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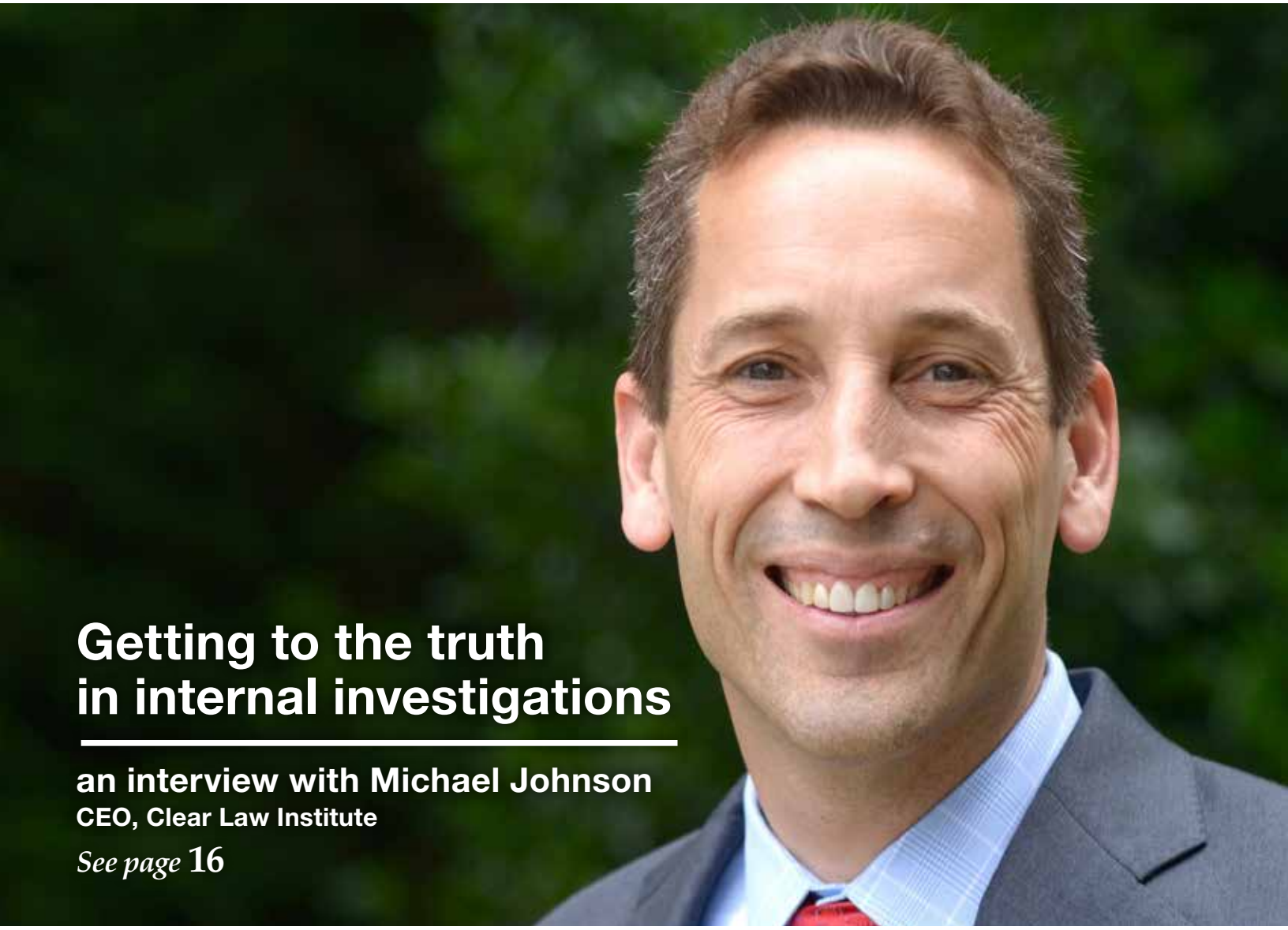

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OIG's revised exclusion criteria: Reducing the risk

» The OIG's exclusion decision will involve its assessment of likely future harm to federal healthcare programs.
» Using the guidance in the OIG's revised exclusion criteria can help reduce the risk of exclusion.
» Some of the new exclusion criteria are more stringent than the prior guidelines.
» Having a strong history of compliance, including self-disclosures and corrective action, can help reduce risk.
» Operating a compliance program is expected and no longer further reduces the risk of exclusion.

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The U.S. Department of Health and Human Services Office of Inspector General (OIG) recently published the updated criteria[1] that it will use when deciding whether to exercise its permissive exclusion authority under section 1128(b)(7) of the Social Security Act (aka, the 2016 OIG Exclusion Guidance). The law gives the OIG discretion to exclude individuals or entities (collectively called "providers") from participation in federal healthcare programs on numerous grounds, including submission of a false or fraudulent claim, retention of an overpayment, provision of unnecessary or substandard services, billing for services furnished by an excluded provider, engaging in unlawful kickback arrangements, and failure to take appropriate corrective action in certain cases.[2]

The new criteria are set forth on the OIG's website[3] and replace the OIG's prior guidelines,[4] which had been in place since 1997. The new guidance is notable because it has raised the bar, making it more difficult in various ways for providers to avoid exclusion. In particular, certain actions that previously helped to reduce the risk of exclusion or other sanctions, such as having a compliance program in place, are now expected and will not provide additional benefits. Moreover, failure to have a compliance program generally will increase the risk of exclusion. The new guidance also indicates how the OIG weighs certain factors in making the exclusion determination and the range of other enforcement options that typically are considered. The specific factors the OIG will consider are described in greater detail later on.


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The newly published criteria that the OIG will use in making permissive exclusion decisions are non-binding. Nevertheless, the criteria provide a useful roadmap for providers and their counsel to use when implementing measures that can help reduce the risk of exclusion.

The new guidance

Some of the key features of the new guidance are briefly described here.

Risk spectrum

The OIG notes that the exclusion decision will be based on an assessment of future risk to federal healthcare programs, based on the following risk spectrum:[5]

- Highest risk (i.e., evidence favors exclusion)
- Heightened scrutiny (i.e., requires unilateral monitoring or providing information to the public)
- Integrity obligations (i.e., a corporate integrity agreement (CIA) will be implemented)
- No further action (i.e., neither exclusion nor integrity obligations are warranted)
- Lower risk/release without integrity obligations (i.e., generally follows a cooperative self-disclosure)

The OIG generally will apply certain factors to determine where on the spectrum a provider's actions fall, thus determining whether exclusion is the appropriate administrative action. For example, the new guidance indicates that heightened scrutiny is often imposed in those cases where providers refuse to enter into a CIA. On the other end of the spectrum, the OIG typically finds low risk exists, eliminating the need for exclusion or integrity obligations, either: (1) when there is relatively little financial loss to federal healthcare programs, assuming the absence of egregious conduct such as patient harm or intentional fraud; or (2) when the government is resolving the matter with a successor owner that satisfies certain criteria.

Exclusion release or reservation

The OIG typically will grant a release of its permissive exclusion authority without requiring integrity efforts (such as a CIA) only when: (1) the provider self-discloses the fraudulent conduct, cooperatively and in good faith, to the OIG; or (2) the provider agrees to stringent integrity obligations with a state or the DOJ (and the OIG determines that the integrity obligations are sufficient). The new guidance also describes certain circumstances where the OIG may reserve its exclusion authorities in a False Claims Act settlement, but notes that such reservation does not necessarily mean that a provider poses a low risk to federal healthcare programs. Providers are encouraged to ask the OIG, prior to settlement, what the reservation of exclusion authorities means under the specific facts and circumstances.

Applicable risk factors

According to the new guidance, the OIG presumes that some period of exclusion should be imposed against providers that have defrauded federal healthcare programs. However, this presumption is rebuttable and the new guidance describes the non-binding factors the OIG is likely to consider in making the exclusion determination.

The risk factors are divided into four broad categories related to: (1) nature and circumstances of the conduct, (2) conduct during the investigation, (3) significant ameliorative efforts/corrective action, and (4) compliance history.[6] The factors listed within each category may indicate a higher risk, a lower risk, or are described as essentially being neutral to the risk assessment. The following lists summarize how the OIG is likely to weigh some of the specified factors during their risk assessment.

Factors increasing the likelihood the OIG will seek exclusion or integrity obligations:

- Conduct that causes or had the potential to cause adverse physical, mental, financial, or other harm to program beneficiaries or other patients;
- Amount of the actual or potential loss to federal healthcare programs (i.e., the higher the amount of loss, the higher the risk);

- Conduct that is part of a pattern of wrongdoing, is continual or repeated, or that occurs over a substantial period of time;
- Improper actions that are ongoing or that were not discontinued until the provider knew of the government's investigation;
- If an individual with managerial or operational control organized, led, or planned the unlawful activity at or on behalf of an entity;
- Prior history of judgments, convictions, decisions, or settlements in prior federal or state criminal, civil, or administrative enforcement actions;
- If the provider is or was previously under a CIA (or refused to enter into a CIA);
- If the provider was previously under a CIA and breached the CIA, lied, or failed to cooperate with the OIG during the CIA process;
- Obstruction of an investigation, audit, or internal or external reporting of the unlawful conduct, including taking any steps to conceal the conduct from the government or others;
- Failure to comply with a subpoena within a reasonable period of time;
- Other adverse action resulting from the improper conduct, including criminal resolution (e.g., conviction, Deferred Prosecution Agreement, Non-Prosecution Agreement) or adverse licensure action;
- Inability to pay an appropriate monetary amount to resolve a fraud case; and
- The absence of a compliance program incorporating the seven elements of an effective compliance program.

Factors decreasing the likelihood of exclusion/integrity obligations:

- Initiating an internal investigation before learning about a government investigation that attempts to determine who was responsible and sharing the investigation results with the government or filing a self-disclosure;
- Demonstrating acceptance of responsibility for the conduct;
- Cooperating with the government;
- Providing cooperation that leads to criminal, civil, or administrative action or resolution against other individuals or entities;
- Taking appropriate corrective action, including disciplinary action, against individuals responsible for the conduct;
- Devoting more resources to the provider's compliance program;
- Having a history of significant self-disclosures made in good faith;
- The licensed practitioner at issue has taken additional steps, including obtaining additional training, to improve future compliance; and
- The provider is sold to an independent and compliant third party in an arm's length transaction after the improper conduct has stopped.

Neutral factors

The new guidance also indicates that certain provider behavior is expected and therefore neutral in the risk assessment process. In other words, providers will not be rewarded with a lower risk assessment for meeting the OIG's basic expectations. For example, providers are expected to promptly respond to a subpoena and to have a compliance program incorporating the seven elements of an effective compliance program. Similarly, the lack of patient harm or absence of criminal sanctions does not affect the risk assessment.

What the OIG's new guidance means for providers

The new guidance demonstrates the importance of having an effective compliance program and taking prompt corrective

action when violations are identified. In those cases where a government investigation is initiated, providers should fully cooperate with the government in order to reduce the risk that the OIG will seek to exclude them or impose other sanctions. Demonstrating that the provider has implemented the requisite corrective action in the case at hand, as well as having a track record of appropriate corrective action and/or self-disclosures on other matters, also can help reduce the risk. Corrective action may include measures such as additional training, taking disciplinary action against the individual(s) responsible for the improper conduct, and devoting significant additional resources to compliance.

1. U.S. Department of Health & Human Services, Office of Inspector General: Criteria for implementing section 1128(b)(7) exclusion authority (hereinafter, "2016 OIG Exclusion Guidance"). April 18, 2016. Available at http://bit.ly/2bYOeFL
2. 42 U.S.C. § 1320a-7(b): Criminal penalties for acts involving Federal health care programs. Available at http://bit.ly/2b4swjt
3. HHS OIG: Special Advisory Bulletin and Other Guidance. Available at http://bit.ly/2bmXWP8
4. 62 Fed. Reg. 67392 (Dec. 24, 1997).
5. 2016 OIG Exclusion Guidance, at 2.
6. 2016 OIG Exclusion Guidance, at 4-7.