

## ACOs: The Fraud & Abuse Waivers – Finding a Path Through the Maze

### The fourth advisory in our series on the newly proposed ACO regulations implementing Section 3022 of the PPACA

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The development and implementation of accountable care organizations will require health care providers to navigate a host of regulatory obstacles originally designed to restrict collaborative activity. As a result, the Patient Protection and Affordable Care Act explicitly authorizes the Secretary of the U.S. Department Health & Human Services to waive the federal fraud and abuse laws as necessary for the implementation of ACOs.

In keeping with this congressional directive, at the same time the Centers for Medicare and Medicaid Services released proposed rules regarding requirements for ACOs, it issued, in cooperation with the HHS Office of Inspector General (OIG), a joint notice outlining proposed waivers of the Stark Law, the Gainsharing Civil Money Penalty (CMP) Law, and the Anti-kickback Statute.

This advisory explains the breadth and limitations of the proposed waivers. In sum, the joint notice demonstrates the government's willingness to modify the fraud and abuse laws to permit the formation of Shared Savings Programs but the waivers fall short with respect to a number of regulatory impediments. Parties interested in forming an ACO and participating in the Shared Savings Program should submit comments to the agencies regarding the need for broader waivers before the June 6, 2011, submission deadline.

#### The proposed waivers

Under the Shared Savings Program, ACO participants would continue to be paid on a fee for service basis for the services they provide to Medicare beneficiaries. ACO participants can earn additional payments if the ACO lowers the overall cost of providing care to beneficiaries assigned to it while maintaining quality of care standards. Congress recognized that ACOs would create financial relationships among health care providers that may not be permissible under existing fraud and abuse laws and granted the HHS Secretary the authority to waive those laws.

The waivers proposed by the Secretary focus on the distribution of ACO shared savings, including savings distributions: (1) to or among ACO participants; or (2) for activities necessary for and directly related to the ACO's participation in the Shared Savings Program. The Gainsharing CMP waiver also requires that shared savings payments are not made knowingly to induce a physician to reduce or limit medically necessary items or services. No protection would be granted for distributions of shared savings to referring physicians outside the ACO unless the distributions were for activities necessary for or directly related to the ACO's participation in and operations under the program.

Beyond the distribution of shared savings, the proposed waivers offer limited protection. The proposed Stark Law waiver does not address any other financial relationships (such as those potentially arising out of capitalization, formation, and operations of the ACO), thereby defaulting to the requirement that any financial relationships involving physicians and designated health service providers fit within a Stark exception.

The proposed waivers for the Gainsharing CMP and the Anti-kickback Statute both require financial relationships other than those created by the distribution of shared savings to fit within a Stark Law exception to qualify for waiver protection. Using a Stark Law exception as the test for whether an arrangement qualifies for either a CMP or Anti-kickback waiver is noteworthy because the government has historically taken the position that the Stark Law, CMP Law, and Anti-kickback Statute are completely different statutes that must be separately analyzed.

Although the government took a cautious approach in crafting the fraud and abuse waivers, it did grant protection to one of the ACOs core functions—the distribution of shared savings. Without this waiver the legality of the fundamental ACO model would have remained uncertain. The proposed waiver gives the industry important assurances that mitigate the level of regulatory risk attendant to participation in the Shared Savings Program.

The remaining challenge is that the proposed waivers do not address the potential fraud and abuse limitations on the ability of health care organizations to capitalize, form, administer, and operate ACOs. Moreover, the waivers do not address the fraud and abuse implications of providing incentives to Medicare enrollees to further the ACO goals of improving quality and reducing costs. Thus, apart from distributions of shared savings, the whole host of financial

relationships that arise out of ACO formation and operations must be structured to fit within a Stark Law exception.

The Stark Law exceptions that might apply in this context include the exceptions for bona fide employees, isolated transactions, fair market value compensation arrangements, and indirect compensation arrangements. Crafting financial arrangements designed to foster collaboration among physicians, hospitals, and other providers in a manner that fits within the existing exceptions to the Stark Law will not be an easy task. It seems likely that the limited scope of the proposed waivers will hamper the industry's ability to effectively structure and operate ACOs.

### Requests for comment

The CMS/OIG joint notice acknowledges that various financial arrangements associated with the formation and operation of an ACO may not be protected under the proposed waivers. CMS and the OIG explicitly request public comment on whether the waiver should be expanded to address: (1) capital investments or startup expenses and various nonmonetary benefits potentially arising out of ACO participation; (2) implementation costs associated with governance and administrative requirements; and (3) expenses arising out of building technological or administrative capacity related to ACO cost and quality goals.

The notice also asks whether fraud and abuse waivers should be expanded to include financial arrangements among ACO participants, suppliers, and providers—as well as arrangements outside the ACO—that are necessary for ACO operations or for achieving the integration, cost savings, and quality goals of the Shared Saving Program. Specifically, the OIG asks what types of financial arrangements should be covered, whether they should be required to be commercially reasonable and reflect fair market value, whether any additional safeguards are necessary, and what the appropriate duration of the waivers should be.

Finally, the agencies also ask for public comment as to (1) whether the two-sided risk model, under which ACO participants share downside risk as well as potential savings, should qualify for broader waiver protection; (2) whether electronic health records arrangements expected to continue after 2013 (the sunset date for the Stark and Anti-kickback EHR donation exceptions) should be protected by a waiver; and (3) whether there should be a waiver of the CMP prohibition on inducements to Medicare beneficiaries.

### Conclusion

The proposed waivers demonstrate the government's willingness to consider new approaches to defining the parameters and application of the fraud and abuse laws. The protection of shared savings distributions is clearly an important and necessary step in encouraging the development of ACOs. Broader waivers of the Stark Law, the CMPs relating to gainsharing and beneficiary inducements, and the Anti-kickback Statute are needed to effectively facilitate the establishment and operation of ACOs.

The infrastructure requirements and investment of time and resources required to form an ACO are daunting. Health care organizations that take on these challenges should be allowed greater flexibility to encourage participant and beneficiary behaviors that will enable the ACO to achieve the dual goals of improving quality and reducing costs. Interested parties should submit comments to the government before June 6, 2011, to urge the agencies to provide greater waiver protection to ACO participants.

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In our ongoing series, we will be issuing a number of separate advisories focusing on specific topics raised by the new regulations and the affiliated guidance and requests for comments including:

- Beneficiary attributions and safeguards
- Quality metrics
- Shared savings calculations
- State law restrictions
- When things go wrong or circumstances change

Please also see our past installments in this series:

["The New ACO Regs: They're Here \(Well, Sort of ...\)"](#) (04.05.11)

["Antitrust Enforcement Agencies Issue Proposed Guidance on ACOs"](#) (04.06.11)

["What the Proposed ACO Regulations Say About Legal Structures and Governance"](#) (04.11.11)

Stay tuned ... and in the meantime, if you have any questions, please contact us.

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