

PUBLICATION

Interim Final Waiver Rule for ACOs

November 10, 2011

On November 2, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) announced the Interim Final Rule for Waivers in Connection with the Shared Savings Program involving Accountable Care Organizations (ACOs).¹ The waivers encompass enumerated provisions of the Physician Self-Referral Law (the Stark Law), the federal anti-kickback statute and the Civil Monetary Penalties Law (CMP). These regulations became effective on November 2, 2011.

Although the majority of the commenters to the proposed rule advocated for a waiver of these laws in their entirety for ACOs, this did not occur. Instead, CMS and the OIG established five specific waivers (two of which were included in the proposed rule and are finalized with some modification) and waiver requirements applicable to specific provisions of the enumerated laws which will "apply uniformly to each ACO, ACO participant and ACO provider/supplier participating in the ACO" (ACO covered group).² These waivers will be self-implementing, meaning that if the parties comply with the requirements, they are entitled to and need not apply for the waiver.

The waivers fall into five categories: (1) pre-participation waivers; (2) ACO participation waivers; (3) Shared Savings distribution waivers; (4) the Stark law; and (5) patient incentives. The first four waivers apply to the Stark law, the federal anti-kickback statute and the gainsharing CMP. The patient incentives waiver applies to the beneficiary inducements CMP and the federal anti-kickback statute for medically-related incentives offered by ACOs under the Shared Savings Program.

Pre-Participation Waiver

CMS and the OIG have enumerated six conditions that must be met to comply with the pre-participation waiver. The conditions apply to "start-up arrangements" as defined in the waiver rule and require good faith, diligent steps in developing the ACO, governing body bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program, and 10 year record keeping requirements related to the documentation and governing body authorization of the ACO arrangement. "Start-up arrangements" occurring during the participation phase of the ACO will be covered under the Participation waiver. The details are set forth in the regulation. The final condition addresses the circumstance when an ACO does not submit an application by the last available application due date; in that instance, the condition requires the ACO to submit a timely statement of reasons it was unable to submit the application in a form determined by the Secretary of HHS. The waiver period is very specific. The rule also sets forth an extension of the waiver period for an ACO which fails to meet the application submission deadline. The extension must be approved by the Secretary in its sole discretion and is not reviewable. The waiver (including extensions granted) may only be used one time.

Participation Waiver

The participation waiver includes five enumerated conditions evidencing the establishment of the ACO, its participation in the Medicare Shared Savings Program, and the documentation which must be retained for a 10 year period. The waiver period begins with the start date of the participation agreement and ends 6 months

following the earlier of its expiration (including renewals) or voluntary termination. If the participation agreement is involuntarily terminated, "the waiver period will end on the date of termination notice."³

The intent of the pre-participation and participation waivers is to facilitate and protect the "bona fide ACO investment, start-up, operating, and other arrangements that carry out the Shared Savings Program, subject to certain safeguards."⁴ The safeguards include among other things, transparency that "requires arrangements for which waiver protection is desired to be publicly disclosed" and recordkeeping with an "audit trail of contemporaneous documentation that identifies the core characteristics of the arrangement."⁵ The public disclosure requirement includes a posting requirement on the ACO website within 60 days of the date of the arrangement. The specifics of the posting are included in the waiver rules for the pre-participation and participation waivers. These two waivers apply to arrangements within the ACO, between and among the ACO group and to ACO-related arrangements with outside providers and suppliers that may not be within the ACO group but "have a role in coordinating and managing care for ACO patients."⁶

Shared Savings Distribution Waiver

There are also five enumerated conditions that must be met for this waiver -- all related to the earned distributions for an ACO which has entered into a participation agreement and remains in good standing. The fifth condition specifically relates to the gainsharing CMP when payments of shared savings distributions are made either directly or indirectly from a hospital to a physician, which may not be made "knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician."⁷

There is no limit to the waiver period since distributions may occur after the expiration of the ACO agreement, but the waiver is limited to earned distributions of shared savings. Other waivers apply to other arrangements. This waiver is also not applicable to an ACO sponsored by a commercial health plan, but that does not necessarily mean that ACOs sponsored by commercial health plans implicate any of the enumerated laws. The ACO group would have to determine that on a case by case basis.

The intent of this waiver is "to protect arrangements created by the distribution of shared savings within an ACO that qualifies for the waiver, as well as arrangements created by the use of shared savings to pay parties outside such an ACO if those payments are reasonably related to the purposes of the Shared Savings Program." Therefore, this waiver not only applies within the ACO group but includes the "downstream" distributions or uses of shared savings between and among the ACO group.

Stark Law Waiver

CMS and the OIG established three conditions for compliance with the Stark Law waiver, which also provides protection under enumerated provisions of the anti-kickback statute and the CMP. The protection applies to the financial relationship between or among the ACO covered group that would otherwise implicate the Stark Law. One of the conditions of the waiver is that the financial relationship itself meet a Stark Law exception. The waiver period extends from the start date of the participation agreement until the earlier of its expiration, (including any renewal periods) or termination.

This waiver is intended to relieve some of the compliance burden under the enumerated laws.

Patient Incentives Waiver

Four conditions must be met in order to satisfy the patient incentives waiver with respect to items and services provided to ACO beneficiaries for free or below fair market value by the covered ACO group. Beneficiaries may

keep items received during this period and receive any service initiated before the expiration or termination date of the participation agreement. As with the Stark Law waiver, the waiver period extends from the start date of the participation agreement until its expiration (including any renewal periods) or termination.

This waiver is intended to foster patient engagement for improvement of quality and care coordination while safeguarding against the risk of inappropriate incentives for beneficiary steering. The waiver does not protect the provision of free or below fair market incentives by manufacturers or other vendors to the beneficiary or the ACO group. Further, other incentives not covered by the waiver may still be protected by other exceptions or safe harbors to the enumerated laws.

If you have questions or need any additional information about the ACO's interim final waiver rules may affect you or your company, please contact your Baker Donelson attorney.

1. 67992-68010 (Nov. 2, 2011).
2. Id. at 67999.
3. Id. at 68001.
4. Id. at 68002.
5. Id. at 68004.
6. Id. at 68005.
7. Id. at 68001.