



Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

APRIL 2018



A smooth transition

an interview with
Gerry Zack

Incoming CEO
SCCE & HCCA



FEATURES

- 16 **Meet Gerry Zack**
an interview by Adam Turteltaub
- 23 **New resolution opportunities in the Medicare appeals process**
by Andrew B. Wachler and Erin Diesel Roumayah
A closer look at new initiatives issued by CMS to expedite settlements in the mushrooming backlog of denied Medicare reimbursement appeals.
- 31 **Passing the HCC Audit: What you need to know**
by Lisa Knowles
Five troublesome areas that auditors will scrutinize when calculating the risk adjustment factor used to determine financial capitation for physicians, physician groups, health systems, and Medicare Advantage plans.
- 37 **A sharpened focus on remediation in federal investigations**
by Precious M. Gittens and Brett Moodie
A multidiscipline, internal investigations team and a strong compliance culture can make a sizable difference in obtaining cooperation credit from enforcement prosecutors.
- 43 [CEU] **Board responsibility for compliance oversight and program effectiveness**
by Gabriel L. Imperato and Anne Novick Branan
A board of directors must satisfy its corporate oversight responsibility or face whistleblower complaints and even personal liabilities for failing to meet its duty of care obligations.



Compliance Today is printed with 100% soy-based, water-soluble inks on recycled paper, which includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

COLUMNS

- 3 **Letter from the Incoming CEO**
by Gerry Zack
- 5 **Letter from the CEO**
by Roy Snell
- 21 **Exhale**
by Catherine Boerner
- 29 **Managing Compliance**
by Lynda S. Hilliard
- 35 **Connectivity**
by Nancy J. Beckley
- 41 **The Compliance–Quality Connection**
by Sharon Parsley
- 49 **Privacy Ponderings**
by Jay P. Anstine
- 54 **Security Awareness Reminder**
by Frank Ruelas

DEPARTMENTS

- 8 **News**
- 15 **People on the Move**
- 88 **Newly Certified Designees**
- 90 **New Members**
- 93 **Takeaways**
- 94 **Upcoming Events**

by Precious M. Gittens and Brett Moodie

A sharpened focus on remediation in federal investigations

- » Recent DOJ fraud enforcement trends reveal prosecutors' heightened focus on corporate remediation.
- » Remediation is a critical factor in DOJ decision-making in criminal and civil False Claims Act resolutions.
- » The DOJ has demonstrated that it will scrutinize an organization's internal reaction to allegations of wrongdoing while it is under investigation.
- » Remediation can be of enormous value to organizations seeking "cooperation credit" in both civil and criminal matters.
- » Organizations that form a multidisciplinary team to oversee internal investigations and remedial actions may be best-positioned to respond to a government investigation or enforcement action.

Precious M. Gittens (pmgittens@health-law.com) is Partner and co-chair of the Fraud and Abuse Practice Group in the Washington DC offices of Hooper, Lundy & Bookman, PC. **Brett Moodie** (bmoodie@health-law.com) is an attorney in the Los Angeles offices of Hooper, Lundy & Bookman, PC.

[in bit.ly/in-PreciousGittens](https://bit.ly/in-PreciousGittens) [www bit.ly/2HflG61](https://bit.ly/2HflG61) [in bit.ly/in-BrettMoodie](https://bit.ly/in-BrettMoodie)

Today, compliance and ethics programs are an integral part of the operations of many healthcare organizations. These organizations aim to prevent, detect, correct, and in some cases even self-disclose potential fraud and abuse before any misconduct is discovered by government agencies. Sometimes these laudable goals are simply unattainable, and organizations learn about potential misconduct only after the government has detected the wrongdoing and initiated an investigation.

In their investigations of corporate misconduct, federal prosecutors, state and local investigators, and private pay auditors all routinely focus on an organization's preexisting compliance program, along with the organization's remediation and compliance actions

after it learned of the allegations of misconduct (i.e., after the organization is served with a *qui tam* action, or receives a Civil Investigative Demand, subpoena, or proffer request related to an investigation). Unfortunately, some organizations neglect to do the same, and they tend to look only to the general risks and historical failures, rather than exercising real-time and forward-looking compliance efforts that are focused on remediating the alleged misconduct at hand.

Failure to engage in remedial actions, including modification of a compliance program that did not detect the allegations that are the subject of a government investigation, can be dangerous. Additionally, an organization that fails to thoroughly, credibly, and promptly investigate and remediate actual misconduct, including misconduct that first comes to the organization's attention as a result of a government investigation, may completely disqualify



Gittens



Moodie

itself from later seeking any cooperation credit from prosecutors in federal civil or criminal investigations and enforcement actions.

Historical perspective

The concept of remediation is not new. Indeed, remediation is one of the seven elements of an effective compliance program detailed in the U.S. Sentencing Commission's *Guidelines Manual*.¹ Remediation is also a mitigating factor that impacts the charging decisions, plea offers, and settlements of the U.S. Department of Justice (DOJ). Federal criminal prosecutors are directed to consider ten factors expressly set forth in the *U.S. Attorneys' Manual (USAM)*.² These factors, also considered by federal civil prosecutors, are listed in *USAM* Section 9-28.300, Factors to be Considered, and are commonly referred to among criminal defense lawyers as the "Filip Factors" because they were initially enumerated in a memorandum issued in 2008 by then-Deputy Attorney General Mark Filip.³

Filip Factor Number 7 specifically focuses on "the corporation's remedial actions" after the potential wrongdoing has been detected. It describes remediation to include "any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies." Notwithstanding the well-established concept of remediation, recent DOJ fraud enforcement trends reveal prosecutors' heightened focus on corporate remediation.

Healthcare fraud and abuse enforcement has been heavily influenced in recent years by several interrelated developments in the DOJ. The priorities established by senior leaders in DOJ's Criminal and Civil Divisions have focused on vigorous investigation of individuals, with a parallel emphasis on encouraging organizations to, inter alia (i.e.,

among other things), operationalize effective compliance programs and take appropriate remedial action.

For more than 15 years, the DOJ has directed prosecutors to pursue cases against criminally culpable individuals responsible for corporate misconduct. In June 1999, former Deputy Attorney General Eric Holder issued a memorandum entitled, "Bringing Criminal Charges Against Corporations" (the Holder Memo), which established the framework that prosecutors use in deciding whether to charge a corporation.⁴ The Holder Memo directed prosecutors to "consider the corporation, as well as the responsible individuals, as potential criminal targets" and to consider the corporation's "willingness to cooperate in the investigation." Additionally, the Holder Memo cautioned that "prosecutors generally should not agree to accept a corporate guilty plea in exchange for non-prosecution or dismissal of charges against individual officers and employees."

In September 2015, former Deputy Attorney General Sally Quillian Yates issued guidance to all federal prosecutors regarding an organization's cooperation in the context of corporate investigations (the Yates Memo).⁵ The Yates Memo outlines six key steps that prosecutors should take in all investigations of corporate wrongdoing. The Yates Memo directives have been incorporated in the *USAM*, and they are being followed by federal prosecutors in U.S. Attorneys offices nationwide. The Yates Memo reiterated existing DOJ policy and established a new "threshold" for organizations to receive cooperation credit pursuant to the Filip Factors, stating that organizations are required to "identify all individuals involved in the wrongdoing" in order to qualify for *any* cooperation credit in the resolution of a matter. Additionally, the Yates Memo specified that "[t]his condition of cooperation applies equally to corporations

seeking to cooperate in civil matters” such as False Claims Act (FCA) cases.

This “threshold” requirement was a change from the DOJ’s prior practice of granting partial cooperation credit to organizations for their significant cooperation, without requiring them to identify the responsible individuals or share all relevant facts implicating those individuals. This new approach to evaluating corporate “cooperation” highlights the DOJ’s expectation that organizations will conduct a thorough investigation, disclose evidence of wrongdoing, and take appropriate remedial actions to address the issues identified in the investigation.

This expectation was reinforced further when, at the end of 2015, the DOJ announced the hiring of a full-time consultant, Hui Chen, as the DOJ’s first Compliance Counsel Expert.⁶ Andrew Weissmann, the former Chief of the Fraud Section of the DOJ’s Criminal Division (the Fraud Section) stated that the Compliance Counsel Expert was brought in to ensure that the DOJ was “holding companies to a high but realistic standard,” and he emphasized the importance of adding compliance expertise to the DOJ, referring to Ms. Chen as “manna from heaven.”⁷

Before her June 2017 departure, Ms. Chen guided, trained, and actively assisted federal prosecutors in making judgements concerning the existence and effectiveness of corporate compliance programs, including whether organizations facing possible criminal prosecution had taken meaningful remediation measures. Additionally, Ms. Chen authored the Fraud Section’s “Evaluation of Corporate Compliance Programs” document, which provides sample topics and questions that prosecutors may raise in making individualized assessments of the effectiveness of corporate compliance programs.⁸

Cooperation credit

Building on the DOJ’s more discerning review of corporate compliance programs in April 2016, the Fraud Section announced the Foreign Corrupt Practices Act Enforcement Pilot Program (FCPA Pilot Program).⁹ The FCPA Pilot Program was designed to incentivize companies to self-disclose potential FCPA-related violations, fully cooperate with the DOJ, remediate flaws in their compliance programs, and disgorge all profits from the improper conduct. In exchange for meeting these requirements, the DOJ offers cooperation credit, a reduction in financial penalties, more lenient charges, and even the possibility of declination of criminal prosecution. In its FCPA Pilot Program guidance, and as adopted into the U.S. Attorneys’ Manual in November 2017 as the FCPA Corporate Enforcement Policy, the DOJ defines remediation in the FCPA context as including the:

[i]mplementation of an effective compliance and ethics program,... [a]ppropriate discipline of employees, and... [a]ny additional steps that demonstrate recognition of the seriousness of the corporation’s misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risks.¹⁰

The FCPA Pilot Program shares the Yates Memo’s sharpened focus on meaningful remediation.

Root cause analysis

Most recently, in February 2017, the Fraud Section released its “Evaluation of Corporate Compliance Programs” document. The document contains detailed, sophisticated, and probing questions. For example, the questions related to the first topic set forth in the document, “Analysis and Remediation

of Underlying Misconduct,” address the corporation’s own root cause analysis of the misconduct, the company’s analysis of whether it missed “prior opportunities to detect the misconduct in question,” and an assessment of whether the company has engaged in specific remediation to address “the issues identified in the root cause and missed opportunity analysis.” The Fraud Section’s latest guidance further evidences the DOJ’s emphasis on the importance of corporate remediation.

The DOJ has demonstrated that it will scrutinize how an organization is dealing with allegations of wrongdoing while it is under investigation or facing an enforcement action. Organizations that find themselves in that position would then be wise to swiftly and purposefully implement remedial changes. If done well, remediation may enhance the effectiveness of any Filip Factors presentation or separate compliance presentation to the DOJ.

For example, an organization’s ability to demonstrate that it has engaged in timely and meaningful remediation in connection with an alleged FCA violation may strengthen its position and arguments in the negotiation of the scope and amount of an FCA settlement. Remediation may also be helpful in responding to audits conducted by governmental or third-party entities, where overpayment settlements often include a component of corrective action. In any case, organizations that are able to demonstrate a clear commitment to their compliance culture, including specific enhancements that have been implemented following an allegation of misconduct, are frequently treated favorably.

Board oversight

Finally, in an increasingly complex regulatory environment and in light of recent DOJ fraud enforcement trends, boards of directors who learn about allegations of misconduct for the

first time from any source that is external to the organization would be wise to work with a multidisciplinary team of professionals¹¹ that can assist the organization in:

- ▶ conducting a thorough and credible investigation of alleged misconduct;
- ▶ ending any actual misconduct;
- ▶ analyzing and addressing how the misconduct occurred in the first place, and why it was not detected by the compliance program; and
- ▶ modifying and operationalizing compliance efforts to effectively prevent and detect future similar misconduct.

Conclusion

Remediation lays the groundwork for counsel to initiate substantive discussions with federal prosecutors, and to negotiate and reach a final resolution that may effectively limit the organization’s civil liability, reduce its criminal culpability score, or mitigate or altogether eliminate criminal prosecution of the organization and its individual directors and employees. 📍

1. U.S. Sentencing Commission’s Guidelines Manual, §8B2.1(b)(7).
2. *United States Attorneys’ Manual*, Section 9-28.300, “Principles of Federal Prosecution of Business Organizations” Available at <http://bit.ly/2FSjqAb>
3. U.S. Department of Justice: Memorandum from Mark Filip, Deputy Attorney General, Principles of Federal Prosecution of Business Organizations. August 28, 2008. Available at <http://bit.ly/2nJ5eCU>
4. U.S. DOJ: Memorandum from Eric H. Holder, Jr., Deputy Attorney General. June 16, 1999. Available at <http://bit.ly/1kyBQWO>
5. U.S. Department of Justice: Memorandum from Sally Quillian Yates, Deputy Attorney General, Individual Accountability for Corporate Wrongdoing. September 9, 2015. Available at <http://bit.ly/2nLMPa4>
6. U.S. DOJ: “New Compliance Counsel Expert Retained By The DOJ Fraud Section” November 3, 2015. Available at <http://bit.ly/1Q9sr4I>
7. Laura Jacobus: “DOJ’s Andrew Weissmann and Hui Chen Talk Corporate Compliance in Exclusive Interview” *EClconnects* February 2, 2016. Available at <http://bit.ly/1P0BpEi>
8. U.S. DOJ, Criminal Division, Fraud Section: “Evaluation of Corporate Compliance Programs.” Available at <http://bit.ly/2lEphmk>
9. U.S. DOJ, Criminal Division, Fraud Section: “The Fraud Section’s Foreign Corrupt Practices Act Enforcement Plan and Guidance” April 5, 2016. Available at <http://bit.ly/2Dr33KL>
10. *United States Attorneys’ Manual*, Section 9-47.120, “FCPA Corporate Enforcement Policy” Available at <http://bit.ly/2oSeggM>
11. Benson Weintraub: “Integrating White Collar Criminal Defense Lawyers Into Health Care Law Firms to Enhance Corporate Compliance Programs for Optimal Mitigation Under the Federal Corporate Sentencing Guidelines” at 12, Health Care Compliance Association, Compliance Institute, New Orleans, April 2008.