HHS OIG Releases Proposed Rules Regarding Increased Authority to Combat Fraud and Abuse under the ACA

The Office of Inspector General (OIG) of the Department of Health and Human Services proposed two new rules last week in order to expand its enforcement authority, implementing changes adopted as part of the Patient Protection and Affordable Care Act of 2010 (ACA). The ACA expanded OIG's authority (1) to exclude individuals and entities from Federal health care programs and (2) to impose Civil Monetary Penalties (CMPs) for certain misconduct. This alert first addresses OIG's exclusionary authority, and then OIG's authority to impose CMP liability.

Exclusionary Authority

By way of background, the Social Security Act grants OIG the authority to exclude individuals and entities from participation in Federal health care programs, in order to protect beneficiaries from "untrustworthy health care providers." OIG has two types of exclusionary authority: mandatory and permissive. Mandatory exclusions are for a period of at least 5 years. Permissive exclusions can have minimum benchmarks and timelines, depending on the basis for exclusion, but OIG generally has discretion to determine both whether to impose an exclusion and the appropriate duration of an exclusion that it has imposed.

The proposed rule implements several provisions of the ACA that authorize OIG to exercise permissive exclusionary authority over individuals or organizations if they:

- Are convicted of an offense in connection with obstruction or interference with an audit (a conviction that historically has been agreed to as part of some plea bargains resolving Federal health care investigations, as it does not trigger automatic exclusion);
- Make false statements, omissions or misrepresentations of material facts in applications to participate as a provider or supplier under a Federal health care program; or
- Fail to supply payment information for items or services for which payment may be made under Medicare or any State health care program (the ACA expanded this provision to apply to individuals who "order, refer for furnishing or certify the need for," in addition to those individuals who furnish items or services for payment).

Other proposed changes (1) allow OIG to issue testimonial subpoenas in investigations for exclusions, which the OIG already had the right to do under its CMP authority; (2) remove the statute of limitations on exclusion actions based on the false or improper claims provision of the Social Security Act, which typically arise because of a related civil False Claims Act proceedings; (3) amend OIG's waiver authority and reinstatement rules for individuals excluded as a result of losing their licenses (including allowing such individuals to participate in Federal heath care programs earlier when appropriate); and (4) modify procedures for exclusionary proceedings, including updates and clarifications to certain aggravating and mitigating factors.

CMP Liability

The ACA also provided OIG with greater latitude to impose CMP liability. Similar to its exclusionary authority, OIG can impose CMPs against individuals and entities that defraud the Federal health care programs. The proposed rule allows OIG to assess CMPs against individuals who, or entities that:

- Make a false statement that is part of a fraudulent claim;

- Make false statements on Federal health care program enrollment applications;
- Fail to report and return overpayments within 60 days after the date the overpayment was identified, or the date any corresponding cost report is due;
- Fail to provide OIG with timely access to documents, as determined on a case-by-case basis; or
- Order or prescribe medicine or services while excluded from Federal health care programs when they know or should know that the item may be paid for by a Federal health care program.

The first two bullets above echo the False Claims Act. The third bullet also relates to the False Claims Act, which, together with other program integrity provisions, requires providers to report and return overpayments within 60 days of their identification. Collectively, these proposals could broaden OIG's ability to assess its own financial penalties in False Claims Act cases.

The proposed rule also clarified that, although not explicitly stated in the ACA, penalties apply to fraudulent omissions, as well as affirmative fraud.

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Historically, OIG's role in settlement of Federal health care investigations has been more equitable (through Corporate Integrity Agreements) than financial, and accordingly has been subject to jurisdictional (*i.e.*, whether there are grounds to impose a Corporate Integrity Agreement) and practical (*i.e.*, whether OIG in fact would exclude) limitations. Taken together, these changes would give OIG additional tools for taking an active role in settlement of Federal health care investigations. For example, OIG's express authority to exclude parties who plead to obstruction of a federal audit would remove any doubt about OIG's ability to impose a Corporate Integrity Agreement in those cases, and would facilitate OIG's ability to exclude particular individuals. Similarly, OIG's express authority to exclude parties without regard to a limitations period would strengthen OIG's position when investigations uncover historic noncompliance. Expansion of OIG's authority to impose CMPs could lead to settlements with more financial components. OIG's rulemaking noted that OIG has collected $165.2 million in CMP penalties over 9 years. While a substantial figure, that pales when held up against False Claims Act settlements in health care fraud cases. The tools that these rules would provide may put OIG in a position to increase that figure substantially.

Comments to the proposed rule are due on July 11, 2014.

For more information on compliance with the OIG's exclusionary or CMP authority, or the effect of the proposed rules, please contact your usual Ropes & Gray lawyer.