**New OIG Guidance Signals Changed View of Compliance Programs**

*By Tony Maida, McDermott Will & Emery LLP*

“You get no bonus points for having a compliance program.”

HHS Inspector General Daniel R. Levinson, remarks at the Health Care Compliance Association’s Annual Compliance Institute, April 18, 2016.

This statement sums up Mr. Levinson’s announcement of the updated guidance explaining the criteria the Office of Inspector General (OIG) uses for exercising its permissive exclusion authority under Section 1128(b)(7) of the Social Security Act. Starting from the premise that everyone in health care has a compliance program, and if you do not you pose a higher risk, is an evolution from OIG’s original guidance published in 1997 that reflects the evolution of the health care industry. In 1997, OIG was attempting to encourage wide adoption of compliance programs. It used this guidance to advance that objective by giving a certain amount of credit to defendants settling False Claims Act (FCA) cases who had implemented a compliance program that followed the seven elements of the U.S. Sentencing Guidelines.

Almost 20 years later, OIG has largely achieved its original goal—virtually every health care provider and supplier has adopted some form of compliance program that, among other things, contains the seven elements and addresses federal health care program compliance. Now OIG is completing its pivot to its next goal that began with the 2008 Open Letter and 2013 updated Self-Disclosure Protocol—moving from encouraging the creation of compliance programs to operating effective compliance programs.

**Section 1128(b)(7) Exclusion Authority and 1997 Guidance**

The permissive exclusion authority at issue, Section 1128(b)(7), is the authority that permits OIG to bring an exclusion action for conduct that also could be pursued under the FCA—namely false or fraudulent claims or anti-kickback or Stark Law violations. Negotiating the resolution of the 1128(b)(7) authority generally is part of the FCA settlement process and formed the basis for why OIG developed Corporate Integrity Agreements (CIAs) more than 20 years ago.

The 1997 guidance contained four general factors on how OIG made exclusion and CIA decisions: circumstances of the misconduct and seriousness of the offense; the defendant's response to the allegations; the likelihood that the offense or similar abuse would occur again; and the defendant's financial ability to continue to provide services post-settlement.

Most of the analytical action happened in the first three factors. The circumstances factor focused on the conduct under investigation, including whether there was a “criminal sanction” imposed, the extent of evidence of “physical or mental” patient harm or financial harm to federal health care programs, and whether the conduct showed a pattern of misconduct over a lengthy period. The second factor, responsiveness to the allegations, dealt with the defendant’s cooperation with the government’s investigation, including “timely response” to document subpoenas and a willingness to settle the allegations for an appropriate monetary resolution. The third factor mostly examined whether the defendant had adopted a compliance program during the covered conduct period that
contained the seven elements. The guidance left the door open for defendants to show that they would agree to adopt a compliance plan at the time of settlement, and that OIG would take this into account. The guidance states that “the implementation of an adequate corporate integrity program is a key consideration” in exclusion and CIA decision making.[8]

Given the state of the legal and compliance landscape in 1997, OIG’s publicizing its analytical framework was laudable at the time. The transparency only went so far—the guidance provided few clues on how the factors were valued against each other. Also, the 1997 guidance was limited to the binary decision between exclusion or CIA. Over time, this came not to reflect OIG’s development of other options, such as “unilateral monitoring” or OIG choosing not to seek a CIA in certain cases and “reserving” the 1128(b)(7) authority. Further, OIG elevated the importance of self-disclosure in the 2008 Open Letter and 2013 updated OIG Self-Disclosure Protocol by creating a “presumption” of not requiring integrity obligations in resolving self-disclosures, making the 1997 notice increasingly out of step with OIG’s current practices.

2016 Updated Guidance Summary

- The Risk Spectrum Continuum

The new guidance articulates, for the first time, OIG’s “risk spectrum” for evaluating cases along a “continuum” and all of the options OIG considers in evaluating individuals and entities along this continuum.[9] These options are in order of high-to-low risk: exclusion; “heightened scrutiny” or unilateral monitoring; a CIA; “reserving” the 1128(b)(7) authority with no further action; and, finally, releasing the 1128(b)(7) authority when the person self-disclosed the matter.

- The Meaning of Reservation

On the higher risk side, OIG provides some insight about what “unilateral monitoring” may involve in the event OIG seeks a CIA but either the defendant declines to enter into a CIA or OIG and the defendant are unable to reach an agreement on the CIA’s obligations. OIG says that it may consider whether to exercise its authorities under the Inspector General Act, meaning that the defendant could become a target of future OIG audit, evaluation, or investigation activity. In addition, OIG may make referrals to the Centers for Medicare & Medicaid Services (CMS) or one of CMS’ contractors to consider the defendant for additional auditing or oversight.

On the lower risk side, OIG explains there are two reasons why it may decide not to seek a CIA in an FCA settlement and reserve its exclusion authority: (1) the absence of egregious conduct such as patient harm, intentional fraud, or relatively low financial harm in proportion to the size of the provider; or (2) there is a successor owner of the provider. In deciding whether to require a CIA of the successor owner, OIG considers whether the new owner: (a) purchased the entity after the subject conduct occurred; (b) has a compliance program; (c) does not have a history of “wrongdoing or fraud settlements” with the United States; (d) took appropriate steps to address the predecessor’s misconduct and reduce the risk of future misconduct; and (e) can demonstrate other facts and circumstances relevant to OIG’s decision making.

Unfortunately, OIG’s decision to pursue unilateral monitoring or conclusion that a CIA is not necessary both result in OIG reserving its 1128(b)(7) exclusion authority in the FCA settlement. As a result, the FCA settlement will look the same when OIG intends to engage in unilateral monitoring or when it intends to close its file. This exclusion reservation inevitably raises questions about OIG’s intended meaning in future due diligence and in an entity’s financial reporting. OIG states that it will explain to the defendant what the reservation means in each case.[10] OIG generally provides this explanation orally from the OIG attorney assigned to the case—written “cold comfort” is not typically done.
New Factors

The new guidance discusses four broad categories of factors that OIG considers in making a risk assessment: nature and circumstances of the conduct, conduct during the investigation, significant ameliorative efforts, and history of compliance. While OIG states that this analysis is to make an assessment of future risk of participation in federal health care programs, the factors OIG uses to make this assessment mostly deal with past conduct, especially the alleged past conduct that the defendant is settling in the FCA case.

Nature and Circumstances of Conduct

The "nature and circumstances" factor relates to OIG’s view of the alleged misconduct being settled. It contains four subtopics: adverse impact on individuals, financial loss and circumstances of the allegations (e.g. length of time, existence of a pattern, etc.), leadership role of individual defendants or corporate executives in the underlying conduct, and history of prior fraudulent conduct.[11] The "patient harm" factor was expanded to cover any actual or potential adverse impact on individuals. In addition, OIG revised its position on criminal sanctions to say that the absence of a criminal sanction does not affect the risk assessment of this factor. The "history of prior fraudulent conduct" subtopic concerns whether the defendant has a history of judgments, convictions, or settlements in prior federal or state criminal, civil, or administrative actions.

It is worth noting that the guidance makes reference in several places to past settlements as creating higher risk. Most people would have little argument with considering past judgments or convictions in making a risk assessment. Health care fraud convictions result in mandatory exclusions, making 1128(b)(7) irrelevant. However, the use of past settlements as an indication of future risk raises some questions. While the guidance in many respects makes considerable effort to be transparent on OIG’s decision-making process, it is unclear how OIG will weigh past settlements in making a future risk assessment, such as evaluating the nature of those allegations and how long ago the settlement occurred. OIG’s ability to determine the relative strength or weakness of the government’s and defendant's positions and circumstances of the past settlement would seem to deteriorate with the passage of time. Further, individuals and entities settle cases for a variety of reasons, such as litigation risk, a desire for closure, to satisfy external or board concerns, and to avoid a protracted fight with a relator, not to mention the potential catastrophic consequences of losing an FCA case. The government also settles cases for various reasons, including litigation risk, conservation of resources, and a desire to avoid creating bad law by a relator pursuing a case that presents significant risks. The consequences of losing are without question more severe for the defendant compared to the government, and that can drive the decision to settle. It can be difficult to draw accurate conclusions about the potential risk a provider currently poses based on the bare fact of a past settlement. The inclusion of “administrative” settlements raises the question of whether this factor includes CMS contractor settlements or payment determinations. Oftentimes, providers may disagree with a contractor's overpayment determination, but decide it is not worth the time or money to continue the appeals process. One need only look at your hospital’s high Administrative Law Judge reversal rate of Recovery Audit Contractors to recognize the peril of relying on past contractor actions as a basis for making a future risk projection.

Conduct During the Investigation

In this factor, OIG takes more expansive positions than it did in the 1997 guidance. While timely responses to document subpoenas and cooperating with the government’s investigation would get credit under the old criteria, under the new criteria “prompt response to a subpoena is expected and does not affect the risk assessment.”[12] Also, in 1997 you could get credit if the conduct was the result of unique circumstances not likely to recur, such as a change in the payment rules or change
in the provider’s business.[13] Under the new guidance, OIG states that “the inability of a person to engage in the conduct again because a contract or arrangement was terminated, or due to a change in the federal health care program rules, does not affect the risk assessment.”[14]

Finally, the guidance discusses credit for cooperating or agreeing to cooperate with the government, but does not provide specifics on what that cooperation needs to involve to receive credit. In a different subsection entitled “internal investigation,” OIG gives favorable treatment to initiating an internal investigation to determine who was responsible for the conduct prior to becoming aware of the government’s investigation and sharing the results with the government (presumably as part of responding to and cooperating with the government). This position echoes the Department of Justice’s (DOJ) Yates Memorandum[15] definition of cooperation as identifying the responsible individuals. In that same subsection, OIG gives additional credit for self-disclosing the conduct prior to becoming aware of the government’s investigation.

- **Significant Ameliorative Efforts**

  The significant ameliorative efforts factor had the most potential to have a future orientation to examine what compliance activities, process changes, or controls have been put in place over time and what the defendant would be willing to voluntarily do in the future. The guidance describes this factor as limited to whether appropriate disciplinary action was taken against responsible individuals and whether the entity devoted “significantly more resources to the compliance function” (presumably either before or after the investigation began); or whether the entity was sold to an independent third party or a licensed individual received additional training and mentorship.

- **History of Compliance**

  This factor repeats OIG’s view that having a history of self-disclosing issues to the government shows a lower risk. It also is where OIG states the position that having a compliance program that meets the seven elements does not affect the risk assessment, but not having a compliance program indicates higher risk.

**Conclusion**

The most immediate impact of the updated guidance is on individuals and entities involved in FCA investigations and settlement negotiations. Presentations to and discussions with OIG about its 1128(b)(7) decision making will need to be tailored to address these factors. When OIG says it is “reserving” its authorities, counsel will need to confirm what that means and document the conversation to explain it to future stakeholders.

This guidance reaches the broader health care community as well. Many compliance professionals, executives, and counsel may be rather disheartened to learn that all of the time, energy, and treasure spent on compliance programs gets “no bonus points” and “does not affect the risk assessment” of OIG. The more nuanced lesson from the guidance is that OIG is seeking to promote its vision of what an “effective” compliance program should do: “promote compliance so that future issues can be prevented or identified, reported, and corrected.”[16] This vision represents a significant shift for OIG, but the seeds for this shift were sown beginning in 2008. In 2016, having a compliance program that meets the seven elements is the expectation of the OIG, as well as DOJ, CMS, and potential buyers, investors, and lenders. Now, the attention of industry, as well as OIG, is focused on trying to identify ways to measure program effectiveness to ensure precious resources are spent in the best way to help protect the individual provider or organization from future risks.

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[8] Id.


[10] Id. at 3.


[12] Id. at 5.


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