

PUBLICATION

ACO Fraud and Abuse Waivers Extended Through November 2, 2015 [Ober|Kaler]

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On October 17, 2014 the Centers for Medicare and Medicaid (CMS) and Office of Inspector General (OIG) within the Department of Health and Human Services published a [continuation notice](#) in the *Federal Register* extending the fraud and abuse waivers applicable to accountable care organizations (ACOs) participating in the Shared Savings Program. The notice extended the waivers through November 2, 2015.

The fraud and abuse waivers were originally established pursuant to an [interim final rule \[PDF\]](#) on November 2, 2011. As a general rule, the timeline for publishing a final rule cannot exceed 3 years from the date of publication of the proposed or interim final rule. Therefore, the waivers would have expired November 2, 2014. The continuation notice explains the Secretary's reasoning for extending the waivers to permit alignment with the Shared Savings Program and balance the needs of ACOs for certainty, innovation, and flexibility.

Brief Overview of the Waivers

The Shared Savings Program interim final rule set forth waivers of (a) certain provisions of the physician self-referral law (Stark Law); (b) the federal antikickback statute; (c) the civil monetary penalty (CMP) law prohibiting hospital payments to physicians to reduce or limit services (Gainsharing CMP); and (d) the CMP law prohibiting inducements to beneficiaries (Beneficiary Inducements CMP). The waivers protect the flow of remuneration in connection with the Shared Savings Program in five different circumstances, as outlined below:

1. ACO pre-participation waiver: Waives the Stark Law, the federal antikickback statute, and the Gainsharing CMP as they would apply to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program.
2. ACO participating waiver: Waives the Stark Law, the federal antikickback statute, and the Gainsharing CMP as they would apply to ACO-related arrangements during the term of the ACO's participation agreement with CMS under the Shared Savings Program and for a specified time period thereafter.
3. Shared savings distribution: Waiver of the Stark Law, the federal antikickback statute, and the Gainsharing CMP as they would apply to distribution and use of shared savings payments earned under the Shared Savings Program
4. Compliance with the physician self-referral law: Waives the Gainsharing CMP and the federal antikickback statute for ACO arrangements that implicate the Stark Law and meet an existing Stark Law exception.
5. Patient incentive waiver: Waives the Beneficiary Inducement CMP and the federal antikickback statute for medically related incentives offered by ACOs to beneficiaries to encourage preventive care and compliance with treatment regimens.

By extending the above waivers, CMS and the OIG have sought to ensure that ACOs participating in the Shared Savings Program are not left with "legal uncertainty."

Next Steps

In its continuation notice, CMS and the OIG also noted that CMS is currently developing a proposed rule regarding the Shared Savings Program in response to stakeholder feedback and CMS's experience operating the program. CMS stressed that it would benefit from stakeholders' input on (a) how and to what extent ACOs are using the waivers; (b) whether the existing waivers serve the needs of ACOs and the Medicare program; (c) whether the waivers adequately protect the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services; and (d) whether there are new or changed considerations that should inform the development of additional notice and comment rulemaking.