COMMENTARY

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Public Branding, the OIG's New Method of Punishing Health Care Entities?

IN SHORT

The Situation: The total number of Corporate Integrity Agreements ("CIAs") between the Office of Inspector General ("OIG") and health care entities has been decreasing, and the OIG has decided to shine a spotlight on entities that decline to participate in these agreements.

The Development: The OIG published the names of two health care entities that it deemed "high risk" as a result of their refusal to enter into CIAs.

Looking Ahead: False Claims Act ("FCA") defendants will need to address what will likely be increased pressure to enter into a CIA when negotiating an FCA settlement, but challenges to the OIG's new approach are likely.

As part of the settlement process in an FCA case, the OIG often will separately seek to impose a CIA on the settling party. Although the OIG has no statutory authority to require a CIA, it is typically presented as an alternative to possible exclusion from participation in federal health care programs or to the OIG's unilateral monitoring. The requirements under a CIA vary depending on the conduct alleged, but they usually include the engagement of an independent review organization to perform periodic audits, required training and education (in addition to any training and education already conducted by the entity), and annual reporting and certification to the OIG. The typical CIA lasts five years, which can be costly and burdensome even for organizations with a mature compliance program.

On September 27, 2018, the OIG released notice of its "Fraud Risk Indicator" webpage. The OIG announced it planned to use the Fraud Risk Indicator to publicize an "assessment of future risk" posed by health care entities that are subject to the OIG's permissive exclusion authority (most often where the entity settled an FCA case with the Department of Justice ("DOJ")), but did not agree to a CIA.

The OIG also explained that it would assess entities based on its previously published "risk spectrum" in the OIG's nonbinding criteria for implementing its exclusion authority. Categories of risk vary from highest risk, which can result in exclusion, to low risk, which typically covers entities that self-disclose. According to the 2016 guidance, the OIG weighs various factors to determine where an FCA defendant falls on that spectrum, including the nature and circumstances of the alleged conduct, cooperation during government investigation, corrective measures taken, and history of compliance.

This new initiative is designed to address what the OIG states are "relatively rare circumstances," where an entity has declined to enter into an integrity agreement as part of settlement. That decision may increase the risk of

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additional scrutiny by agencies following the settlement, such as the initiation of unilateral monitoring or an audit by the OIG or the Centers for Medicare and Medicaid Services. With the OIG's new Fraud Risk Indicator, that risk may further increase as the OIG deems certain entities as "high risk."

"future trustworthiness" based solely on the OIG's Fraud Risk Indicator.

Indeed, on November 6, 2018, the OIG published the names of the first entities that the OIG designated as "high risk" based on each entity's decision not to enter into a CIA. The OIG not only identified the entities' names, but also the date of relevant settlement agreements, the city and state where the entity is located, and a link to the DOJ's press release regarding the settlement. The press release further broadcasted the OIG's determination that "the companies pose a continuing high risk to the Federal health care programs and their beneficiaries."

The OIG's Fraud Risk Indicator comes more than two years after the 2016 exclusion guidance was released, but on the heels of an April 2018 U.S. Government Accountability Office Report that found that the total number of CIAs in effect had decreased by 44 percent between 2006 and 2016.

In a recent Bloomberg article, the OIG's chief counsel was quoted as saying that the purpose of the Fraud Risk Indicator is to promote transparency but also acknowledged the OIG would welcome any behavioral changes resulting from the public listing. Notably, entities that enter into FCA settlement agreements historically have not admitted any liability or misconduct, but those that refuse CIAs may now be publicly questioned as to their "future trustworthiness" based solely on the OIG's Fraud Risk Indicator.

The advent of the "high-risk" classification appears to be another way for the government to publicize allegations of fraud, even when they are disputed, and attempt to foreclose the possibility that an entity may challenge its published classification on the OIG's risk spectrum or request removal from the public listing after a certain time period. Further, the OIG acknowledges on the Fraud Risk Indicator webpage that the assessment is based solely on the information received in the context of the FCA case (rather than a comprehensive review of the entity).

Given the potential effects of such public denouncements, challenges to the OIG's new approach are likely.

TWO KEY TAKEAWAYS

1. The OIG recently announced it would begin publishing a list of entities that refuse to enter into CIAs that the OIG labels "high risk." And on November 6, 2018, the OIG publicized the names of the first providers it has deemed "high risk" as part of this new initiative.
2. Although the OIG's new approach may be subject to challenge, its potential effects will certainly be another factor entities will be forced to consider when engaging in FCA settlement discussions.


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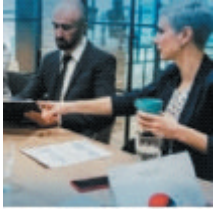

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