OIG's Fraud Risk Indicator: Strategic implications for resolving exclusion liability

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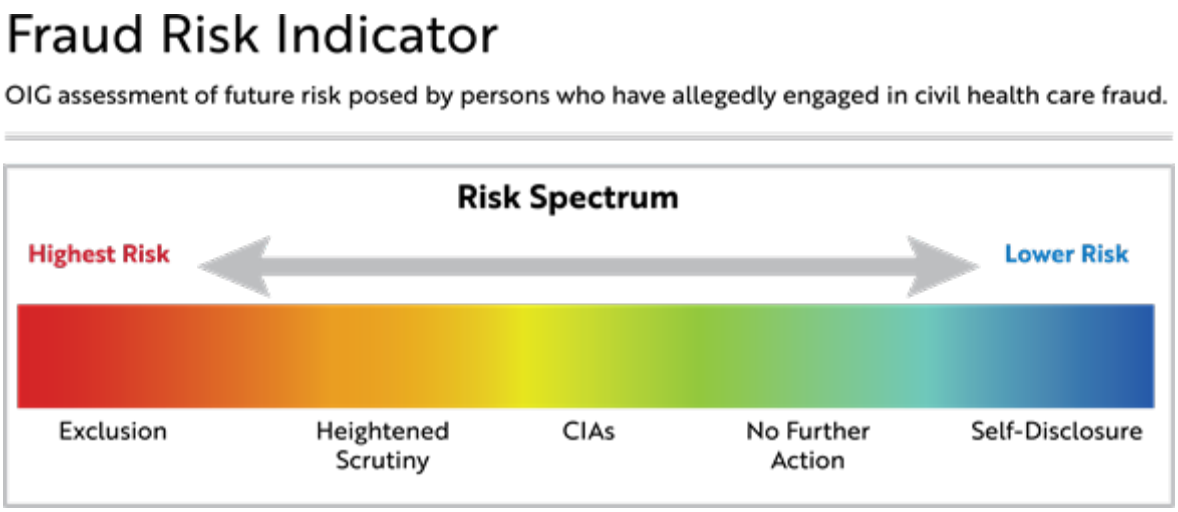
The Office of Inspector General for the U.S. Department of Health and Human Services (OIG) recently unveiled the use of a new tool called the Fraud Risk Indicator. OIG's stated purpose behind this new initiative is to provide more transparency to industry stakeholders (e.g., patients, family members, healthcare industry professionals) regarding OIG's risk assessment of a party to a False Claims Act (FCA) settlement and where that particular party falls on the OIG exclusion risk spectrum in cases where there is no corporate integrity agreement (CIA).

OIG has the authority to exclude any individual or entity from participation in the federal healthcare programs if they engage in certain healthcare fraud conduct. The government's primary tool for enforcing healthcare fraud violations is the FCA. Most FCA cases where the government alleges fraudulent conduct are resolved through settlement agreements in which the settling parties do not admit liability. OIG's permissive exclusion authority under section 1128(b)(7) of the Social Security Act[1] is oftentimes implicated in the context of FCA healthcare fraud cases, because conduct that allegedly violates the FCA can also trigger exclusion liability. As a result, OIG is typically a party to FCA healthcare settlements in order to resolve its permissive exclusion authority. In determining whether it should exercise discretion under its exclusion authority, OIG evaluates future risk to the federal healthcare programs based on information gathered during the FCA case and applies certain factors and exclusion criteria[2] to assess where a settling party falls on the OIG risk spectrum (see Figure 1).

Figure 1: Risk spectrum



The OIG risk spectrum contains five different categories, and exclusion authority is resolved differently for each level of risk. OIG laid out the risk spectrum for the first time in its April 2016 exclusion authority criteria.[3] At the lowest level of risk, OIG releases its exclusion authority when a party self-discloses the conduct. The next category, in which OIG does not release its authority but takes no further action, is reserved for situations either involving successor liability or relatively low financial harm in the absence of egregious conduct. At a medium risk level, OIG determines that an integrity agreement (CIA) is appropriate to protect the federal healthcare programs and beneficiaries, and the party agrees to enter into a CIA in exchange for a release of OIG's exclusion authority. At what OIG terms "High Risk – Heightened Scrutiny," OIG determines that a CIA is necessary to protect the program, but the settling party did not agree to one. And finally, at the highest risk level, OIG will pursue exclusion.

OIG will provide stakeholders and the public with a list of settling parties who fall into the "High Risk – Heightened Scrutiny" category—information that was not previously publicized.[4] Historically, there has not been much publicly available information about FCA settlements where there is no CIA as part of the resolution, and it was difficult to determine how OIG viewed a party settling without a CIA or an exclusion release. A party that refused a CIA was indistinguishable to stakeholders from a party against whom OIG decided to simply take no further action. In an effort to increase transparency, OIG announced that, starting October 1, 2018, settling parties who refuse to enter into a CIA that OIG deemed necessary to protect the programs will be listed under the High Risk – Heightened Scrutiny category on the OIG website.

Since launching the new Fraud Risk Indicator, two settling parties that refused to enter into a CIA have been posted on the High Risk list by OIG. On October 31, 2018, ImmediaDent of Indiana, LLC and Samson Dental Partners, LLC agreed to pay $5.1 million to resolve their FCA liability stemming from allegations that they improperly billed Indiana's Medicaid program for dental services.[5] As a result of refusing to agree to the proposed CIA in connection with this FCA settlement, OIG determined that, in the absence of such recommended oversight, the

companies posed a high risk and warranted heightened scrutiny. Notably, the Department of Justice (DOJ) press release states that "the companies have been determined to continue to be a high risk to the United States health care program and their beneficiaries."[6]

OIG also recently published statistics regarding where parties to 53 total FCA settlements during the first quarter of Fiscal Year 2019 fell on the OIG risk spectrum.[7] During the time period between October 1, 2018 and December 31, 2018, four settling parties were determined to be in the lowest level of risk based on self-disclosures, and OIG provided a release from potential exclusion with no CIA or other requirements. Thirty-two settling parties were deemed relatively low risk and OIG did not seek exclusion, require a CIA, or take further action. Eleven settlements resulted in CIAs, one settlement (as mentioned above) resulted in a high risk determination for declining a CIA, and five settlements resulted in exclusions.

Strategic considerations

The Fraud Risk Indicator tool, in combination with the 2016 exclusion criteria, creates both challenges and opportunities for providers involved in FCA cases and negotiations. The public nature of the Indicator maintained on the OIG website increases the importance of understanding OIG's position early in negotiations, and the importance of ensuring that OIG is provided all relevant context before it determines where a provider falls along the risk spectrum.

By understanding and applying the criteria that OIG uses to weigh where a provider falls along the risk spectrum, a provider can ensure that the information it presents to OIG is relevant and effective in demonstrating a lower risk level. OIG qualifies its assessment by clarifying that the risk assessment will be based on the information OIG "gathers" and "has reviewed in the context of the resolved FCA case." Some information relating to the OIG criteria that could demonstrate lower risk would not be available to OIG in the normal course of an FCA case, unless the provider supplies it. For example, if a provider has a history of self-disclosing conduct or returning overpayments to OIG, DOJ, the Centers for Medicare & Medicaid Services (CMS), or state agencies, that information might not be readily available to OIG as part of the FCA case but, under the criteria, demonstrates lower risk. Ensuring that OIG has access to all relevant, mitigating information is critical.

The timing of presenting this information and discussing potential resolution with OIG is even more important in light of the new Fraud Risk Indicator. Initiating an open dialogue with OIG early in FCA settlement negotiations can help a provider understand how OIG views the provider's conduct and their risk level and also allows the provider to present valuable context to the OIG attorney conducting the risk assessment. This can help avoid a situation in which OIG concludes prematurely that a provider is higher risk, leaving the provider to try to dissuade OIG from its position. Earlier communication can also assist in ensuring that a provider understands

OIG's position and reasoning. Providers may be able to successfully implement remedial measures to mitigate risk early in negotiations, which may not be feasible in negotiating a settlement only days before a court deadline.

One of the many lingering questions stemming from the Indicator is how it will affect or be affected by OIG and DOJ's continued focus on individual accountability. The exclusion criteria makes clear that in determining a party's perceived future risk, OIG will take into account disciplinary action taken against culpable individuals, the involvement of leadership and higher-level individuals in the alleged FCA conduct, and whether the settling party cooperated against culpable individuals. In situations where OIG is concerned about the continued involvement of allegedly culpable individual(s) within the organization, particularly where that person is a named defendant to the FCA case, a provider may be faced with difficult decisions regarding how to resolve its liability with OIG. Although the exclusion criteria is not new, the public nature of the Indicator posted on the OIG website may change the calculus for providers who must weigh the potential stigma of being labeled "High Risk" against the various implications of an executive or employee being excluded and/or disciplined in a manner sufficient to satisfy OIG's concerns.

Providers who are told definitively that OIG believes a CIA is necessary to protect the federal healthcare programs will need to consider the relative costs (financial and otherwise) of accepting a CIA or being publicly listed under the "High Risk – Heightened Scrutiny" category. In doing so, providers whose concerns about acceptance of a CIA stem from onerous claims review requirements or anticipated significant or costly changes to an existing compliance program should consider carefully how a CIA can be tailored to be more effective for their compliance needs. Although not all provisions of a CIA are negotiable, OIG has shown flexibility in tailoring the claims and arrangements reviews to a provider's specific conduct and structure.

Conclusion

While the exact impact of the new Fraud Risk Indicator remains to be seen, it does seem likely that providers who are determined to be in the "No Further Action" category will benefit from the added transparency. Although these providers will not have the benefit of an exclusion release, they (and their stakeholders) will have a clear understanding that, based on its assessment of the FCA case, OIG does not consider them to be a future risk to the federal healthcare programs. Providers can hope to see more clarity, earlier in the negotiation process, regarding OIG's risk assessment, supporting criteria, and ultimate position on exclusion liability in FCA cases.

This article is educational in nature and is not intended as legal advice. Always consult your legal counsel with specific legal matters.

Takeaways

- Conduct an internal investigation as early as possible to determine who is responsible for the misconduct and be prepared to share the results with the government.
- Ensure that the misconduct has ended and be prepared to demonstrate that the organization has taken significant ameliorative steps in response to the conduct.
- Take appropriate disciplinary action against individuals responsible for the misconduct, provide training and education to address the misconduct, and demonstrate additional resources have been devoted to the compliance function.
- Evaluate the benefits of self-disclosing the misconduct and/or returning an overpayment, and consider the appropriate forum to do so.
- Clearly demonstrate acceptance of responsibility for the misconduct.

1 42 U.S.C. § 1320a-7(b)(7) Exclusion of Certain Individuals and Entities from Participation in Federal Health Care Programs. https://bit.ly/2TrB206
2 HHS Office of Inspector General, Criteria for implementing section 1128(b)(7) exclusion authority, April 18, 2016. https://bit.ly/2T70cC9
3 Idem
4 OIG: High Risk – Heightened Scrutiny website. https://bit.ly/2GRdz2u
5 Department of Justice press release, "$5.1 Million Dollar Settlement Reached with Indiana Dental Firm to Resolve False Claims Allegations" November 6, 2018. https://bit.ly/2IIJ5lj
6 Idem
7 OIG: False Claims Act Settlements on the Risk Spectrum FY 2019 Q1. https://bit.ly/2DYSikX