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Health Care ADVISORY ■

**MAY 27, 2014**

# OIG Announces Proposed Rules That Would Expand Exclusion Authority and Impose Steeper Civil Monetary Penalties

The Department of Health and Human Services' (DHHS) Office of the Inspector General (OIG) proposed two new rules this month that could soon subject health care providers to more expansive exclusion rules and steeper civil monetary penalties (CMPs). The proposed Exclusion Rule was published in the *Federal Register* on May 9, 2014, while the proposed CMP Rule was published on May 12, 2014.

The OIG's exclusion authority, found in Sections 1128(a)–(b) of the Social Security Act ("the Act"), is "intended to protect the Federal health care programs and their beneficiaries from untrustworthy health care providers, i.e., individuals and entities who pose a risk to program beneficiaries or to the integrity of these programs." The OIG's exclusion authority includes both mandatory exclusions (Section 1128(a) of the Act) and permissive exclusions (Section 1128(b) of the Act). Under its mandatory exclusion authority, the OIG is required to exclude: (1) any individual or entity convicted of a "program-related" crime; (2) a crime related to patient abuse or neglect; or (3) certain felonies related to health care delivery, governmental health care programs or controlled substances. Mandatory exclusions are for a period of at least five years. Under its permissive exclusion authority, the OIG is not required but may exclude an individual or entity (1) based on actions previously taken by a court or other law enforcement or regulatory agency ("derivative" exclusions) or (2) based on OIG-initiated determinations of misconduct, e.g., poor quality of care, kickbacks or submission of false claims to a federal health care program ("affirmative" exclusions).

The proposed Exclusion Rule would amend the existing exclusion regulations to "incorporate statutory changes, propose early reinstatement procedures, and clarify existing regulatory provisions." Specifically, the OIG aims to implement provisions of the Affordable Care Act (ACA), which state that exclusions may now be imposed for:

- conviction of an offense in connection with obstruction of an audit;
- failure to supply payment information; and
- making, or causing to be made, any false statement, omission or misrepresentation of a material fact in applications to participate as a provider of services or supplier under a federal health care program.

The implementation of the ACA provisions by the proposed Exclusion Rule would amend Section 1128(b) of the Act to broaden the permissive exclusion authority of the OIG. For example:

- Prior to the ACA, Section 1128(b)(2) of the Act permitted the OIG to exclude any individual or entity that had been convicted of an offense in connection with the obstruction of an investigation into any criminal offense described under any of the mandatory exclusion authorities or under the permissive exclusion authority related to health care fraud or fraud in a governmental program. However, if an individual or entity was convicted of an offense in connection with the obstruction of an audit, the OIG did not have a basis for exclusion under the Act. The ACA and the proposed Exclusion Rule expands the OIG's authority by allowing the exclusion of an individual or entity "that has been convicted of an offense in connection with the obstruction of an investigation ***or audit***…" (emphasis added).

- Similarly, Section 1128(b)(2) of the Act currently permits the OIG to exclude an individual or entity "furnishing items or services for which payment may be made" under Medicare or a state health care program that fails to supply payment information as required. The proposed Exclusion Rule would broaden the scope of the permissive exclusion authority by revising the first phrase as follows: "Any individual or entity furnishing, ordering, referring for furnishing, or certifying the need for items or services…" thus expanding the exclusion authority to individuals or entities that also order such items, refer such items for furnishing, or certify the need for such items.

- Finally, the proposed Exclusion Rule introduces a new permissive exclusion authority in which the OIG may "exclude any individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program." The OIG proposes adding a new section to the regulations, titled "Making False Statements or Misrepresentation of Material Facts."

The ACA also established a new authority for the OIG to issue testimonial subpoenas in investigations of exclusion cases, which the OIG has also included in the proposed Exclusion Rule. Prior to the enactment of the ACA, the OIG's testimonial subpoena authority was limited to cases in which the OIG was pursuing CMPs under the Act.

Additionally, the OIG interprets its exclusion authority in the proposed Exclusion Rule to mean there is no statute of limitations on exclusions imposed under Section 1128 (b)(7) of the Act for false or improper claims. The OIG states, "An exclusion is neither time barred nor subject to any Statute of Limitations period, even when exclusion is based on violations of another statute that might have a specific limitations period." This would be a huge expansion of the OIG's exclusion authority and could presumably subject entities and individuals to exclusion for actions that occurred more than six years prior.

Lastly, the OIG proposes a modification to the reinstatement rules for individuals excluded as a result of losing their license to allow them to rejoin the programs earlier, when appropriate. For special circumstances, "such as when the OIG imposes a permissive exclusion on the basis of a licensing board action and subsequently determines that the individual poses little or no threat to patients or the programs and when license reinstatement by the original licensing board is extremely unlikely," the OIG is considering a process for "early reinstatement" pursuant to its authority under Sections 1128(b) and (g) of the Act. The OIG proposes to amend the regulations to allow for early reinstatement, and to include a list of factors it will consider in determining whether early reinstatement is appropriate. For example, the OIG "would allow an excluded individual to request early reinstatement if, after fully and accurately disclosing the circumstances surrounding the original license action that formed the basis for the exclusion, the individual obtained a health care license, was allowed to retain a health care license in another State, or retained a different health care license in the same State" or it "would allow an excluded individual to request early reinstatement if he or she did not have a valid health care license of any kind provided that the individual could demonstrate that he or she would no longer pose a threat to Federal health care programs and their beneficiaries."

The proposed CMP Rule aims "to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments and exclusions to improve readability and clarity." The primary new authority the proposed CMP Rule aims to incorporate, much like the proposed Exclusion Rule, is the ACA. The proposed CMP Rule would implement several provisions of the ACA that provide for CMPs, assessments and exclusions for:

- failure to grant the OIG timely access to records;
- ordering or prescribing while excluded;
- making false statements, omissions or misrepresentations in an enrollment application;
- failure to report and return an overpayment; and
- making or using a false record or statement that is material to a false or fraudulent claim.

In what the OIG states is an effort to add clarity and improve transparency to its decision-making processes regarding CMPs, the OIG also proposed changes to the factors relevant to determining the amount of CMPs. In the proposed CMP Rule, the OIG sets out five primary factors for determining the amount of CMPs: (1) the nature and circumstances of the violation, (2) the degree of culpability of the person, (3) history of prior offenses, (4) other wrongful conduct and (5) other matters as justice may require. However, the OIG notes that these factors are "illustrative" rather than a comprehensive list. The proposed CMP Rule also suggests increasing the claims-mitigating factor from $1,000 to $5,000. The OIG explains, "A dollar threshold as a mitigating factor for CMP purposes differentiates between conduct that could be considered less serious and more serious. Conduct resulting in more than $5,000 in federal health care program loss is an indication of more serious conduct."

Finally, the proposed CMP Rule also sets forth an alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill the federal health care programs for furnishing items or services. The proposed regulations address how penalties and assessments will be imposed for two distinct types of violations: (1) instances when items or services provided by the excluded person may be separately billed to the federal health care programs and (2) instances when the items or services provided by the excluded person are not separately billable to the federal health care programs, but are reimbursed by the federal health care program in some manner as part of the item or service claimed.

"OIG anticipates that CMP collections may increase in the future in light of the new CMP authorities and other changes proposed in this rule," the CMP Rule proposal states. "However, it is difficult to accurately predict the extent of any increase due to a variety of factors, such as budget and staff resources, the number and quality of CMP referrals or leads, and the length of time needed to investigate and litigate a case. In calendar years 2004-2013, the OIG collected between $10.2 million and $26.2 million in CMP resolutions for a total of over $165.2 million."

Given the broad expansion of the OIG's exclusion authority and new CMP authorities, health care entities should consider providing comments on the proposed rules. Comments for the proposed rules are due on or before July 8, 2014, and July 11, 2014, respectively.

The proposed Exclusion Rule can be found here.

The proposed CMP Rule can be found here.

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