

DOJ and OIG Increasing Focus on Personal Executive and Board Accountability

In Light of Recent Changes, Compliance Officers Should Incorporate a Number of Guidelines into Their Everyday Practice

Meghana Joshi



Meghana Joshi is an associate at Strategic Management Services, LLC. She conducts regulatory research and analysis focusing on various health care and compliance program issues, including federal health care program requirements and corporate integrity agreements. She can be reached at mjoshi@strategiccm.com.

Deputy Attorney General Sally Yates recently issued a memorandum (the "Yates Memo") on behalf of the Department of Justice (DOJ). The Yates Memo emphasizes DOJ efforts to hold individual wrongdoers accountable for corporate misdeeds. The guidance in the memo includes a combination of existing and new policies that have not previously been issued in writing. It highlights six key measures that DOJ attorneys will utilize when investigating corporate wrongdoing:

1. requiring organizations to meet additional conditions to receive any cooperation credit;
2. focusing on individual actors within the organization at the beginning of civil and criminal corporate investigations;
3. routine communicating and information sharing between civil and criminal attorneys handling corporate investigations;
4. eliminating corporate resolutions that protect individuals absent extraordinary circumstances;
5. creating a clear plan to resolve individual cases before resolving corporate cases; and
6. pursuing civil actions against an individual regardless of the individual's resources or ability to pay.

The Yates Memo's stated goal is to hold individuals who break laws personally accountable for wrongful activity rather than allowing them to hide behind their corporation during settlement agreements. This initiative will affect health care entities just as strongly as it will impact other corporations. However, government pursuit of individual wrongdoers has a long history in the health care industry.

INDIVIDUAL LIABILITY IN CIAs

Over the years, numerous health care providers have been under corporate integrity agreements (CIAs) as part of settlements with the Department of Health and Human Services Office of Inspector General (OIG). Agreeing to a CIA with the OIG allows health care providers and other entities to circumvent exclusion from the federal health care programs. CIAs contain several common elements¹ but vary depending on the fact-specific circumstances of each case. Some CIAs, for example, require the organization's officers — “certifying employees” — to sign a management certification each reporting period stating that the organization is complying with specified requirements. Most management certifications, such as the certification in the 2015 North Broward Hospital District CIA, contain the following language:

I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and [organization] policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of [organization] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.²

The North Broward CIA required over 25 individuals to sign the management certification, including the chief executive officer

(CEO), general counsel, director of internal audit, and chief medical officer.

RECENT ACCOUNTS OF INDIVIDUAL WRONGDOING

Just this year, the OIG reported several criminal and civil enforcement cases against executive officers for health care fraud. These cases resulted in large penalties for key players within each organization. In April, the government settled with the co-founder and former CEO of Health Diagnostic Laboratory (HDL), a cardiovascular testing disease laboratory in Virginia, for allegedly violating the False Claims Act.³ HDL paid \$48.5 million under the settlement, and the former CEO resigned following a federal investigation.⁴ HDL entered into a CIA as part of its settlement, which requires the new CEO to sign a management certification.⁵

Four months later, the CEO of Michigan-based Kentwood Pharmacy pled guilty to a charge of conspiracy to commit health care fraud and was sentenced to 10 years in prison. Other employees at Kentwood Pharmacy, including the vice president of sales and the chief pharmacist, also faced prison sentences for their involvement in the scheme. HHS OIG Regional Inspector General Lamont Pugh III claimed that the CEO's sentence “should serve as a significant deterrence to those who may be contemplating the execution of similar healthcare fraud schemes.” Pugh further stated that the OIG would “root out those who would put the public's health and safety at risk through the commission of healthcare fraud and ensure that they are held accountable.”⁶

While the OIG continues to hold entire organizations liable for health care fraud, it is also making a point to target specific individuals who have engaged in wrongdoing.

INCREASED FOCUS ON BOARD ACCOUNTABILITY

The health care industry is digesting the Yates Memo and its potential implications.

At the same time, the spotlight is on the DOJ and how closely it follows through on its new commitments to hold more individuals accountable aside from their organizations. Independent of the DOJ, the health care industry is already witnessing a growing increase in individual personal liability and accountability for corporate misconduct. The OIG is focusing more on ensuring that board members meet their fiduciary obligations to oversee their organization's compliance with applicable laws and regulations.

On two separate occasions, the OIG and American Health Lawyers Association (AHLA) issued white papers on individual and board member liability. The 2010 version provides information to assist corporate directors to demonstrate that they have followed a reasonable compliance oversight process.⁷ The most recent addresses a board's oversight and review of compliance program functions, including the relationships between an organization's various departments and the board's duty to act in good faith.⁸

Recent OIG CIAs also require board members to sign annual resolutions specifying the activities that the board has undertaken to assess compliance with federal health care program and CIA requirements.⁹ This is not a new concept on the OIG's part. Almost a decade ago, the OIG's CIA with Tenet Healthcare Corporation required the board to adhere to specific obligations, including a requirement to review and oversee the performance of compliance staff and submit a resolution describing its review to the OIG.¹⁰ Today, however, the OIG is incorporating this concept more regularly into settlement agreements by requiring board members to make attestations, which state the following:

The Board of Directors has made a reasonable inquiry into the operations of [organization]'s Compliance Program including the performance of the Compliance Officer and the

Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, [organization] has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.¹¹

In the recent landmark Stark case of Tuomey Healthcare System, Tuomey's CIA further contained a provision requiring the board to appoint a board compliance expert responsible for assisting the board in fulfilling its obligations under the CIA.¹² This is yet another concept that the OIG has increasingly employed in CIAs. Such provisions mandate that the board retains a board compliance expert who will attend each board meeting that includes a compliance officer presentation, periodically offer recommendations regarding Compliance Program effectiveness, and prepare a Compliance Program Review Report, among other tasks. The provision also prohibits hiring a compliance expert who has previously represented or been engaged by the organization or has had a relationship with the organization that would cause a reasonable person to question the compliance expert's impartiality. The OIG is authorized to determine whether the compliance expert is acceptable, which could affect an organization's ability to retain the expert.

Over the past several years, a growing number of CIAs have contained management certifications targeting specific individuals within senior management. Of the 26 CIAs that various providers entered into in 2011, only six contained management certifications for certifying employees.¹³ However, in just the first three quarters of 2015, 19 of the 26 CIAs had management certifications.¹⁴ This noticeable shift demonstrates that the emphasis on individual liability has been a growing focus for the OIG as well as the DOJ, as embodied in the Yates Memo.

THE FUTURE OF INDIVIDUAL ACCOUNTABILITY IN LIGHT OF THE YATES MEMO

Recent CIAs and now the Yates Memo are signaling a greater focus on executives and boards meeting their obligations and duties to ensure their organizations comply with applicable laws and regulations. The OIG has certainly indicated that it will continue applying certifications and independent oversight of Compliance Programs to organizations under CIAs. It also will continue to address the substantive areas of violation that brought the parties to settlement. Further, CIAs may see a change in management certification requirements, giving greater responsibility to certifying employees to ensure that the organization is in compliance with the CIA and federal health care programs.

Health care entities and the executive officers who lead them cannot expect to avoid personal liability by hiding behind their organizations' settlements with the DOJ and OIG. The government is sure to pay more attention to personal accountability in the coming years; however, it is hard to predict to what degree the DOJ will follow this new guidance. This change in focus will also have an impact on the settlement agreements process. There are questions as to what effect it will have on the willingness of companies to settle without a release of their executive leadership — and how committed and successful the DOJ will be in prosecuting individuals for their roles in permitting fraud to occur in their environment.

Given these changes to the CIA environment, compliance officers should incorporate the following guidelines into their everyday practice:

- Educate executive leadership and board members regarding the increased focus on personal responsibility and potential liability for neglecting their duties.
- Take precautions to limit the potential for individual liability within the organization by ensuring that boards and executive leadership are kept informed of compliance issues.

- Engage in more board training on providing proper Compliance Program oversight.
- Establish metrics evidencing Compliance Program effectiveness to executive leadership and the board.
- Evidence prompt corrective action to all compliance issues identified during ongoing monitoring and auditing, and ensure follow-up of hotline and other complaints.
- Devote enough time to creating a culture of compliance within the organization itself and use employee surveys to measure changes and improvements.
- Ensure periodic independent evaluation of Compliance Program effectiveness by experts and submission of the resulting report to the executive and board-level compliance committees.
- Continually stress that compliance is not solely the compliance officer's responsibility, but rather everyone's responsibility.
- Ensure the creation and implementation of policies and procedures that address situations involving individual wrongdoers, and enforce them consistently.
- Prepare CEOs and other members of senior management for potentially handling increased individual accountability.

Endnotes:

1. oig.hhs.gov/compliance/corporate-integrity-agreements
2. oig.hhs.gov/fraud/cia/agreements/North_Broward_Hospital_District_08312015.pdf
3. www.justice.gov/opa/pr/two-cardiovascular-disease-testing-laboratories-pay-485-million-settle-claims-paying
4. www.virginiabusiness.com/news/article/u-s-government-sues-tonya-mallory-hdls-former-ceo-and-co-founder
5. oig.hhs.gov/fraud/cia/agreements/Health_Diagnostic_Laboratory_03312015.pdf
6. www.justice.gov/usao-wdmi/pr/2015_0827_KMulder
7. oig.hhs.gov/compliance/compliance-guidance/docs/Health_Care_Directors_Compliance_Duties.pdf
8. oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf

9. oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf
10. oig.hhs.gov/compliance/compliance-guidance/docs/Health_Care_Directors_Compliance_Duties.pdf
11. oig.hhs.gov/fraud/cia/agreements/Tuomey_dbat_Tuomey_Healthcare_System_10162015.pdf
12. *Id.*
13. oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp
14. *Id.*



Reprinted from Journal of Health Care Compliance, Volume 18, Number 1, January–February 2016,
pages 23–27, with permission from CCH and Wolters Kluwer.
For permission to reprint, e-mail permissions@cch.com.
