

by Gabriel Imperato, Esq., CHC

Department of Justice increases focus on organizational compliance

- » The Department of Justice Compliance Counsel will focus on the effectiveness of organizational compliance programs.
- » Measurements are evolving for effective compliance and for compliance professional expertise.
- » Compliance professionals should expect escalating criminal and civil liability for healthcare fraud.
- » Individual criminal and civil liability for healthcare fraud and non-compliance are also expected to increase.
- » Developments and consequences should be monitored.

Gabriel Imperato (gimperato@broadandcassel.com) is the Managing Partner at the Fort Lauderdale law offices of Broad and Cassel and the Immediate Past President of the Society of Corporate Compliance and Ethics and the Health Care Compliance Association.

The Department of Justice (DOJ) has recently articulated important enforcement policies and created the position of Compliance Counsel, which are expected to have a dramatic impact on criminal and civil prosecution of healthcare fraud matters. The



Imperato

policy pronouncements are related to the systematic review of civil *qui tam* complaints for potential criminal culpability and also review for individual liability for organizational healthcare fraud.

The goal is to raise the stakes and consequences for misconduct with a more direct deterrent effect.

The compliance counsel is also expected to hold organizations more directly accountable for the effectiveness of their compliance programs. The following article will discuss these recent developments and the expected impact on enforcement and compliance in the healthcare industry.

DOJ creates new position

The DOJ Criminal Division's new Compliance Counsel will serve as the Department's full-time compliance expert. Assistant Attorney General Leslie Caldwell and the newly appointed Compliance Counsel, Hui Chen, have presented detailed presentations on the role of the compliance counsel and identified metrics that will be applied to assess a particular organization's compliance program. Caldwell recognized the need for improvement within the Department's Criminal Division to evaluate compliance programs and suggested tailored reforms to these programs when the DOJ resolves a corporate matter. Specifically, Caldwell noted that "the Criminal Division will continue to review companies' compliance programs as one of the many factors to be considered when deciding whether to criminally charge a company or how to resolve criminal charges."¹ DOJ believes that the hiring of a compliance counsel with significant, high-level compliance experience will further facilitate its goal of ramping up criminal prosecution.

The DOJ's press release regarding appointment of the compliance counsel explains that the newly created position will provide expert

guidance to DOJ prosecutors. This expertise will come into play when DOJ attorneys consider “the existence and effectiveness of any compliance program that a company had in place at the time of the conduct giving rise to the prospect of criminal charges, and whether the corporation has taken meaningful remedial action, such as the implementation of new compliance measures to detect and prevent future wrongdoing.”² This clearly has been a task performed by line criminal prosecutors for some time, although now it will also apparently be the focus of the compliance counsel’s responsibilities. The compliance counsel will also help federal prosecutors develop appropriate benchmarks for evaluating corporate compliance and remediation measures, and communicate with stakeholders in setting those benchmarks. In developing these benchmarks, the compliance counsel will provide expert guidance to help prosecutors evaluate whether the implementation of such measures has been effective and/or has had a remediation effect, and perhaps even reduced corporate recidivism.

Caldwell also highlighted two key benefits the DOJ seeks to attain from the compliance counsel. First, assistance to the Criminal Division in assessing an organization’s compliance program, as well as testing the validity of its claims about its program, such as whether the program is thoughtfully designed or essentially “window dressing.” Furthermore, the compliance counsel will help guide DOJ prosecutors when seeking remedial compliance measures as part of a resolution with an organization. This may be the most important contribution of the compliance counsel, especially for the uninterested DOJ criminal

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attorney. The goal is to ensure that restrictions placed on these companies by the DOJ are not unnecessary or unduly burdensome, while at the same time, making sure that appropriate compliance enhancements are applied for remediation and effectiveness.

Ultimately, the creation of the compliance counsel position serves to highlight the DOJ’s increased focus on ensuring

that companies are in compliance with the government’s fraud and abuse laws and regulations. Notably, Caldwell made clear that the “hiring of a Compliance Counsel should be an indication to companies about just how seriously [the Department] take[s] compliance.”³

Hallmarks of an effective compliance program

Caldwell further discussed the importance of “full-throated compliance programs” in preventing fraud and corruption. Caldwell highlighted several important “hallmarks” of an effective compliance program that will enable the DOJ to determine whether the organization and its program actually support compliance in an effective way.

The hallmarks outlined by Caldwell are summarized in seven core considerations that the compliance counsel is expected to use to assess corporate compliance programs:

- ▶ Does the institution ensure that its directors and senior managers provide strong, explicit, and visible support for its corporate compliance policies?
- ▶ Do the people who are responsible for compliance have stature within the company? Taking the corporation’s size into consideration, do compliance personnel get adequate funding and access to necessary resources?

- ▶ Are the institution's compliance policies clear and in writing? Are they easily understood by employees?
- ▶ Does the institution ensure that its compliance policies are effectively communicated to all employees? Are the written policies easy to find? Do employees have repeated training that includes direction regarding what to do or with whom to consult when issues arise?
- ▶ Does the institution review its policies and practices to keep them up to date with evolving risks and circumstances?
- ▶ Are there mechanisms to enforce compliance policies? This includes both incentivizing good compliance and disciplining violations. Is the discipline even-handed? Importantly, the Department will not look favorably on situations in which low-level employees who may have engaged in misconduct are terminated, but more senior employees who either directed or deliberately turned a blind eye to the conduct suffer no consequences.
- ▶ Does the institution sensitize third parties like vendors, agents, or consultants to the company's expectation that its partners are also serious about compliance? This means taking action, including termination of a business relationship, if a partner demonstrates a lack of respect for laws, policies, and compliance best practices.

The DOJ has made it clear that these are just some of the elements of a strong compliance program, and its review of a particular program is not limited to the measures identified above. Importantly, this assessment not only encompasses a review of how the compliance policy looks on paper, but also the messages conveyed to employees through

in-person meetings, email, telephone calls, and compensation.

Chen, in her first appearance in her new role as Compliance Counsel, also articulated her own views on compliance and the framework through which she approaches compliance programs. She emphasized that an effective compliance program will function differently depending on the industry and company served. She noted that "[compliance] work is a constant struggle . . . There is not likely to be a day when there are zero conduct issues. But an indicator of a real program is that effort of trying to figure out how to make it better, how to make it more real, and how to make it more real to the little guys in the room."⁴

Chen stressed that she will focus on four questions as Compliance Counsel:

- ▶ **Thoughtful design of the compliance program:** Does a program address the main causes of problems? Do the corporation's stakeholders have ownership over their respective pieces of the program?
- ▶ **How operational is the program?** Chen opined that the "frontline gatekeepers are low-level employees." She will look to see whether the corporation has a healthy process for handling complaints once they are received, and whether the company takes whistleblower complaints seriously and responds appropriately.
- ▶ **How well do the stakeholders communicate?** Chen recommended daily communication with Finance, Legal, Human Resources, Audit, and investigatory groups, as well as communication with ground-level operatives in the field. Additionally, Chen will look at whether a corporation's culture facilitates an open door atmosphere in which employees feel free to raise issues.

- ▶ **Is the compliance program well resourced?** Chen will look to see whether the program receives adequate funding, as well as adequate attention and commitment from the organization's leadership.

There is acute interest in the work and impact of the DOJ compliance counsel in the healthcare compliance community. This position will be a focus for establishing benchmarks for effective compliance programs, and the concern is whether sufficient input from the industry compliance community will be considered for this important topic and in connection with future developments. Healthcare compliance professionals have had more than 20 years' experience with effectiveness for organizational compliance programs, and the DOJ is just now embarking on focusing on this in a dedicated and systemic way. The hope is that DOJ will allow for constructive input from the compliance community on the meaningful measures of an effective compliance program.

Increased scrutiny of *qui tam* suits

The Department of Justice has also embarked on new enforcement policy initiatives involving a more systemic review of civil *qui tam* complaints for criminal investigation and culpability. Additionally, the Department has made it clear and has instructed DOJ attorneys to investigate cases carefully for individual criminal and/or civil culpability and liability for organizational healthcare fraud.

The DOJ's increased systematic review of criminal culpability in *qui tam* actions has been well-documented since late 2014. At that time, Caldwell announced the formal adoption of a new policy within the Criminal Division, which requires criminal prosecutors to "more closely scrutinize" and actively investigate civil *qui tam* complaints filed by private relators under the False Claims Act. This type of

review is not new, but the intention to make it more "systematic" has been a new goal by the DOJ; its efforts are being felt in some recent enforcement actions.

In her past comments, Caldwell noted that "*qui tam* cases are a vital part of the Criminal Division's future efforts."⁵ She noted that the DOJ is "determined to root out health care fraud," and it has the resources and experience to do so. Caldwell further highlighted that the opportunity to greatly enhance the effectiveness of our nation's *qui tam* system of fraud prevention will be through departments and agencies such as the Criminal Division's Medicare Fraud Strike Force, and the vast experience its federal prosecutors have in complex healthcare, financial fraud, and corruption cases. Caldwell believes that the vast tools that the Criminal Division has at its disposal will help DOJ investigate and uncover fraud more quickly and efficiently.

The new policy directive in the Yates Memo mandated that all new *qui tam* complaints be shared by the Civil Division with the DOJ Criminal Division as soon as the cases are filed. As part of the initiative, Caldwell announced that "experienced prosecutors in the Criminal Division will immediately review *qui tam* cases when they are received to determine whether to open a parallel criminal investigation." If a case raises potential criminal issues and needs investigative support, Caldwell pointed to a myriad of experienced fraud investigators from a variety of federal law enforcement agencies that would assist in the investigation and criminal prosecution.⁶

Caldwell also encouraged *qui tam* relators' counsel to actively work with the DOJ in bringing the wrongdoers to justice. Specifically, she encouraged them to reach out to criminal authorities in appropriate cases, even when counsel is discussing the case with civil authorities. She notes that the earlier the Criminal Division begins its investigation, the

more legal tools and investigative techniques will be available.

It still remains to be seen whether there will actually be an increase in criminal health-care fraud investigations and prosecutions as a result of this elevated review of civil *qui tam* complaints. There have been some recent criminal investigations of healthcare fraud activities that have

previously only been addressed in civil cases. However, there is always going to be a question of whether the DOJ actually

has the resources to roll out criminal fraud cases and maintain the volume of prosecutions that have been achieved to date under the HEAT Program. Additionally, the potential cooperation of the Relators' Bar in responding to the invitation by the DOJ to submit evidence of criminal wrongdoing to criminal prosecutors is somewhat tenuous, because criminal investigation and prosecution normally delays civil monetary recovery—the ultimate objective of any *qui tam* case, relator, and relator's counsel.

The Yates Memorandum and individual culpability and liability

Additionally, Deputy Attorney General, Sally Quillian Yates distributed a Memorandum to federal prosecutors on September 9, 2015. The Memorandum details substantial changes to the methods and procedures that should be taken in any investigation of criminal and civil corporate misconduct. The Yates Memorandum discusses and instructs DOJ attorneys on pursuing healthcare corporations and their individual employees and agents involved in fraud allegations. Importantly, Yates indicated that the purpose of the Memorandum is to insure that “all attorneys across DOJ are consistent in best efforts to hold to account the individuals

responsible for illegal corporate conduct.” The Memorandum recognizes the importance of maintaining a focus not only on the organization as the wrongdoer, but also, specifically focusing DOJ's attention on corporate executives and employees. Notably, the Memorandum explicitly states that the policy changes in prosecuting illegal corporate conduct will apply

equally to criminal and civil corporate matters.⁷

The Memorandum outlines six key “steps” to strengthen DOJ's pursuit of individual corporate

wrongdoing, and to insure that the DOJ fully leverages its resources to identify culpable individuals at all levels in civil and criminal corporate cases. The specific details of each “step” are described more thoroughly below.

1. Corporations must provide to DOJ all relevant facts relating to individuals responsible for corporate misconduct.

In this first “step,” the DOJ seeks to entice corporations, charged with criminal and civil wrongdoing, into disclosing culpable employees at the risk of receiving diminished cooperation credit. In fact, the Memo calls on federal prosecutors to not issue *any* credit for cooperation to the company unless sufficient individualized disclosures are made.

Specifically, the Memorandum emphasizes that “to be eligible for any credit for cooperation, the company must identify all individuals involved or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to DOJ all facts relating to that misconduct.” Notably, the Memorandum does not indicate what kind of disclosure would satisfy this threshold requirement of relevant facts in order for the corporation to be eligible for cooperation credit. However, several

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factors are identified to determine whether such disclosures are sufficient. These include, but are not limited to, the timeliness of the cooperation; the diligence, thoroughness, and speed of the corporation's internal investigation; and the proactive nature of the cooperation. Most importantly, the Memorandum indicates that "full cooperation" under the False Claims Act, will be that, at

a minimum, "all relevant facts about responsible individuals must be provided."

Furthermore, federal prosecutors are requested to be proactive in investigating individuals at every step of the process, which may be even before any corporate cooperation occurs. However, if continued corporate cooperation is necessary post-resolution, plea and settlement agreements should include a provision that requires the organization to provide information about all culpable individuals. Failure to provide such information will result in specific penalties and/or a material breach of the settlement agreement.

The cooperation guidelines, in the first "step," state that pursuit of culpable individuals in civil and criminal corporation prosecutions are of utmost importance to the DOJ. So much so, that the DOJ will do whatever it takes to make sure the corporations reveal all relevant facts about potential culpable individuals at the expense of receiving leniency in its own prosecution.

2. Criminal and civil corporate investigations should focus on individuals from the inception of the investigation.

In this second "step," the Memorandum calls on federal prosecutors to focus on individual wrongdoing from the very beginning of any

investigation of corporate misconduct. DOJ believes that three very important goals will be accomplished if the attorneys prosecuting corporate misconduct maintain their focus on culpable individuals.

First, it will maximize the DOJ's ability to vet out the full extent of the corporate misconduct, "[b]ecause a corporation only acts through individuals and investigating the conduct of the individuals is the most efficient and effective way to determine the facts and extent of corporate misconduct." Second, individualized focus will increase the

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likelihood that individuals with knowledge will cooperate with the investigation and provide key information against the individuals higher up in the organization. Third, it will maximize the chances that final resolution will also include criminal and civil charges against these culpable individuals as well as the organization.

All three of these goals seek to strengthen and increase the scope of the DOJ's investigation and prosecution of individuals involved in corporate criminal and civil wrongdoing.

3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.

The Memorandum also encourages civil and criminal attorneys to work together and exchange information about each other's investigations. DOJ believes that such exchange will permit consideration of the "full range of the government's potential remedies" against culpable individuals in each and every case. The prospect of such coordination between criminal and civil DOJ attorneys may be more

aspirational than practically achievable, given the different pace and procedural demands on criminal and civil prosecutions.

4. DOJ will not release culpable individuals from civil and criminal liability absent extraordinary circumstances and not without Department approval.

This fourth “step” makes clear that individual DOJ attorneys do not have sole discretion to determine whether a corporate resolution should contain immunity or a release against prosecution of, or cases brought against, corporate officers and employees.

The Memorandum commands that in circumstances where DOJ reaches a resolution with the organization before resolving matters with the responsible individuals, DOJ attorneys should not agree to a corporate resolution that includes an agreement to dismiss charges against, or provide immunity for, or release individual officers or employees. The Memorandum instructs that such relief for individuals should not take place absent extraordinary circumstances, which is approved pursuant to Departmental policy. Notably, there is no explanation of what kind of extraordinary circumstances would justify such immunity or release. However, the Memorandum makes clear that “any release of [individual] criminal or civil liability due to extraordinary circumstances must be personally approved in writing by the relevant Assistant Attorney General or United States Attorney.”

5. DOJ attorneys should not resolve matters with an organization without a clear plan to resolve related individual cases.

To further insure that culpable individuals are, in fact, prosecuted civilly or criminally, the Memo requires DOJ attorneys to obtain approval by their supervisor prior to making a determination not to bring a civil case or criminal charges.

Specifically, if a decision is made at the conclusion of the investigation to not bring civil claims or criminal charges against the individuals who committed the misconduct, the reasons for that determination must be memorialized and approved by the United States Attorney or Assistant Attorney General whose office handled the investigation.

This fifth “step” makes clear that DOJ’s policies regarding charging decisions are issued on a department-wide basis, and not left to the individualized determination of a line attorney. This will likely bog down corporate investigations and resolutions, because release from individual liability will require significant investment by DOJ attorneys to obtain the necessary approvals within the DOJ.

6. Civil attorneys should not base their decision on whether to bring suit against an individual on that individual’s ability to pay. Finally, the Memo concludes by emphasizing that a determination to pursue civil claims against a culpable individual should not be based on whether that individual has the ability to pay a significant fine.

Specifically, “the fact that an individual may not have sufficient resources to satisfy a significant judgment should not control the decision on whether to bring suit.” Rather, in making a determination to bring criminal charges, the Department attorneys should consider facts that include, but are not limited to:

- ▶ whether the person’s misconduct was serious,
- ▶ whether it is actionable,
- ▶ whether the admissible evidence will be sufficient to sustain a judgment, and
- ▶ whether the action reflects an important federal interest.

Additionally, when deciding to bring a civil case against a culpable individual, DOJ

attorneys should make individualized assessments, taking into account factors such as the individual's misconduct and past history, and circumstances relating to the commission of the misconduct.

Conclusion

Although in the short term, certain cases against individuals may not provide a significant monetary return, pursuing individual actions in civil corporate matters will result in significant long-term deterrence—the DOJ's ultimate goal in minimizing corporate fraud. There may, however, be a minimum of enthusiasm for pursuing a case where there will be no financial recovery and, therefore, no "credit" for the enforcement agency.

Overall, the Department believes that these six "steps" or procedural guidelines will maximize its ability to deter misconduct and

hold individuals who engage in it accountable. Importantly, the Department's targeted focus on pursuing claims against individuals culpable in corporate wrongdoing will have a significant impact and long-lasting effect in the healthcare industry. ☺

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