer ACO, and Pioneer Provider/Supplier have the meanings set forth in the participation agreement.

Participation agreement refers to the Pioneer ACO Model Innovation Agreement between the Pioneer ACO and CMS for the Pioneer ACO's participation in the Pioneer ACO Model.

Purposes of the Pioneer ACO Model means one or more of the following purposes: promoting accountability for the quality, cost, and overall care for a Medicare patient population; managing and coordinating care for Medicare fee-for-service beneficiaries through a Pioneer accountable care organization; or encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.

A. Pioneer ACO Participation Waiver

Pursuant to section 1115A(d)(1) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law¹), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP²), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute³) are waived with respect to any arrangement of the Pioneer ACO, one or more of its Pioneer Providers/Suppliers, or a combination thereof, provided all of the following conditions are met:

1. The Pioneer ACO has entered into a participation agreement and remains in good standing under its participation agreement.
2. The Pioneer ACO meets the requirements set forth in its participation agreement concerning its governance, leadership, and management.
3. The Pioneer ACO's governing body has made and duly authorized a bona fide determination, consistent with the governing body members' duty set forth in section IV(B)(4) of the Pioneer ACO's participation agreement, that the arrangement is reasonably related to the purposes of the Pioneer ACO Model.
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

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

² Sections 1128A(b)(1) and (2) of the Act (42 U.S.C. 1320a-7a(b)(1) and (2), the "Gainsharing CMP").

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

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/or goods covered by the arrangement (including non-medical items, 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 Pioneer ACO's governing body that the arrangement is reasonably related to the purposes of the Pioneer ACO Model.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

6. The Pioneer ACO's participation agreement does not provide that this Pioneer 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 Pioneer 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), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), 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 Pioneer ACO, provided all of the following conditions are met:

1. The Pioneer ACO has entered into a participation agreement and remains in good standing under its participation agreement.
2. The shared savings are earned by the Pioneer ACO pursuant to the Pioneer ACO Model.
3. The shared savings are earned by the Pioneer 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 Pioneer ACO, its Pioneer Providers/Suppliers, or individuals and entities that were its Pioneer Providers/Suppliers during the year in which the shared savings were earned by the Pioneer ACO; or
 - b. Used for activities that are reasonably related to the purposes of the Pioneer ACO Model.
5. With respect to the waiver of sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), payments of shared savings distributions made directly or indirectly from a

hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.

6. The Pioneer ACO's 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 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP) and 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 Pioneer ACO and its Pioneer Providers/Suppliers that implicates the Physician Self-Referral Law, provided all of the following conditions are met:

1. The Pioneer ACO has entered into a participation agreement and remains in good standing under its participation agreement.
2. The financial relationship is reasonably related to the purposes of the Pioneer ACO Model.
3. The financial relationship fully complies with an exception at 42 CFR 411.355 through 411.357.
4. The Pioneer ACO's 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 Incentives

Pursuant to section 1115A(d)(1) of the Act, section 1128A(a)(5) of the Act (relating to the Beneficiary Inducements CMP⁴) 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 Pioneer ACO or its Pioneer Providers/Suppliers to beneficiaries for free or below fair market value if all four of the following conditions are met:

1. The Pioneer 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.
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 Pioneer ACO's participation agreement does not provide that this Waiver for Patient Incentives is inapplicable.

⁴ Section 1128A(a)(5) of the Act (42 U.S.C. 1320a-7a(a)(5)), the "Beneficiary Inducements CMP").

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 Waiver Requirements

Where applicable, we interpret the waivers described in this Notice consistently with the waivers described in section IV.B. of the interim final rule with comment period (IFC), establishing final waivers in connection with the Shared Savings Program (76 FR 67992 (Nov. 2, 2011)). Section V. of the IFC provides guidance to help stakeholders interpret the waiver requirements established therein.

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; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate 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, the Federal anti-kickback statute, the Beneficiary Inducements CMP, and the Gainsharing CMP. Failure to fit in a waiver is not, in and of itself, a violation of the laws.

The waivers in this Notice apply uniformly to arrangements entered into by each Pioneer ACO and Pioneer Provider/Supplier participating in the Pioneer 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 in order 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 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.

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

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

Dated: [12/8/11]

/Marilyn B. Tavenner/

Marilyn B. Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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

Dated: [12/8/11]

/Daniel R. Levinson/

Daniel R. Levinson,

Inspector General,

Department of Health and Human Services.