

# Issue Brief

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## KEY POINTS

- The rule finalizes waivers of the application for the physician self-referral law, the federal anti-kickback statute and the civil monetary penalties law provision.
- The rule does not finalize waivers of the application for the civil monetary penalties law provision relating to “gainsharing” arrangements.

## CMS and OIG Issue Final Waiver Rules in Connection With the Shared Savings Program

The Centers for Medicare & Medicaid Services and the U.S. Department of Health & Human Services’ Office of the Inspector General have issued a rule that finalizes waivers of the application of the physician self-referral law, the federal anti-kickback statute and the civil monetary penalties law provision relating to beneficiary inducements to specified arrangements involving accountable care organizations under section 1899 of the Social Security Act (the “Shared Savings Program”).

The rule was placed on public display at the *Federal Register* office today. The 129-page rule is scheduled to be published on Oct. 29. The effective date will be Oct. 29, 2015 — the same as the publication date. CMS is waiving its traditional 30-day notice of rulemaking.

### COMMENT

As with most final rules, this rule includes lengthy discussions regarding comments received and CMS/OIG responses. It also discusses the relationships between anti-kickback issues and the need to promote shared savings organizations. The rule includes a good section on the final waiver requirements.

### THE WAIVERS AND APPLICABLE REQUIREMENTS

#### ACO Pre-Participation Waiver

“Pursuant to section 1899(f) 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 start-up arrangements that pre-date an ACO’s participation agreement, provided all of the following conditions are met.

1. “The arrangement is undertaken by a party or parties acting with the good faith intent to develop an accountable care organization that will participate in the Shared Savings Program starting in a particular year (the “target year”) and to submit a completed application to participate in the Shared Savings Program for that year. The parties to the arrangement must include, at a minimum, the ACO or at least one ACO participant of the type eligible to form an ACO (as set forth at 42 CFR 425.102(a)). The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment suppliers or home health suppliers.

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2. “The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year, including taking diligent steps to meet the requirements of 42 CFR 425.106 and 425.108 concerning the ACO’s governance, leadership and management.
  3. “The ACO’s governing body has made and duly authorized a bona fide determination, consistent with a duty to the ACO that is equivalent to the duty owed by ACO governing body members under 42 CFR 425.106(b)(3), that the arrangement is reasonably related to the purposes of the Shared Savings Program.
  4. “The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, the documentation of the authorization must be contemporaneous with the authorization, and the documentation of the diligent steps must be contemporaneous with the diligent steps. All such documentation must be retained for at least 10 years following completion of the arrangement (or, in the case of the diligent steps, for at least 10 years following the date the ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application, as described in item 6) and promptly made available to the Secretary upon request. The documentation must identify at least the following.
    - “A description of the arrangement, including all parties to the arrangement; the date of the arrangement; the purpose(s) 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.
    - “The date and manner of the governing body’s authorization of the arrangement. The documentation of the authorization must include the basis for the determination by the ACO’s governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.
    - “A description of the diligent steps taken to develop an ACO, including the timing of actions undertaken and the manner in which the actions relate to the development of an ACO that would be eligible for a participation agreement.
  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. “If an ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement on or before the last available application due date for the target year, in a form and manner to be determined by the Secretary, describing the reasons it was unable to submit an application.
- “For arrangements that meet all of the preceding conditions, the pre-participation waiver applies as follows.

- “The waiver period would start on –
  - The date of publication of the IFC for target year 2012; or
  - One year preceding an application due date (the “selected application date”) for a target year of 2013 or later.
- “The waiver period would end –
  - For ACOs that submit an application by the selected application date and enter into a participation agreement for the target year, on the start date for that agreement;
  - For ACOs that submit an application by the selected application date for the target year, but whose application is denied, on the date of the denial notice, except with respect to any arrangement that qualified for the waiver before the date of the denial notice, in which case the waiver period would end on the date that is 6 months after the date of the denial notice; and
  - For ACOs that fail to submit an application by the selected application due date for the target year, on the earlier of the selected application due date or the date the ACO submits a statement of reasons for failing to submit an application, except that an ACO that has been unable to submit an application, but can demonstrate a likelihood of successfully developing an ACO that would be eligible to participate in the Shared Savings Program by the next available application due date, may apply for an extension of the waiver, pursuant to procedures established by the Secretary in guidance. The determination whether to grant a waiver will be in the sole discretion of the Secretary and will not be reviewable.
- “An ACO may use the pre-participation waiver (including any extensions granted) only one time.

### **ACO Participation Waiver**

“Pursuant to section 1899(f) 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 of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof, provided all of the following conditions are met.

1. “The ACO has entered into a participation agreement and remains in good standing under its participation agreement.
2. “The ACO meets the requirements of 42 CFR 425.106 and 425.108 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 under 42 CFR 425.106(b)(3), that the arrangement is reasonably related to the purposes of the Shared Savings Program.
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 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.
- “The date and manner of the governing body’s authorization of the arrangement. The documentation must include the basis for the determination by the ACO’s governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.

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.

“For arrangements that meet all of the preceding conditions, the waiver period will start on the start 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 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.

### **Shared Savings Distribution Waiver**

“Pursuant to section 1899(f) 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 an ACO, provided all of the following conditions are met:

1. “The ACO has entered into a participation agreement and remains in good standing under its participation agreement;
2. “The shared savings are earned by the ACO pursuant to the Shared Savings Program;
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 –
  - “Distributed to or among the ACO’s ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or
  - “Used for activities that are reasonably related to the purposes of the Shared Savings Program.

### **Compliance With the Physician Self-Referral Law Waiver**

“Pursuant to section 1899(f) 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, its ACO participants, and its ACO providers/suppliers that implicates the physician self-referral law, provided all of the following conditions are met:

1. “The 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 Shared Savings Program.
- 3. “The financial relationship fully complies with an exception at 42 CFR 411.355 through 411.357.

“For arrangements that meet all of the preceding conditions, the waiver period will start on the start 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.

- Adherence to a follow-up care plan.
- Management of a chronic disease or condition.

“For arrangements that meet all of the preceding conditions, this waiver period will start on the start 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.”

### Waiver for Patient Incentives

“Pursuant to section 1899(f) of the Act, section 1128A(a)(5) of the Act (relating to the Beneficiary Inducements CMP) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair market value if all four of the following conditions are met:

1. “The 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 –
  - “Are preventive care items or services; or
  - “Advance one or more of the following clinical goals:
    - Adherence to a treatment regime.
    - Adherence to a drug regime.

*Analysis provided for MHA  
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