

Publications

Health Care Alert: CMS Releases Interim Final Rule for ACO Fraud & Abuse Waiver Provisions

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In conjunction with its October 20, 2011 issuance of the Medicare Shared Savings Program for Accountable Care Organizations ("MSSP") final regulations, the Centers for Medicare and Medicaid Services ("CMS") and the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") jointly released an interim final rule establishing waivers of the application of certain health care fraud and abuse laws to specified arrangements involving Accountable Care Organizations ("ACOs") participating in the MSSP (the "Interim Rule"). This interim final rule was published in the November 2, 2011 edition of the *Federal Register* (76 Fed. Reg. 67992.).

The MSSP is a Medicare program designed to promote quality and cost accountability within the Medicare patient population, coordinate care delivery and under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. In the Interim Rule, CMS and OIG recognize that certain fraud and abuse laws may impede development of some of the innovative integrated-care models envisioned by the MSSP. To enable the MSSP to most effectively promote ACOs, CMS and OIG have deemed it necessary to waive certain provisions of the Physician Self-Referral Law ("Stark Law"), the Federal Anti-Kickback Statute ("AKS"), the Civil Monetary Penalty ("CMP") law prohibiting inducements to beneficiaries ("Beneficiary Inducement CMP"), and the CMP law prohibiting hospital payments to reduce or limit services ("Gainsharing CMP").

Waiver Requirements

CMS and OIG have established five separate, independent waivers intended to afford flexibility to ACOs in structuring their operations and sharing costs and revenues as part of the ACO. The waivers are intended to be self-implementing (i.e., no separate grant or approval of a waiver to an ACO by CMS or OIG is necessary assuming all requirements are met). Arrangements that do not fit into a waiver have no additional protection by virtue of existing within an ACO construct, and must be evaluated on a case-by-case basis for compliance with all

applicable laws. The waiver authority under the MSSP does not extend to any other laws or regulations, including, without limitation, antitrust laws, the Internal Revenue Code ("IRC") or state laws and regulations. Moreover, nothing in the interim final rule changes any Medicare program reimbursement or coverage rules, or alters any obligations parties may have under the MSSP.

Set forth below is a brief description of the requirements of each waiver.

1. *ACO Pre-Participation Waiver*

The Stark Law, the Gainsharing CMP, and the AKS are waived with respect to a start-up arrangement that pre-dates an ACO's participation agreement, provided all of the following conditions are met:

- The arrangement is undertaken by parties intending in good faith to develop an ACO that will participate in the MSSP, must include one participant eligible to form an ACO, and may not include drug and device manufacturers, distributors, DME suppliers, or home health suppliers.
- The parties developing the ACO must be taking diligent steps to satisfy MSSP governance, leadership, and management requirements.
- The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP.
- The start-up arrangement, its authorization by the governing body, and the diligent steps to develop the ACO must be contemporaneously documented with documents retained for at least 10 years following completion of the arrangement.
- The description of the arrangement is publicly disclosed in accordance with guidance issued by the Secretary of HHS. However, the public disclosure shall not include financial or economic terms of the arrangement.
- The ACO must file an application for participation in the MSSP on or before the last applicable due date for the target year or the reasons for the failure to submit the application must be submitted to the Secretary of HHS.

If all these conditions are met, the waiver period starts on October 20, 2011 for a 2012 target date, or one year preceding an application due date for later target dates. The waiver period end dates vary: (1) for ACOs that timely submit an application and enter into a participation agreement for the target year, on the start date for that agreement; (2) for ACOs that apply for participation but whose application is denied, on the date of the denial notice, unless the arrangement qualified for the waiver before the date of the denial notice, in which case the waiver period ends 6 months after the denial notice; or (3) for ACOs that fail to timely apply, the application due date or the date the ACO submits its reasons for not applying, with some exceptions.

CMS and OIG offer by way of example the provision of the following items, services, facilities, and goods which may qualify as start-up arrangements:

- Infrastructure creation and provision;
- Network development and management;

- Care coordination mechanisms;
- Clinical management systems;
- Quality improvement mechanisms;
- Creation of governance and management structure;
- Care utilization management;
- Creation of incentives for performance-based payment systems and transitions from fee-for-service;
- Hiring of new staff, including care coordinators, quality leadership, organization management, analytical team, liaison team, IT support, and risk management;
- Information technology, including EHR systems, electronic health information exchanges, data reporting systems, and data analytics;
- Consultant and other professional support, including market analysis, legal services, and financial and accounting services;
- Organization and staff training;
- Incentives to attract primary care physicians; and
- Capital investments, including loans, capital contributions, grants, and withholds.

1. *ACO Participation Waiver*

The Stark Law, the Gainsharing CMP, and the AKS are waived with respect to any arrangement of an ACO, one or more of its ACO participations or ACO providers/suppliers, or a combination thereof, provided all of the following conditions are met:

- The ACO has entered into a participation agreement and remains in good standing thereunder.
- The ACO meets the MSSP requirements concerning its governance, leadership, and management.
- The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP.
- Both the arrangement and its authorization by the governing body must be contemporaneously documented with documents retained for at least 10 years following completion of the arrangement.
- The description of the arrangement is publicly disclosed in accordance with guidance issued by the Secretary of HHS. However, the public disclosure shall not include financial or economic terms of the arrangement.

If all these conditions are met, the waiver period begins on the start date of the participation agreement and will end six months following the earlier of the expiration of the agreement, including any renewals, or the date of the ACO's voluntary termination.

1. *Shared Savings Distribution Waiver*

The Stark Law, the Gainsharing CMP, and the AKS are waived with respect to distributions or use of shared savings earned by an ACO, provided all of the following conditions are met:

- The ACO has entered into a participation agreement and remains in good standing thereunder.
- The shared savings are earned by the ACO pursuant to the MSSP.
- 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.
- The shared savings are either:
 - Distributed to or among the ACO participants, ACO providers/suppliers, or individuals and entities that were its ACO participants or ACO providers/suppliers during the year in which the shared savings were earned; or
 - Used for activities reasonably related to the purposes of the MSSP.
- With respect to the waiver of 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.

1. *Compliance With the Stark Law Waiver*

The Gainsharing CMP and the AKS are waived with respect to any financial relationship between or among the ACO, its participants, and its ACO providers/suppliers that implicates the Stark Law, provided all of the following conditions are met:

- The ACO has entered into a participation agreement and remains in good standing thereunder.
- The financial relationship is reasonably related to the purposes of the MSSP.
- The financial relationship fully complies with an exception to the Stark Law at 42 C.F.R. §§ 411.355 to 411.357.

If all these conditions are met, the waiver period begins on the start date of the participation agreement and will end on the earlier of the expiration of the participation agreement, including any renewals, or the date the agreement is terminated.

1. *Waiver for Patient Incentives*

The Beneficiary Inducement CMP and the AKS are waived with respect to items or services provided by an ACO, its ACO participations, or its ACO providers/suppliers to beneficiaries for free or below fair-market-value, or a combination thereof, provided all of the following conditions are met:

- The ACO has entered into a participation agreement and remains in good standing thereunder.
- There is reasonable connection between the items or services and the 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 following clinical goals:
 - Adherence to a treatment regime;
 - Adherence to a drug regime;

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

If all these conditions are met, the waiver period begins on the start date of the participation agreement and will end on the earlier of the expiration of the participation agreement, including any renewals, or the date the agreement is terminated.

"Reasonably Related to the Purposes of the MSSP"

Several waivers described above require that arrangements be "reasonably related to the purposes of the MSSP." CMS and OIG define this phrase to include the following:

- Promoting accountability for the quality, cost, and overall care for a Medicare population.
- Managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO.
- Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.
- Evaluating health needs of the ACO's assigned population.
- Communicating clinical knowledge and evidence based medicine to beneficiaries.
- Developing standards for beneficiary access and communication, including beneficiary access to medical records.

CMS and OIG make clear that arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waivers. Moreover, the arrangement need only be reasonably related to one enumerated purpose. Although this definition is broad, CMS and OIG expect parties to apply a "reasonable interpretation" of the waiver terms. The interim final rule provides that CMS and OIG will closely monitor ACOs entering the MSSP in 2012 through 2013, and will narrow the waivers unless the Secretary of HHS determines that the waivers have not had the unintended effect of shielding abusive arrangements. CMS and OIG are soliciting additional comments on whether and how they should further define the "reasonably related to the purposes of the MSSP" standard. This indicates that while the waiver provisions provide a significant amount of flexibility to structure financial arrangements within an ACO, and with ACO participating providers and suppliers, OIG and CMS anticipate further changes to the waiver provisions after the initial period of ACO participation and operation.