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Special Section

HEALTH LAW

New Guidance for Health Care Program Exclusions

Policy statement comes amid crackdown on fraud and abuse

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On April 18, the U.S. Department of Health and Human Services Office of Inspector General (OIG) published a new policy statement detailing revised criteria that the OIG considers in determining whether to exercise its discretionary authority to exclude an individual or entity from participation in federal health care programs under Section 1128(b)(7) of the Social Security Act. The

OIG has the authority to exclude individuals and entities from participation in Medicare, Medicaid and any other federal health care programs as a consequence of fraudulent or abusive conduct. Once an individual or entity has been excluded by the OIG, no federal program monies can be used to cover services (1) furnished by that individual or entity or (2) directed or prescribed by an excluded provider or supplier.

The OIG's updated policy statement supersedes and replaces previous guidance regarding Section 1128(b)(7) exclusions issued by the OIG in 1997. The policy statement also follows the OIG's publication of a special advisory bulletin on the effect of exclusion from participation in federal health care programs in May 2013. The policy statement provides more comprehensive guidance to health care providers, and their legal counsel, on aggravating and mitigating factors that the OIG will take into account when considering exclusion as a remedy under Section 1128(b)(7).

Exclusion Presumption

The OIG operates under the presumption that any individual or entity that defrauds Medicare or any other federal health care program merits some period of exclusion. That presumption may be rebutted under certain circumstances, and the policy statement outlines the OIG's approach in cases involving health care fraud.

Alternative Remedies

The OIG assesses individuals and entities involved in health care fraud cases on a spectrum projecting future risk to federal health care programs under which the highest-risk actors merit exclusion, whereas alternative remedies may be appropriate for lower-risk actors. The OIG's alternative remedies include heightened scrutiny, such as unilateral monitoring of program compliance and integrity obligations, often including a corporate integrity agreement with OIG. In limited cases, the OIG may reserve its exclusion authority or provide a release from exclusion. The OIG policy statement also provides for special consideration of alternative remedies where an individual or entity is an independent successor owner of an entity previously involved in fraud and such successor has a history of federal health care program compliance.

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OIG Risk Factors

The OIG policy statement lists nonbinding factors that the OIG considers in health care fraud cases and that may increase, decrease or have no impact on the OIG's assessment of future risk to health care programs. The OIG factors are grouped into four categories: (1) nature and circumstances of conduct; (2) conduct during investigation; (3) significant ameliorative efforts; and (4) history of compliance.

Factors that indicate higher risk include, but are not limited to, (1) conduct having an adverse impact on individuals (whether physical, mental, financial or other); (2) actual or intended financial loss to federal health care programs; (3) conduct occurring as part of a pattern of wrongdoing or over a substantial period of time, or repeat conduct; (4) a history of judgments or settlements in prior criminal, civil or administrative enforcement actions; and (5) obstructing or impeding an investigation, audit, or internal or external reporting of unlawful conduct.

Factors indicative of lower risk include, but are not limited to, (1) initiation of an internal investigation before becoming aware of a governmental investigation; (2) self-disclosure of conduct cooperatively and in good faith; (3) cooperation with the government; and (4) implementation of disciplinary action against responsible individuals.

Most interestingly, the OIG policy statement also enumerates certain factors that if met will not affect the OIG's risk assessment but can indicate higher risk if unmet. For example, the OIG states that having a compliance program that incorporates the U.S. Sentencing Commission Guidelines Manual's seven elements of an effective compliance program does not affect an entity's risk assessment, but the absence of a compliance program incorporating such elements is indicative of higher risk. The OIG's approach to compliance programs within the policy statement is somewhat inconsistent, however, as the OIG separately notes that having a compliance program can help a successor owner indicate lower risk. Additionally, prompt response to a subpoena is expected and does not affect a risk assessment, but failure to comply with a subpoena within a reasonable time is indicative of higher risk. Thus, the OIG's updated policy statement effectively establishes certain baseline expectations for all participants in federal health care programs.

Takeaways for Providers

The OIG's updated exclusion policy statement provides important guidance for health care providers at a time of increased enforcement activity targeting fraud and abuse throughout federal health care programs. Participants in federal health care programs are on notice that the OIG operates under a presumption in favor of excluding providers involved in health care fraud, but that presumption may be rebutted under certain circumstances. Health care providers may use the policy statement's risk factors to anticipate potential OIG remedies in the event of an investigation into health care fraud or kickbacks. Although the OIG emphasizes that the risk factors are nonbinding, the policy statement may also provide guidelines to inform legal arguments in favor of nonexclusion remedies on behalf of individuals or entities subject to exclusion under Section 1128(b)(7).

Moreover, given the potential for overlapping investigations into health care fraud between the U.S. Department of Justice and the OIG, the factors cited by the OIG in its updated policy statement should, in certain circumstances, be read and considered in tandem with the DOJ's recent guidelines on holding individuals accountable for corporate misconduct. Individuals who may be subject to prosecution in connection with health care fraud should be cognizant of the interplay between the DOJ's expectations and the OIG's, as well as the fact that the Social Security Act separately requires exclusion for certain convictions related to health care fraud under Section 1128(a). As a result, these individuals may wish to consult with counsel to tailor an approach that minimizes legal and regulatory exposure to criminal and/or civil penalties, including exclusion.

Finally, the OIG's updated policy statement also provides valuable guidance to individuals and entities considering the purchase (or sale) of an entity previously implicated in an investigation into health care fraud or similar activity. The policy statement provides reassurances that successor owners can avoid being subject to remedies on account of previous misconduct, including by demonstrating that the successor owner is an independent third party who acquired the entity via an arm's-length transaction. As a result, the policy statement may clear the way for smoother transfers of entities previously tainted by health care fraud allegations to individuals or entities capable of complying with all requirements for participation in federal health care programs. ■

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