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USF Health at the University of South Florida

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A growing voice in the compliance chorus: The Department of Justice Criminal Division

- » DOJ's Criminal Division has provided detailed guidance on its view of compliance programs.
- » This guidance accompanies greater Criminal Division involvement in False Claims Act cases.
- » DOJ and OIG carefully examine compliance programs for sign of effectiveness during an investigation.
- » The federal government expects entities will make compliance a priority, starting with senior management involvement in compliance program oversight.
- » Compliance programs are important in both preventing problems as well as contributing to the defense of an entity during a government investigation.

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Over the past several months, senior U.S. Department of Justice (DOJ) Criminal Division officials have increasingly discussed how DOJ views compliance programs and cooperation with the government as part of determining whether to prosecute a case or in determining an appropriate resolution.



Maida

Assistant Attorney General Leslie R. Caldwell has been the most frequent and detailed speaker on this topic during her first year leading the Criminal Division.¹⁻⁵ This effort of greater transparency comes at the same time Caldwell increased the Criminal Division's scrutiny of False Claims Act (FCA) cases. In the fall of 2014, Caldwell

announced a new procedure that all new FCA *qui tam* complaints would be shared by the Civil Division with the Criminal Division as soon as the cases are filed, with prosecutors "immediately reviewing" the *qui tam* complaint to determine whether to open a parallel criminal investigation.⁶ This policy is a change from the Civil Division taking the lead on deciding whether to make a referral of a particular case to the Criminal Division. Caldwell also appealed to relators' counsel to reach out to criminal prosecutors when shopping a potential FCA case, just as they do with the civil attorneys in Main Justice and the U.S. Attorney's Offices.

With the Criminal Division potentially becoming more active in FCA investigations, their views on compliance programs provide insight into how they will examine an entity's compliance program in the course of an investigation. The healthcare industry has a long history of receiving compliance guidance

from a different federal agency—the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. Over almost two decades, OIG has issued various industry specific Compliance Program Guidance documents as well as guidance tailored to boards of directors, the most recent of which was issued this April.⁷

Characteristics of effective compliance programs

Both OIG and DOJ repeatedly have stated that they recognize there is no “one size fits all” compliance program. Rather, the agencies agree that effective compliance programs are those that are tailored to the unique needs, risks, and structure of each business or industry. However, while the agencies say they have not created specific program requirements, both DOJ and OIG have articulated a fairly detailed list of characteristics they look for when evaluating a compliance program. DOJ’s recent comments show the spotlight continues to shine on compliance program effectiveness.

Tone and commitment from the top

The government always trumpets the need for entity leadership to provide strong, explicit, and visible commitment to its corporate compliance policy—from the boardroom, C-suite, and upper and middle management. In an investigation, Caldwell says DOJ will be looking at how these individuals behaved or reacted to compliance issues and what messages they sent to employees about compliance, including through in-person meetings, emails, and telephone calls. Decisions about compensation and employee incentives or rewards may also be examined to determine whether those decisions were made consistent with, or opposed to, the stated goals of the compliance program. If compliance is important, then DOJ expects that employees are given meaningful incentives to encourage that behavior.

Written policies

A basic part of compliance programs is to have a well-articulated and visible corporate compliance code of conduct. This can provide employees guidance on what to do or not do. An entity’s policies should be clear, in writing, and should easily be understood by employees to make it as easy as possible to find the answer or know where to go to get the answer.

Proper oversight and independence

Responsibility for the implementation and oversight of the compliance program should be given to senior executive team members. Echoing OIG’s longstanding guidance, DOJ wants compliance officials to have the authority to report directly to the board of directors. They should also have sufficient resources to run the program and have appropriate stature within the entity. Caldwell gave an example of certain Wall Street banks that housed their compliance programs in New Jersey as a sign that compliance was “out of sight, out of mind.”

Training and guidance

Mechanisms designed to ensure that the compliance code and policies are effectively communicated to all directors, officers, and employees is another basic program element. Caldwell expanded this concept beyond traditional training efforts to include other ways that an entity can facilitate communication and provide guidance when issues arise. Caldwell emphasized the role of senior leadership in helping communicate these messages to demonstrate the right “tone at the top” and executive buy-in.

Periodic risk-based reviews and auditing

Consistent with OIG’s latest guidance on internal auditing, DOJ also expects periodic evaluation of compliance policies and audit activities through a risk assessment that addresses the individual circumstances of the entity. These reviews and

audits are ways to prevent and detect problems and to identify policies that need updating or clarification. Plus, entities change over time through natural growth, mergers, and acquisitions, which may alter the risk assessment. Changes in the regulatory environment and program rules and structures may also create reasons to conduct a policy review.

Internal reporting

An entity should have an effective system for confidential, internal reporting of compliance violations. Caldwell praised entities that had multiple mechanisms for internal reporting, presumably because it addresses both convenience and anonymity for the employee.

Third-party relationships

In several speeches, Caldwell remarked on DOJ's perceived need for including oversight of third parties, such as agents, consultants, and business partners, in their compliance program. If the entity finds problems, DOJ's expectation is that the entity will take similar actions as it would if the actor were internal, such as warnings, education, and even considering terminating relationships with partners who fail to behave in a compliant manner.

Internal investigation and disclosure

Establishing an effective process with sufficient resources for responding to, investigating, and documenting allegations of violations is another key compliance program element. Caldwell often spoke about the importance of internal investigations in the context of DOJ's evaluation of whether to give the entity cooperation credit following the entity's disclosure of potential criminal wrongdoing. Although such a disclosure would be reserved for the most serious circumstances, Civil Division attorneys, U.S. Attorneys' Offices, and OIG attorneys conduct similar reviews of internal investigations for matters that are disclosed

to them. The agencies would likely agree with five basic principles:

- ▶ There is no one right way to do an internal investigation;
- ▶ The government expects the entity to conduct a "thorough" investigation to identify the facts, gather evidence, and identify the individuals involved in or responsible for the conduct, including high-level executives;
- ▶ The government expects a "timely" investigation and disclosure, which, as Caldwell said, "doesn't mean you need to call us on Day One" because "in most cases, it is in everyone's interest for there to be an orderly internal investigation";
- ▶ There is not an expectation that, as Caldwell said, entities "boil the ocean" to track down every possible fact or to "look under every rock and pebble" for all possible misconduct, because doing so may waste the entity's and the government's time and resources; and
- ▶ The government will review the quality of the internal investigation in assessing whether the entity is appropriately cooperating with the government in the disclosure process.

The practical reality is, what constitutes a "thorough" and "timely" investigation is sometimes in the eye of the beholder. Here, the government is in the unavoidable position of reviewing, with the benefit of hindsight, the decisions made at the time the investigation was unfolding, which is when the situation is only slowly coming into focus. Considerable judgment is needed to chart the course of an internal investigation, and to know when to adjust that course depending on what happens in real time.

Focusing on the problem at issue, determining the scope of that problem, and identifying the "who, what, where, when, why, and how" behind the problem provides some guideposts for a thorough investigation. In a disclosure context, the government is also going to be interested in knowing what process or systems

improvements or safeguards have been implemented to help prevent the problem from recurring. This is not necessarily related to the investigation, but is an important part of ensuring a successful disclosure outcome.

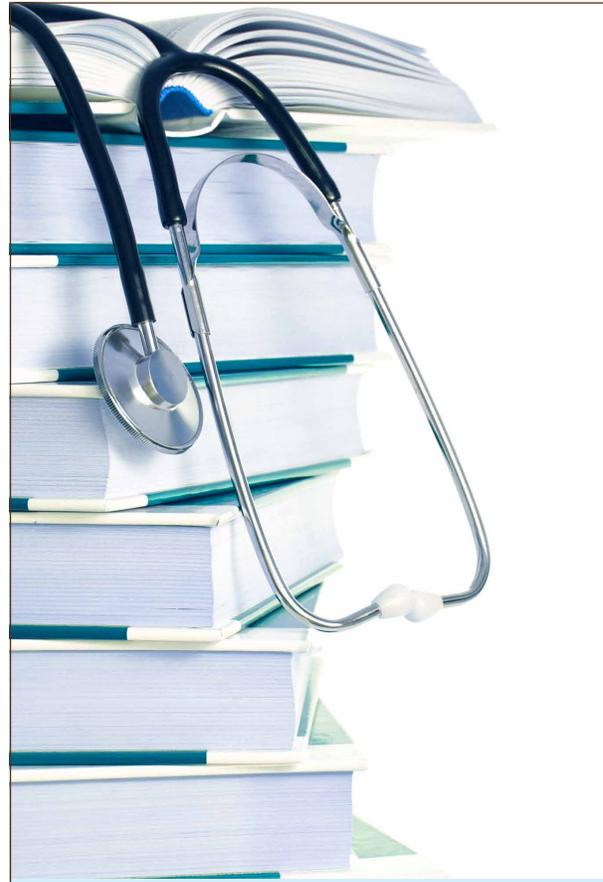
Enforcement and discipline

Once misconduct is found, the government expects that compliance programs will enforce its compliance code in an even-handed manner, which may include additional training, supervision, and disciplinary consequences. The government's focus on individual responsibility for misconduct means it is going to examine whether just low-level employees are disciplined, and whether those above them—who may have seen what was happening or maybe even directed the conduct—experience consequences.

Summary

As has been true for many years, the federal government's pursuit of healthcare fraud and abuse remains a top priority. DOJ's growing interest in examining compliance programs highlights their importance in both preventing problems as well as effectively defending the entity during a government investigation. With the potential for the increased involvement of DOJ's Criminal Division in the FCA enforcement landscape, robust and active compliance programs can be the ounce of prevention that proves to be worth a pound of cure in avoiding or mitigating potential problems within the highly regulated healthcare environment. ☺

1. See, e.g., Remarks of Assistant Attorney General Leslie R. Caldwell, 22nd Annual Ethics and Compliance Conference, October 1, 2014. Available at <http://bit.ly/12cbdrd>
2. Remarks of Assistant Attorney General Leslie R. Caldwell, New York University Law School's Program on Corporate Compliance and Enforcement, April 17, 2015. Available at <http://bit.ly/1REbE7G>
3. Remarks of Assistant Attorney General Leslie R. Caldwell, New York City Bar Association's Fourth Annual White Collar Crime Institute, May 12, 2015. Available at <http://1.usa.gov/1fQFn3>
4. Remarks of Assistant Attorney General Leslie R. Caldwell, American Bar Association's 25th Annual National Institute on Health Care Fraud, May 14, 2015. Available at <http://1.usa.gov/1e55DYz>
5. Remarks of Assistant Attorney General Leslie R. Caldwell, Compliance Week Conference Washington, May 19, 2015. Available at <http://1.usa.gov/1J5diDa>
6. Remarks by Assistant Attorney General Leslie R. Caldwell, Taxpayers Against Fraud Education Fund Conference, Washington, D.C., September 17, 2014. Available at <http://1.usa.gov/1Lf7msS>
7. Office of Attorney General, Association of Healthcare Internal Auditors, American Health Lawyers Association, and Health Care Compliance Association: *Practical Guidance for Health Care Governing Boards on Compliance Oversight*, April 20, 2015. Available at <http://1.usa.gov/1J5dqmf>



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