

New Legal Waivers for ACOs

In the spring of this year, the Centers for Medicare and Medicaid Services (CMS) released the proposed rules governing Accountable Care Organizations (ACOs) participating in the CMS Shared Savings Program. Under the Shared Savings Program, if an ACO is able to reduce the cost of caring for Medicare patients without compromising quality, it will be entitled to split the savings with CMS. But many providers felt CMS did not do enough in the proposed rules to protect ACO participants from potential liability under the fraud and abuse laws. In response, CMS has issued an interim final rule that establishes five new waivers of fraud and abuse laws for providers participating in ACOs. CMS released the interim final rule in conjunction with the final regulations governing ACOs, which CMS also heavily revised in response to criticism from providers. An outline of the changes between the proposed ACO regulations and the final ACO regulations can be found in a [comparison chart](#) provided by CMS. A summary of the five new fraud and abuse waivers is provided below.

ACO Pre-Participation Waiver

Purpose: This waiver is meant to allow providers to effectively collaborate to form ACOs.

Waives: Portions of the Stark law, the civil monetary penalties law, and the anti-kickback law.

Requirements: The arrangement must be undertaken by the parties in a good-faith effort to develop an ACO. The parties to the arrangement must not include drug and device manufacturers, distributors, durable medical equipment suppliers, or home health providers. The parties must be taking diligent steps to develop the ACO. The ACO governing body must make a bona fide determination that its purpose is related to the Shared Savings Program with CMS. The parties must document their steps to develop an ACO.

Term: The waiver period will begin one year preceding the due date of the application to join the Shared Savings Program. The waiver period will end on the start date of the participation agreement with CMS or the date of the denial of the application or the due date for the application if the ACO never turns in an application. An ACO may use the pre-participation waiver only once.

ACO Participation Waiver

Purpose: This waiver protects ACO participants after they have entered into a participation agreement with CMS.

Waives: Portions of the Stark law, the civil monetary penalties law, and the anti-kickback law.

Requirements: The ACO must have entered into a participation agreement with CMS and must remain in good standing. The ACO must meet all the requirements of the Shared Savings Program. The ACO board must make a bona fide determination that the arrangement is for the purposes of the Share Savings Program.

Term: The waiver begins on the date that the participation agreement starts and ends six months after the expiration of the participation agreement.

Shared Savings Distribution Waiver

Purpose: This waiver allows the ACO to distribute the shared savings it earns from CMS to the ACO participants without violating the fraud and abuse laws.

Waives: Portions of the Stark law, the civil monetary penalties law, and the anti-kickback law.

Requirements: The ACO must have entered into a participation agreement with CMS. The shared savings must have been earned by the ACO during the term of the agreement. The shared savings must be distributed among the ACO participants or the ACO providers/suppliers or the shared savings must be used for activities related to the purposes of the Shared Savings Program. The payments must not knowingly be made to induce a physician to reduce or limit medically necessary items or services to patients.

Physician Self-Referral Law Waiver

Purpose: This waiver is meant to allow the ACO and its participants to establish financial relationships between each other that are necessary for the administration of the ACO without violating the fraud and abuse laws.

Waives: Portions of the civil monetary penalties law and the anti-kickback law.

Requirements: The ACO must have entered into a participation agreement with CMS. The financial relationship must be reasonably related to the Shared Savings Program. The financial relationship must comply with a Stark law exception found in the regulations at 42 CFR § 411.355 to § 411.357.

Term: The waiver period begins with the start date of the participation agreement and ends with the expiration of the participation agreement.

Waiver for Patient Incentives

Purpose: This waiver allows the ACO to provide items and services to ACO beneficiaries that will advance the cost-reduction goals of the ACO without violating the fraud and abuse laws.

Waives: Portions of the civil monetary penalties law and the anti-kickback law.

Requirements: The ACO must have entered into a participation agreement with CMS. There must be a reasonable connection between the items or services and the medical care of the beneficiary. The items or services must be in-kind (not cash). The items or services must be preventative care items or services or must be to advance one or more of the following goals: 1) adherence to a treatment regime, 2) adherence to a drug regime, 3) adherence to a follow-up care plan, or 4) management of a chronic disease or condition.

Term: The waiver period begins with the start date of the participation agreement and ends with the expiration of the participation agreement.

CMS issued the waivers as an interim final rule, which means that the waivers take effect immediately, but the providers may still submit comments. After the comment period ends, CMS may decide to make changes to the regulations implementing the waivers based on the public comments.

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