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The role of compliance in government enforcement

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As recent developments in corporate enforcement indicate, the United States Department of Justice (DOJ) continues to emphasize transparency, cooperation, and the importance of a strong compliance program. Enforcement trends indicate a continued focus on fraud in the healthcare industry. In fact, of the $3 billion in False Claims Act (FCA) recoveries in the 2019 fiscal year, $2.6 billion related to matters involving healthcare.[1] (DOJ's strong emphasis on healthcare fraud is not unique to the current administration. Healthcare fraud was also a central focus of the Obama administration. For example, in 2009, a joint DOJ and Department of Health & Human Services task force known as the Health Care Fraud Prevention and Enforcement Action Team was created.) Further, the COVID-19 stimulus programs have paved the way for new types of healthcare fraud. This article explores recent governmental enforcement activity, including recent guidance documents, pronouncements, and memoranda. It discusses a powerful enforcement tool used by the DOJ in corporate enforcement—independent compliance monitors. Lastly, this article explores the evolution of corporate integrity agreements (CIAs), which provide a perspective on the Department of Health & Human Services Office of Inspector General's priorities for healthcare compliance program structure and content.

Government perspectives on corporate compliance

Corporate compliance can play a significant role in the DOJ's resolution of corporate investigations. This article focuses on several recent DOJ guidance documents that provide companies with increased transparency in corporate enforcement actions. DOJ's guidance on cooperation credit in FCA investigations explains how the DOJ determines financial penalties and settlements in FCA actions, particularly where a company voluntarily discloses misconduct to DOJ. Another guidance document examines how a prosecutor can evaluate claims that a corporation is unable to pay a proposed fine or monetary penalty. A third describes the attributes of an effective compliance program, and a fourth details the circumstances in which, as a part of a resolution, DOJ may require a corporate monitor. These policies should serve as guideposts for companies to gauge the DOJ's expectations on compliance, analyze strategic decisions, and conform their conduct to appropriate standards.[2]

Cooperation credit

The past year has witnessed several notable developments in corporate enforcement. For example, in May 2019, the DOJ released long-awaited guidance concerning cooperation credit in FCA investigations.[3] (The FCA is an important statute that protects the US government against fraud. It imposes liability on any person who knowingly submits a false claim seeking government funds. Both the DOJ and private citizens, known as "relators," are allowed to bring actions on behalf of the United States asserting FCA violations.) The guidance identified factors the DOJ will consider when determining financial penalties and settlement amounts in

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corporate resolutions. Specifically, the guidance defines three types of conduct the DOJ will recognize as cooperation: (1) voluntary self-disclosure, (2) other forms of cooperation, and (3) remediation.

Voluntary disclosure

DOJ has referred to voluntary self-disclosure as "the most valuable form of cooperation."[4] In simplest terms, voluntary self-disclosure is approaching the government to report a potential violation. The disclosure must be both proactive and timely.[5] A company may receive credit for voluntary disclosure, even if the government has already initiated an investigation, if the company apprises the DOJ of other misconduct outside the scope of the government's existing investigation that is unknown to the DOJ.[6]

Other forms of cooperation

The new guidance includes a nonexhaustive list that includes 10 examples of cooperation that could "meaningfully assist" DOJ in its FCA investigation.[7] These actions include:

- "Identifying all individuals substantially involved in or responsible for the misconduct";
- "Preserving … and disclosing relevant documents and information … beyond existing business practices or legal requirements";
- "Making available for meetings, interviews, examinations, or depositions … officers and employees who possess relevant information";
- "Disclosing facts relevant to the government's investigation gathered during the entity's independent investigation" (i.e., attributing facts to specific sources and providing updates on any internal investigation); and
- "Providing facts relevant to potential misconduct" by third parties.

Remediation

Under the new guidance, the DOJ will also consider whether appropriate remedial actions have occurred. Such measures include:

- Undertaking "a thorough analysis of the cause of the underlying conduct" and remediating the root cause;
- "Implementing or improving an effective compliance program" to prevent future misconduct;
- Appropriately disciplining or replacing the individuals directly involved in the misconduct, including "those with supervisory authority over the area where the misconduct occurred"; and
- "Any additional steps demonstrating recognition of the seriousness of the entity's misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct."

Historically, FCA settlements rarely included a formal cooperation credit component. Accordingly, this guidance signifies a shift in the DOJ's approach, perhaps signaling the DOJ's desire to incentivize increased cooperation—even in civil cases.

Inability to pay

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In October 2019, the then-Assistant Attorney General for the DOJ Brian A. Benczkowski announced new guidance on how to evaluate a company's claim that it is unable to pay a criminal fine or monetary penalty as part of its corporate misconduct settlement.[8] Benczkowski's corresponding guidance memo includes an 11-prong questionnaire that companies may use to assess financial hardship. These questions focus on the company's current assets, liabilities, cash flows, financial statements, and tax returns. In determining whether to reduce a penalty amount, the DOJ may recommend an adjustment "only to the extent necessary to avoid (1) threatening the continued viability of the organization, and/or (2) impairing the organization's ability to make restitution to victims." While enforcing the FCA reportedly remains a "top priority" for the DOJ,[9] it has taken the stance that, in some instances, corporate defendants may require a reduction in fines and penalties based on an inability to pay.[10]

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