

“What keeps you up at night?”

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Interim Final Rule – Final waivers in connection with the Medicare Shared Savings Program

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SUMMARY

On October 20, 2011, the Centers for Medicare and Medicaid Services and the Department of Health and Human Services – Office of Inspector General jointly issued an interim final rule with comment period establishing waivers for accountable care organizations from certain provisions of the Federal fraud and abuse laws. These waivers are intended by CMS/OIG to give providers additional flexibility in developing effective legal and business strategies for ACO initiatives. Careful planning should be used to maximize the potential benefits afforded by the waivers.

In a release coordinated with the Centers for Medicare and Medicaid Services' (CMS') final regulations on the Medicare Shared Savings Program, CMS and the Department of Health and Human Services – Office of Inspector General (OIG) jointly issued an interim final rule (IFR) with comment period establishing waivers for accountable care organizations (ACOs) from certain provisions of the Federal "fraud and abuse" laws (Fraud & Abuse Laws) - [http://www.oig.gov/OFRUpload/OFRData/2011-27461_PI.pdf]. For the purposes of the IFR, the Fraud & Abuse Laws include the following: (i) Physician Self-Referral Law, (ii) Anti-Kickback Statute and (iii) Civil Monetary Penalties (CMP) Law. The goal of the waivers is to address concerns that the restrictions these laws place on certain financial relationships between physicians, hospitals, and other individuals and entities could significantly hinder the development and implementation of innovative, integrated-care delivery models contemplated under the Medicare Shared Savings Program and the Advanced Payment Initiative.

The Medicare Shared Savings Program encourages organizations and providers to form and/or join ACOs to provide integrated, comprehensive care across the spectrum of inpatient and outpatient care (i.e., hospitals, physicians, etc.). Fraud & Abuse Laws are presently geared toward preventing improper payments for referrals and unnecessary under- or overuse of services or tests, which are suitable to a fee-for-service reimbursement system. These laws, however, are thought by many to effectively prevent the types of risk-based compensation arrangements that are integral to the formation of legitimate ACOs. The waivers contemplated in the IFR focus on existing fraud and abuse provisions which prohibit (i) providing direct payments for referrals, (ii)

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improper inducements to beneficiaries and (iii) hospital payments to physicians to reduce or limit services, while also leaving in place other provisions of the Fraud & Abuse Laws necessary to ensure that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs.

The following is a summary of the waivers established in the IFR:

- An "ACO pre-participation" waiver of the Fraud & Abuse Laws that applies to ACO-related start-up arrangements in anticipation of participating in the Medicare Shared Savings Program;
- An "ACO participation" waiver of the Fraud & Abuse Laws that applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Medicare Shared Savings Program and for a specified time thereafter;
- A "shared savings distributions" waiver of the Fraud & Abuse Laws that applies to distributions and uses of shared savings payments earned under the Medicare Shared Savings Program;
- A "compliance with the Physician Self-Referral Law (Stark Law)" waiver of the Gainsharing CMP and the Federal Anti-Kickback Law for ACO arrangements that implicate the Stark Law and meet an existing Stark Law exception; and
- A "patient incentive" waiver of the Beneficiary Inducements CMP and the Federal Anti-Kickback Law for medically related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

These waivers provide flexibility for ACOs and their constituent parts to pursue a wide array of activities, including start-up and operating activities that further the purposes of the Medicare Shared Savings Program. The IFR also acknowledges that additional Fraud & Abuse Law waivers may be necessary in the future to foster the innovation and relationships necessary for successful participation in the Shared Savings Program.

CMS and OIG, as evidenced in the IFR, are putting forth major

efforts to facilitate the development of new approaches to delivering care that reduce fragmented or unnecessary care and excessive costs for Medicare beneficiaries and other patients. This IFR, as well as the related rules and guidance issued by the Federal Trade Commission, the Department of Justice and the Internal Revenue Service demonstrate the Federal Government's commitment to pursuing new and different ways to redesign the Medicare program. The reinvigorated commitment to health care reform makes it more important than ever for providers to redouble their efforts to develop effective business and legal strategies for ACO development.

View two earlier alerts issued on the Final Rule by visiting http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf for one on the release of the CMS' Final Rule for ACOs; and http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf for another defining the "safety zone" for certain ACOs.

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