PUBLICATION

OIG Proposes Updates to Exclusion and CMP Authority [Ober|Kaler]

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The Department of Health and Human Services, Office of Inspector General (OIG) recently issued a pair of proposed regulations to update its exclusion and civil monetary penalty (CMP) authority. The proposed regulations implement new authority provided by the Affordable Care Act (ACA) as well as general clarifications and updates. The proposed exclusion regulation was published on May 9, 2014. 79 Fed. Reg. 26,810 [PDF]. The proposed CMP regulation was published on May 12, 2014. 79 Fed. Reg. 27,080 [PDF]. Comments on the proposed regulations are due to the OIG are due no later than July 8, 2014 and July 11, 2014, respectively.

Below is a summary of the major provisions of each of the proposed regulations. We also highlight those changes that may warrant formal comment.

Proposed Exclusion Regulations

The OIG has long had the authority to exclude individuals and entities from participation in Medicare, Medicaid, and other federal health care programs. The OIG has both mandatory and permissive exclusion authority. Under its mandatory exclusion authorities, the OIG is required to impose a minimum five-year exclusion upon individuals and entities convicted of certain criminal offenses. Under its permissive exclusion authorities, the OIG has the discretion to impose exclusion on a case-by-case basis where individuals and entities have engaged in certain conduct. Given the large percentage of federal health care program patients treated by most health care providers and suppliers, exclusion is commonly viewed as an economic death penalty.

The proposed exclusion regulations would enhance the OIG's exclusion authority in several important ways.

New Exclusion Authorities

The ACA expanded the grounds upon which the OIG can exercise its permissive exclusion authority. The OIG is permitted to exclude individual and entities based on:

1. Conviction of an offense in connection with obstruction of an audit;
2. Failure to supply payment information, as applicable to any individuals who order, refer for furnishing, or certify the need for items or services paid by Medicare or any state health care program; and
3. Making, or causing to be made, any false statement, omission, or misrepresentation of a material fact in a participation application.

Testimonial Subpoenas

The ACA also expanded the OIG's authority to issue testimonial subpoenas in connection with the investigation of exclusion cases. (Previously, the OIG's power to issue testimonial subpoenas extended only to CMP claims, and did not reach exclusion cases.) This significantly expands the OIG's investigative power with respect to certain non-derivative exclusions, i.e., those exclusion cases that do not already involve an underlying conviction.

Modification of Reinstatement Rules

The OIG has indicated that it is considering an "early reinstatement" process for those individuals excluded as a result of the loss, suspension, or revocation of their state license. In doing so, the OIG highlighted specific instances in which it believes early reinstatement may be warranted, including: (1) where a medical board in one state permanently revokes a physician's license, yet another medical board in another state subsequently grants the physician a license; and (2) where an individual who has since changed professions, with no intent to regain his or her original license, still wishes to practice in a new health care related profession. The OIG specifically requested comments as to potential approaches to the “early reinstatement” process, and any factors that it should consider in an individual's request for reinstatement

Statute of Limitations in False Claims Exclusions

In the proposed regulation, the OIG seeks to bar the application of any statute of limitations to exclusion actions based upon the submission of false or improper claims. While recognizing that the age of conduct should be a factor in determining whether to exercise its permissive exclusion authority, the OIG rejected the notion that the age of the conduct may prevent the exercising of its exclusion authority. Accordingly, even where the government or a relator is time barred from pursuing a False Claims Act case, the OIG's exclusion authority will remain.

Modifications to Exclusion Proceedings

Finally, the OIG proposes a number of modifications to exclusion proceedings, including adjusting the dollar amounts of government losses that trigger aggravating and mitigating factors. The OIG also proposes expanding the ability of parties to present oral argument prior to the imposition of a permissive exclusion based on making false statements or misrepresentation of material facts. The OIG proposes clarification of several definitions as well as reorganizing the location of certain definitions.

Proposed CMP Regulations

The OIG has long had the authority to impose CMPs on individuals and entities who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. Over the years, Congress has expanded the CMP authority to cover various types of fraud and abuse. Ultimately, the goal of the CMPs is to protect federal health care programs and their beneficiaries from fraud, waste, and abuse.

The proposed CMP regulations would enhance the OIG's CMP authority in several important ways. The proposed regulation would also reorganize the OIG's existing CMP authority to improve readability and clarity and to address some substantive issues.

New CMP Authorities

The ACA expanded the grounds upon which the OIG can impose CMPs to include:

4. Failure to grant OIG timely access to records, upon reasonable request;
5. Ordering or prescribing while excluded when the excluded person knows or should know that the item or service may be paid for by a federal health care program;
6. Making false statements, omissions, or misrepresentations in an enrollment or other application to participate in a federal health care program;
7. Failure to report and return a known overpayment; and
8. Making or using a false record or statement that is material to a false or fraudulent claim.

Expanded Liability in Connection with Medicare Advantage and Part D

The ACA expanded CMP liability against Medicare Advantage (MA) or Part D contracting organizations when their employees or agents (or any provider or supplier who contracts with them) engages in prohibited conduct.

The OIG points out that "[t]his statutory change broadens the general liability of principals for the actions of their agents under our existing regulations… to include contracting providers and suppliers who may not qualify as agents of the contracting organization."

The proposed rule also establishes CMP liability, consistent with the ACA, against MA or Part D contracting organizations that:

9. Enroll an individual without his or her prior consent;
10. Transfer an enrollee from one plan to another without his or her prior consent;
11. Transfer an enrollee solely for the purpose of earning a commission;
12. Fail to comply with statutory or regulatory marketing restrictions; or
13. Employ or contract with any person who engages in conduct described in section 1857(g)(1) of the Social Security Act related to contracts with Medicare+Choice organizations.

Reorganization of CMP Regulations

The OIG contends that the existing regulatory structure for CMPs in Part 1003 has become "cumbersome" over time as Congress has added various grounds for imposing CMPs. The goal of this reorganization is to improve the clarity of the regulations.

The OIG proposes creating a single list of factors that are applicable across all grounds for imposing CMPs. The list includes:

14. The nature and circumstances of the violation,
15. The degree of culpability of the person,
16. The history of prior offenses,
17. Other wrongful conduct, and
18. Other matters as justice may require.

The OIG also proposes to adjust the dollar amounts used to trigger aggravating and mitigating factors.

Technical Changes and Clarifications

The OIG proposes various technical changes and clarifications. For example, the OIG proposes changes to the regulatory language to make it clear that each act that constitutes a violation is subject to penalties. The OIG proposes to consistently use the term *federal health care programs*. Finally, the OIG proposes changes to the regulations clarifying that although a principal may be liable for the acts of its agents, this does not limit the liability of the agent for its misconduct.

Ober|Kaler's Comments

Given the current enforcement environment and the significant potential impact of exclusion and CMPs, health care providers and suppliers should carefully review these two proposed regulations. While the various proposed changes are characterized as relatively minor updates and clarifications, some of the changes could have significant impacts. For example, the elimination of the statute of limitations defense to exclusion based on false claims greatly expands the liability of health care providers and suppliers. Likewise, the expansion of the OIG's CMP authority to include failure to report and return a known overpayment creates broader exposure to potential liability. Health care providers and suppliers should carefully consider whether some of these changes warrant formal comment to the OIG.