

PUBLICATION

OIG Updates Permissive Exclusion Criteria – Suggests Compliance Programs Are Expected [Ober|Kaler]

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On April 18th, the Office of Inspector General (OIG) issued updated guidance [PDF] describing the factors it will consider in determining whether to exercise its permissive authority to exclude individuals and entities from federal health care programs. The new guidance supplants the criteria the OIG identified in its last guidance on the topic in 1997 [PDF].

Overall, the new criteria reflect higher expectations by the OIG with respect to cooperation and compliance. The previous guidance described the existence of an effective compliance programs as a "key" factor in determining whether exclusion was appropriate. In contrast, the new guidance describes the existence of a compliance program as a "neutral" factor in evaluating whether exclusion is appropriate. The new guidance also encourages affirmative self-disclosure to avoid potential sanctions. This approach is consistent with other recent efforts to increase accountability for wrongdoing at both a corporate and an individual level, such as the Department of Justice's so-called [Yates memorandum \[PDF\]](#), which sets forth high standards for determining that an entity has cooperated with a federal investigation.

Noting that the question of whether exclusion is appropriate often arises in the context of False Claims Act cases, the OIG states that it operates under a "rebuttable presumption" that some period of exclusion should apply to individuals and entities that have defrauded the government. A "rebuttable presumption" turns the tables and places a burden on the individual or entity to establish that exclusion is not appropriate. This concept did not appear in the prior exclusion guidance. The new guidance also contextualizes exclusion as part of a range of options that the OIG is to consider in determining which of its available remedies will best minimize future risk to federal health care programs. Under this "risk spectrum," exclusion is appropriate for the highest risk cases, while full release from exclusion is appropriate for cases presenting the lowest risk of future program harm (primarily, those arising out of self-disclosures).

In determining where on the risk spectrum a provider falls, the OIG will consider several factors:

1. the nature and circumstances of the conduct, including the degree of loss and any adverse impact on individuals;
2. conduct during the investigation;
3. significant ameliorative efforts; and
4. compliance history.

Certain factors, if present, indicate higher risk, such as the involvement of entity leaders in a fraudulent scheme, a pattern of fraudulent conduct over an extended period of time, and failure to respond promptly to subpoenas. Other factors indicate lower risk, such as the initiation of internal investigations prior to becoming aware of the government investigation, and cooperation with the government that leads to sanctions against another individual or entity. Timely subpoena response and the presence of a compliance program are now merely "neutral" factors.

In addition to exclusion, the guidance states that the OIG will consider heightened scrutiny of providers (such as unilateral post-settlement audits and investigations) where exclusion is not deemed appropriate but the risk

of future fraud is deemed to be on the high end of the spectrum. Integrity obligations (e.g., corporate integrity agreements) may be appropriate where risk is present but exclusion is deemed to be unnecessary. The OIG states that it will consider a full release of exclusion without integrity obligations only where i) the conduct at issue was self-disclosed, or ii) substantial integrity obligations apply through either the Department of Justice or a state.

Overall, the new guidance is consistent with overarching trends encouraging increased self-disclosure of overpayments and fraud, higher expectations for rigorous internal self-monitoring, and heightened expectations for cooperation with the government during investigations. The new guidance also reflects a shift (in the form of a rebuttable presumption) toward placing the burden on providers to establish that their conduct does not merit permissive exclusion.