

November 10, 2011

## INTERIM FINAL RULE ON WAIVERS OF FRAUD AND ABUSE LAWS

### A. Background

In the Proposed Rule, CMS briefly discusses waivers of the federal fraud and abuse laws (the physician self-referral law (the “Stark Law”), the Anti-Kickback Statute and the Civil Monetary Penalty provision, sections 1877(a), 1128B(b)(1) and (2), and 1128A(b)(1) and (2), respectively) (collectively, the Fraud and Abuse laws). Detailed information regarding these critical waivers was published in a second document—CMS-1345-NC2—entitled “Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center” (the Notice). Despite being classified as a “notice with comment period,” CMS and OIG actually proposed three types of waivers for the Shared Savings Program and sought comments on additional waivers and criteria for waivers that might be necessary to form and operate Shared Savings Programs or delivery systems operating under the authority of CMS’s Center for Medicare and Medicaid Innovation (the Innovation Center).

Based on CMS’s and OIG’s consideration of numerous comments regarding the proposed waivers, the interim final rules (IFC) establish five waivers that are intended to provide flexibility to ACOs in a number of situations anticipated before, during and after the formation of the ACO. Moreover, they are self-executing (i.e., no need to file additional notices/materials to CMS or OIG), apply consistently across waived fraud and abuse laws, and apply uniformly to each ACO, ACO participant and ACO provider/supplier participating in the Shared Savings Program. The IFC is effective on the date of its publication in the Federal Register and subject to a comment period of 60 days. In that regard, there may be further changes to the waivers based on the comments CMS may receive during that time.

### B. Key Changes

- An ACO arrangement only needs to meet the criteria for one waiver, but it may meet other waivers.
- There is no requirement that there be written and signed agreements, but it is “best practice to do so” according to CMS, since a written or signed agreement would be required for compliance with the Stark Law if a waiver does not apply.
- As currently drafted, the waivers do not require that an arrangement be at fair market value or be commercially reasonable, but CMS will closely monitor for abuse and may incorporate additional restrictions.
- Arrangements need only be “reasonably related” to one of the purposes of the Shared Savings Program rather than a narrower approach of being “directly related,” which was CMS’s response in simplifying the process and addressing public comments requesting a broader approach.
- An ACO may provide incentives to all new primary care physicians such as covering the EHR proportionate expense or various office service benefits (but cannot pay based on volume of services or require that physicians refer patients to the ACO or ACO participants).
- Waivers are applicable to private payor arrangements, but these must show they are reasonably related to ACO participation in the Shared Savings Program.
- Satisfying the requirements of the Compliance with Stark Law Waiver essentially means that if an ACO arrangement satisfies the Stark law, it need not also comply with the Anti-Kickback Statute or CMP Laws.

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## C. Pre-Participation Waiver

- The Fraud and Abuse laws are waived with respect to an ACO's start-up arrangement if all of the following are satisfied:
  - The arrangement is undertaken with good faith intent to develop an ACO that will participate in the Shared Savings Program and a complete application has been submitted.
  - The parties to the arrangement include the ACO and at least one ACO participant.
  - No party to the arrangement can be a drug and device manufacturer, distributor, DME supplier or home health supplier.
  - Diligent steps must be taken to develop an ACO that will meet all requirements of the Shared Savings Program rules, including governance, leadership and management requirements.
  - The ACO governing body has determined that the start-up arrangement is reasonably related to the purposes of the Shared Savings Program.
  - The arrangement, the governing body's authorization and the diligent steps to develop the ACO are documented concurrent with such actions. All documentation must be in place for at least 10 years.
  - Public disclosure of the arrangement (other than financial/economic terms) in such manner as required by HHS.
  - If the ACO does not submit an application for the targeted year, it must file a statement on or before the last application due date for the targeted year explaining why it was unable to submit a timely application.
- The waiver period starts on the date of publication of the IFC for a 2012 target date or one year preceding an application due date for subsequent target dates.
- The waiver period ends:
  - On the start date of the ACO participation agreement (if entered into ACO participation agreement).
  - On the denial date (for ACOs that apply for participation but are denied from participation) or six months thereafter for an arrangement that qualified for the waiver before the denial.
  - (No newly created arrangements would be protected during the six-month period.)
  - On the application due date (if the ACO fails to submit an application).
  - On the date the ACO submits reasons for not applying (if the ACO fails to submit an application but provides reasons why it failed to do so, with some ability to extend the time for good reasons for failing to submit an application).
- Pre-application waivers may only be used one time during a single-year period.

## D. Participation Waiver

- The Fraud and Abuse laws are waived with respect to an ACO's relationship among the ACO, one or more ACO participants and/or ACO providers/suppliers involving all arrangements, including drug and device manufacturers, distributors, DME and home health suppliers, if all of the following conditions are met:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - The ACO meets the requirement addressing governance, leadership and management for ACOs of the Shared Savings Program.
  - The ACO governing body has determined that the arrangement is consistent with the duties under 42 CFR § 425.106(b) (3), and that the arrangement is reasonably related to the purposes of the Shared Savings Program.
  - Both the arrangement and the governing body's authorization are documented concurrent with such actions. All documentation must be in place for at least 10 years and available to HHS upon request.
  - Public disclosure of the arrangement (other than financial/economic terms) in such manner as required by HHS
- The waiver period starts on the start date of participation in the Shared Savings Program.
- The waiver period ends six months after expiration of such participation agreement, including any renewals, or the date of the ACO's voluntary termination.
- The waiver extends to private payor arrangements if activity is reasonably related to the ACO's participation in the Shared Savings Program.

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## E. Shared Savings Waiver

- The Fraud and Abuse laws are waived with respect to the distribution or use of shared savings earned by the ACO under the Shared Savings Program, if all of the following conditions are met:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - The shared savings are earned by the ACO pursuant to the Shared Savings Program.
  - The shared savings are earned by the ACO during the term of its participation agreement (even if actual distribution/use of savings occurs after expiration of program).
  - The shared savings are: (i) distributed to or among the ACO participants, ACO providers/suppliers, or individuals or entities that were its ACO participants or ACO providers/suppliers during the year the shared savings were earned, or (ii) used for activities that are reasonably related to purposes of the Shared Savings Program.
  - With respect to the waiver of the gainsharing portions of the Civil Monetary Penalty provisions, shared savings distributions that are made directly or indirectly from a hospital to a physician must not be made knowingly to induce a physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.
- Comments suggest that “medically necessary” will be interpreted consistent with Medicare program rules and accepted standards of practice.
- Comments also indicate that arrangements to incentivize alternate and appropriate medically necessary care consistent with the purposes of the Shared Savings Program, such as through use of evidence-based protocols, are permitted, but arrangements tied to drugs or devices known to be less effective clinically shall be prohibited.
- Waiver only applies to distribution of shared savings. All other arrangements would need to qualify for one of the other waivers or an existing safe harbor, or must otherwise comply with the law.
- Waiver applies to payments made to referring physicians outside the ACO with shared savings for services reasonably related to the Shared Savings Program or if they were ACO participants at the time the shared savings were earned.

## F. Compliance with Stark Law Waiver

- The Fraud and Abuse laws are waived with respect to any financial relationship between or among the ACO, its ACO participants and its ACO providers/suppliers that implicates the Stark Law, if all of the following conditions are met for each arrangement:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - The financial relationship is reasonably related to the purposes of the Shared Services Program.
  - The financial relationship fully complies with an applicable Stark Law exception (under 42 C.F.R. § 411.355 to § 411.357).
- The waiver period starts on the start date of participation in the Shared Savings Program.
- The waiver period ends on the earlier of expiration or termination of the participation agreement, although CMS is considering an extension period.
- The waiver does not apply to non-ACO arrangements.

## G. Patient Incentives Waiver

- The fraud and abuse laws are waived with respect the beneficiary inducement portions of the Civil Monetary Penalty provisions and the Anti-Kickback Statute for 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 of the following conditions are met:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - There is a reasonable connection between the items or services and medical care of the beneficiary.
  - The items or services are in-kind.
  - The items or services are preventive care items or services or advance one or more of the clinical goals of adherence to a treatment regime, drug regime or follow-up care plan, or management of a chronic disease or condition.

- Waiver only protects in-kind services that relate to medical care and management provided to patient, not financial incentives such as waiving co-pays and deductibles.
- CMS is considering whether the Final Rule will apply only to beneficiaries assigned to ACO or to all beneficiaries.
- ACOs are prohibited from providing gifts or other remuneration to patients as an incentive to receive services or remain in ACO.
- Waiver does not protect the provision of free or below fair market value of goods or services by vendors to beneficiaries or to ACOs, ACO participants or ACO providers/suppliers.
- Waiver period starts on the start date of participation in the Shared Savings Program.
- Waiver period ends on the earlier of expiration or termination of the participation agreement.
- Items legitimately provided can be retained by beneficiary and services initiated during a participating contract period can be continued beyond termination/expiration date.
- The waiver applies to all beneficiaries of the ACO.

## Comments and Recommendations

- The waivers apply to the Shared Savings Program and all participating ACOs. They also apply to any ACOs that are participating in the Advance Payment Initiative. However, these waivers do not apply to any other demonstration or pilot programs or any other Medicare-enrolled provider.
- It is possible that additional guidance may be needed to clarify some of the waivers. Hence, if there are questions, comments should be submitted to CMS before the end of the comment period (60 days from the date of publication in the Federal Register on November 2, 2011). For example, the Pre-Participation Waiver provides for an applicant to request an extension of the waiver if the applicant fails to timely submit an application but also shows that it is likely that the applicant will develop a qualifying ACO by the next application due date. The HHS Secretary has discretionary authority on whether to approve or deny such a request. There is no specific guidance on what factors the HHS Secretary will review in granting an extension. Further, no guidance has yet to be provided on the steps needed to get the extension.
- The Compliance with Stark Law Waiver may not really afford additional protections for financial arrangements that already satisfy the Stark Law because certain Stark Law exceptions already require compliance with the Anti-Kickback Statute and in some cases with the gainsharing portion of the Civil Monetary Penalty Laws. But it does avoid the need for a separate analysis in addition to Stark Law compliance, streamlining the process by which participants can review for compliance.

## IRS NOTICE ON TAX-EXEMPT HOSPITALS PARTICIPATING IN ACOs

The IRS issued Notice 2011-20 (2011-16 I.R.B. 652 (April 18, 2011)) (the Notice) to address whether Section 501(c)(3) hospitals and other tax-exempt health care entities participating in the Shared Savings Program through an ACO may be affected by current limitations on such entities under the Internal Revenue Code. On October 20, 2011, the IRS issued Fact Sheet 2011-11, which confirms that Notice 2011-20 continues to reflect the IRS's expectations regarding the Shared Savings Program and ACOs.

Generally, as indicated in the Notice, the IRS expects that a tax-exempt hospital's participation in ACO arrangements under the Shared Savings Program will not result in private inurement or benefit if the following factors are present:

- The terms of the tax-exempt hospital's participation in the Shared Savings Program through an ACO are set forth in advance in a written agreement negotiated at arm's length.
- CMS has accepted the ACO into, and has not terminated the ACO from, the Shared Savings Program.
- The tax-exempt hospital's share of the economic benefits derived from the ACO (including its share of Shared Savings Program payments) is proportional to the benefits or contributions that the hospital provides to the ACO.

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- The ownership interest received by the tax-exempt hospital, if any, is proportional and equal in value to its capital contributions to the ACO, and all ACO returns of capital, allocations and distributions are made in proportion to such ownership interest.
  - The tax-exempt hospital's share of ACO losses (including its share of Shared Savings Program losses) does not exceed the share of ACO economic benefits to which the hospital is entitled.
  - All contracts and transactions entered into by the tax-exempt hospital with the ACO and the ACO participants, and by the ACO with the ACO participants and other parties, are at fair market value.

## Comments and Recommendations

- The IRS's approach to a tax-exempt hospital's participation in ACO arrangements is consistent with its approach to any joint venture between a tax-exempt entity and unrelated, non-exempt parties. The same factors apply, including the following:
  - Economic benefits to the tax-exempt hospital are proportionate to its contributions.
  - Ownership interest of the tax-exempt hospital in the ACO is proportionate to the value of its capital contributions, and all distributions and allocations are made in proportion to the ownership interest.
  - Sharing in any profits and losses is proportionate.
  - All transactions and interactions are on a fair market value basis.

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## Contact Us

If you have any questions about the Final ACO Rule or ACO participation, please contact your Katten Muchin Rosenman LLP attorney, or any of the following members of **Katten's Health Care Practice**.

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