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CMS and OIG Issue Final Fraud and Abuse Waivers for ACOs

On October 29, 2015, the Centers for Medicare & Medicaid Services and the Office of Inspector General of the Department of Health & Human Services (jointly, the “Agencies”) issued a [final rule](#) (Final Rule) regarding waivers (ACO Waivers) of the Physician Self-Referral Law (Stark Law), the federal Anti-Kickback Statute (AKS), and the Civil Monetary Penalties Law (CMP) provision relating to beneficiary inducements (collectively, the “Fraud and Abuse Laws”) for Medicare accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP). The ACO Waivers, first set forth in an interim final rule in 2011 (Interim Rule), waive application of the Fraud and Abuse Laws to certain ACO activities that are reasonably related to the purposes of the MSSP.

The Final Rule implements the following ACO Waivers, which are consistent with the five waivers set forth in the Interim Rule, effective as of October 29, 2015:

- 1. ACO Pre-Participation Waiver** – covers certain start-up arrangements that predate an ACO’s MSSP participation agreement
- 2. ACO Participation Waiver** – covers arrangements of an ACO, one or more of its participants, or its ACO providers or suppliers during the term of its MSSP participation (and for a specified period thereafter)
- 3. Shared Savings Distribution Waiver** – covers distributions or use of shared savings earned by an ACO under the MSSP
- 4. Compliance with the Physician Self-Referral Law Waiver** – covers financial relationships among an ACO, its ACO participants, and its ACO providers or suppliers that implicate the Stark Law and satisfy the requirements of an existing Stark Law exception
- 5. Waiver for Patient Incentives** – covers items or services provided by an ACO, its ACO participants, or its ACO providers or suppliers to Medicare beneficiaries for free or below fair market value.

ACOs are not required to obtain any type of prior approval from the government to use an ACO Waiver, but the ACO Waivers only apply to the MSSP. To take advantage of an ACO Waiver, an arrangement must comply with certain conditions set forth in the Final Rule. These conditions are largely unchanged since the Interim Rule (described in detail in a [previous edition](#) of *Pulse*); however the Final Rule does include a few updates. First, the ACO Waivers no longer apply to the so-called “Gainsharing CMP.” The Gainsharing CMP previously prohibited hospitals from paying physicians to reduce or limit any health services, including medically *unnecessary* services. It was recently amended to only prohibit payments that induce physicians to limit or reduce medically *necessary* services (discussed in a [previous Pulse](#)). As a result, the Agencies determined that a waiver of the Gainsharing CMP is now unnecessary to carry out the MSSP because ACOs are no longer prohibited from making payments to physicians to reduce medically unnecessary services.

The Final Rule also clarifies that, with respect to the ACO Pre-Participation Waiver and the ACO

Participation Waiver, documentation of the ACO governing body's authorization for the arrangement *must* (rather than *should* from the Interim Rule) include the basis for the governing body's determination that the arrangement is reasonably related to the purposes of the Shared Savings Program. Additionally, the Final Rule defines "home health supplier" for purposes of the ACO Waivers to mean a provider, supplier, or other entity that is primarily engaged in providing home health services. Finally, the Final Rule makes certain other technical and clerical corrections to the Interim Rule.

To reduce potential scrutiny under the Fraud and Abuse Laws, ACOs relying on ACO waivers for particular arrangements are encouraged to review the Final Rule to ensure that such arrangements comply with an applicable ACO Waiver. Robinson+Cole's Health Law Group has extensive experience counseling clients on compliance with the ACO Waivers and the MSSP generally.

If you have any questions, please contact a member of Robinson+Cole's [Health Law Group](#):

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