Current Compliance Guidance and Scrutiny by HHS OIG and DOJ

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HCCA Compliance Institute

Panel

- **Ted Radway**
  *Vice President of Compliance, Kindred Healthcare*

- **Lisa Rivera**
  *Member, BASS BERRY SIMS, PLLC*

- **Karen Schandler Glassman**
  *Senior Counsel, Office of Counsel to the Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services*

- **Benjamin S. Schecter**
  *Assistant United States Attorney, Civil Healthcare Fraud Coordinator, U.S. Attorney’s Office, W.D. Ky.*
Audience Poll

My organization has been involved in ( = the subject of) a government investigation.

- Yes
- No
- Not sure

Overview

- Key Considerations from OIG’s Effectiveness Resource Guide
- Demonstrating Compliance in Response to Government Scrutiny
- Best Practice Compliance Measures
Disclaimer

Opinions and wild speculations expressed herein or during this panel presentation do not necessarily reflect the views of the U.S. Department of Justice.

What has the Government said about Compliance?

Measuring Compliance Program Effectiveness: A Resource Guide

U.S. Department of Justice
Criminal Division
Fraud Section
Evaluation of Corporate Compliance Programs

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation that triggers the application of the False Statements Act, the fraud victims do not see any relief from the elements of the offenses. To the contrary, the enforcement actions against a company may lead to the death of the company or a business unit.

There are, however, common elements in each case of misleading information. This document provides a framework for assessing the extent of the false statements and evaluating a corporate compliance program. The risks and possible sanctions are significant, so it is essential to identify the elements of the False Statements Act and to determine whether there may be a substantial likelihood of a criminal conviction.

None of the elements below was found in the United States Supreme Court’s “SAND” or in the United States Attorney’s Office’s “Guide.” The following are general elements of the False Statements Act. They are intended to be general and illustrative of the factors that might be considered in assessing the likelihood of a criminal conviction. They are not exhaustive and may be more or less relevant to the particular facts at issue.

Elements:

1. False or Material Misrepresentation
2. Knowing or Intentional Misrepresentation
3. With the Purpose of Influencing an Official Action
4. False or Material Misrepresentation
5. With the Intent of Influencing an Official Action
6. False or Material Misrepresentation
7. With the Intent of Influencing an Official Action
8. False or Material Misrepresentation
9. With the Intent of Influencing an Official Action
10. False or Material Misrepresentation
11. With the Intent of Influencing an Official Action
12. False or Material Misrepresentation
13. With the Intent of Influencing an Official Action
14. False or Material Misrepresentation
15. With the Intent of Influencing an Official Action
16. False or Material Misrepresentation
17. With the Intent of Influencing an Official Action
18. False or Material Misrepresentation
19. With the Intent of Influencing an Official Action
20. False or Material Misrepresentation
21. With the Intent of Influencing an Official Action

The elements above are the key factors in determining the likelihood of a criminal conviction. They are intended to be general and indicative of the factors that might be considered in assessing the likelihood of a criminal conviction. They are not exhaustive and may be more or less relevant to the particular facts at issue.

Audience Poll

Management in my organization takes compliance seriously (and dedicates appropriate resources to compliance).

- Yes
- No
- It’s Complicated

Measuring Compliance Program Effectiveness: A Resource Guide

Issue Date: March 27, 2017

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 / Washington, DC
Compliance Program Effectiveness Guidance:  
**What It Is**

- Structured Around HCCA Seven Elements
- Compilation of Questions Used by Experienced Compliance Professionals
- A ToolKit
- Stimulus

Compliance Program Effectiveness Guidance:  
**What It Is Not**

- NOT a Checklist
- NOT a Standard
- NOT a Guarantee
Compliance Program Effectiveness Guidance: 

**Ways to Use**

- Prevention
- Detection
- Response
- Structure of Compliance Program
- Accountability of Organization
- Measurement of Impact
- Culture

Compliance Program Effectiveness Guidance: 

**Senior Leadership**

- Commitment From the Top
- Compliance Representatives Present at Every Senior Management & Governance-Level Meeting
- Management Accountability for Compliance
Compliance Program Effectiveness Guidance: *Middle Management*

- Manager Performance Evaluation
- Organizational Retaliation
- Job Descriptions of Management
- Subordinate Conduct

**OIG Revised Exclusion Guidance**


- Replaced criteria issued in 1997

- Increases OIG’s expectations for providers to implement robust compliance programs, promptly respond to government investigations, and self-disclose fraud
OIG Revised Exclusion Guidance

• Begins with presumption that exclusion should be imposed

• Provides a compliance “risk spectrum” from low to high risk based on: (1) nature and circumstances of conduct; (2) conduct during government investigation; (3) significant ameliorative efforts; and (4) history of compliance

• Highest risk will result in exclusion; below highest risk, OIG may choose to impose heightened scrutiny or no further action
Evaluation of Corporate Compliance Programs

DEPARTMENT
OF
JUSTICE

Evaluation of Corporate Compliance Programs

COMPLIANCE

NON-COMPLIANCE
Evaluation of Corporate Compliance Programs

“The government should provide incentives for companies to engage in ethical corporate behavior. That means fully cooperating with government investigations, and doing what is necessary to remediate misconduct – including implementing a robust compliance program. Good corporate behavior also means notifying law enforcement about wrongdoing.”

- Deputy Attorney General Rod Rosenstein, November 29, 2017, Remarks at the 34th International Conference on the FCPA

Evaluation of Corporate Compliance Programs: Background

USAM 9-28.000 - Principles of Federal Prosecution Of Business Organizations
10 Factors to be considered in determining whether to charge a corporation 9-28.300

No. 4: the corporation's willingness to cooperate in the investigation of its agents;
No. 5: the existence and effectiveness of the corporation's pre-existing compliance program;
No. 6: the corporation's timely and voluntary disclosure of wrongdoing;
No. 7: the corporation’s remedial actions, including 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.
**Evaluation of Corporate Compliance Programs: Background**

**USAM 9-28.800 – Corporate Compliance Programs**

While the Department recognizes that no compliance program can ever prevent all criminal activity by a corporation’s employees, the critical factors in evaluating any program are:

i. whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees; and  
ii. whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct to achieve business objectives.

**Evaluation of Corporate Compliance Programs: Background**

**USAM 9-28.800 – Corporate Compliance Programs**

The fundamental questions any prosecutor should ask are:

- Is the corporation’s compliance program well designed?  
- Is the program being applied earnestly and in good faith?  
- Does the corporation’s compliance program actually work?
Evaluation of Corporate Compliance Programs: \textbf{Background}

9-47.120 – FCPA Corporate Enforcement Policy

\textit{Credit for Voluntary Self-Disclosure, Full Cooperation, and Timely and Appropriate Remediation in FCPA Matters}

- When a company has voluntarily self-disclosed misconduct in an FCPA matter, fully cooperated, and timely and appropriately remediated, all in accordance with the standards set forth below, there will be a presumption that the company will receive a declination absent aggravating circumstances involving the seriousness of the offense or the nature of the offender.

- The presumption may be overcome only if there are aggravating circumstances related to the nature and seriousness of the offense, or if the offender is a criminal recidivist.

If a criminal resolution is warranted for a company that has voluntarily self-disclosed, fully cooperated, and timely and appropriately remediated, the Fraud Section:

- will accord, or recommend to a sentencing court, a 50% reduction off of the low end of the U.S. Sentencing Guidelines fine range, except in the case of a criminal recidivist; and

- generally will not require appointment of a monitor if a company has, at the time of resolution, implemented an effective compliance program.
Evaluation of Corporate Compliance Programs

- Issued February 2017
- Includes 11 key compliance program evaluation topics
- Includes a corresponding set of “common questions” in assessing compliance programs within the context of a criminal investigation.

Evaluation of Corporate Compliance Programs

Areas of Relevant Inquiry

1. Analysis and Remediation of Underlying Misconduct;
2. Senior and Middle Management;
3. Autonomy and Resources;
4. Policies and Procedures;
5. Risk Assessment;
6. Training and Communications;
7. Confidential Reporting and Investigation;
8. Incentives and Disciplinary Measures;
9. Continuous Improvement, Periodic Testing and Review;
10. Third Party Management; and
Evaluation of Corporate Compliance Programs

Areas of Relevant Inquiry

- The topics and questions are neither a checklist nor a formula.
- These topics and questions may not all be relevant, whereas others may be more salient given the particular facts at issue.

“We [Main Justice Criminal Division] intend to embrace, where appropriate, a similar approach and similar principles [to the FCPA Corporate Enforcement Policy] — rewarding voluntary self-disclosure, full cooperation, timely and appropriate remediation — in other contexts.”

“When a company discovers corporate misconduct and quickly raises its hand and tells us about it, that says something. It shows the company is taking misconduct seriously and not willing to tolerate it. And we are rewarding those good decisions.”

- Acting Assistant Attorney General John P. Cronan, March 1, 2018, Remarks at the 32nd Annual ABA National Institute on White Collar Crime
Evaluation of Corporate Compliance Programs

Relevancy for Criminal or Civil Cases?

- September 30, 2016 DOJ’s Criminal Division, Fraud Section and the USAO-NDGA enter into a Non-Prosecution Agreement with Tenet Healthcare Corporation.

- Requires Tenet to retain an Independent Compliance Monitor.

- Reporting is to DOJ and USAO-NDGA.

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**United States v. Merck-Medco Managed Care, L.L.C.**

Allegation that Medco violated the False Claims Act because Medco had no effective corporate compliance program to detect and prevent false claims.

*United States v. Merck-Medco Managed Care, L.L.C. 2003 WL 23194580 (E.D. Pa., 2003)*
Evaluation of Corporate Compliance Programs

“When something does go wrong, the greatest consideration should be given to companies that do not just adopt compliance programs, but incorporate them into the corporate culture. If you want us to treat a corporate entity as a victim, you should act like a victim who wants to see the perpetrators held accountable.”

- Deputy Attorney General Rod Rosenstein, March 2, 2018, Remarks at the 32nd Annual ABA National Institute on White Collar Crime

Demonstrating Real-World Compliance

GET A LIFE! by Tim Lachowski

“Of course I doctored your files—I’m a doctor.”
Demonstrating Real-World Compliance

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Associate Attorney General Brand Announces
Enforcement Authority to Enforce Antitrust

Today, as a follow-up to a memo issued by Attorney General Rachel Brand, Attorney General Jeff Sessions issued a new policy that prohibits enforcement authority to convert agency guidance documents into new policy. Department civil litigators are prohibited from using guidance documents to establish violations of law in a particular case.

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Although guidance documents can be helpful in educating the public about the risks of an investigation, they cannot be relied on as evidence that a violation has occurred.

The new policy, which is contained in a memo issued by Attorney General Jeff Sessions, is intended to provide clarity on the use of guidance documents. The memo states that guidance documents are not considered evidence of a violation of law unless they are used as a basis for an investigation or enforcement action.

The new policy applies to all guidance documents issued by the Department of Justice, including those issued by the Antitrust Division, the Civil Division, and the Criminal Division.

The new policy is effective immediately.

Jefferson B. Sessions, III
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Attorney General

November 17, 2017
The Brand Memo

First ... there was the Sessions Memo (11/16/2017)

• Intended to implement Trump Administration goal of reducing over-regulation
• Discussion of importance of only using established rule-making authority (APA)

“It has come to my attention that the Department has in the past published guidance documents ... that effectively bind private parties without undergoing the rulemaking process.

The Department will no longer engage in this practice. Effective immediately, Department components may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch ....

To the extent guidance documents set out voluntary standards (e.g., recommended practices), they should clearly state that compliance with those standards is voluntary and that noncompliance will not, in itself, result in any enforcement action.”

• Note – Sessions Memo was limited to DOJ-issued guidance.
The Brand Memo

Next came the Brand Memo (01/25/2018) – expounds on Sessions Memo.

The principles from the Guidance Policy are relevant to more than just the Department’s own publication of guidance documents. These principles also should guide Department litigators in determining the legal relevance of other agencies’ guidance documents in affirmative civil enforcement (“ACE”).

Guidance documents cannot create binding requirements that do not already exist by statute or regulation.

Accordingly, effective immediately for ACE cases, the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules.

Likewise, Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases.

The Brand Memo

However, the Department should not treat a party’s noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation. That a party fails to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements; agency guidance documents cannot create any additional legal obligations.

“However, the Department should not treat a party’s noncompliance with an agency guidance document as presumptively or conclusively establishing that the party violated the applicable statute or regulation. That a party fails to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements; agency guidance documents cannot create any additional legal obligations.”
What’s potentially at issue?

Agency guidance = “any agency statement ... that is designed to advise parties outside the federal Executive Branch about legal rights or obligations.”

Does not include documents describing agency enforcement priorities, internal directives, or factors considered in exercising prosecutorial discretion.

We don’t know yet.

1. Can failure to comply with agency guidance be a basis for FCA action by DOJ?
   - We know it can be used to establish scienter.

2. Guidance documents that “simply explain or paraphrase legal mandates from existing statutes or regulations” are OK; that’s where the litigation will be.

3. Internal DOJ guidance (such as on prosecution decisions) is not affected. (USAM, Principles of Prosecution of Business Organizations, DOJ “Fraud Checklist”)

4. Criminal Division is – so far – not impacted.

5. Comments in Federal Register are part of formal rulemaking process, so presumably would not be impacted.

6. Does NOT apply to OIG or CMS’s CMP authority – only to DOJ (Civil Division and USAOs) (also doesn’t apply to ADRs or ALJ proceedings)
Real-World Concerns: What is Driving the Guidance?

What is the Government concerned about?

✓ Protecting the integrity of federal health care programs
✓ Protecting the safety of federal health care program beneficiaries
✓ Protecting the public fisc

Is the company adequately detecting/learning about problems?
Is the company adequately addressing root causes of the problems?

Audience Poll – Yes or No

If the government walked into your office today and asked about a specific compliance matter, would your company be able to clearly demonstrate:

• the scope of the issue
• how it was first raised/discovered
• the timeline of the company’s response
• any/all investigative steps/inquires made
• how conclusions were reached and why limited to that issue
• any overpayments/refunds made and
• any changes in policies, procedures, or disciplinary action taken as a result?
Demonstrating Real-World Compliance

Goal: Show the government you’ve got a good system. Demonstrate efforts to increase compliance, in reference to generally accepted (or recommended) criteria.

- Make sure you have records of inquiries, actions related to allegations
- Explain remedial action (why this time frame, this geographic area, etc.)
- Compliance hotline activity
- Staffing of Compliance Department
- Annual risk assessments
- Compliance and code of conduct training

Look to recent CIAs – what is OIG requiring?

Demonstrating Real-World Compliance

When and how to demonstrate compliance?

✓ Negotiating response to subpoena
✓ Middle of government investigation
✓ CMS/contractor audit
✓ ADR / ALJ appeal
✓ While under CIA / trying to exit from CIA / trying to avoid CIA
✓ Self-disclosure
Measuring Compliance Against Recent CIAs

Do your training and policies cover:

✓ Third parties who perform billing and coding functions
  • OR else certify that 3rd party biller screens against LEIE and gives FWA training to individual billers
✓ Directly or indirectly owned or controlled subsidiaries
✓ Affiliated physician practices managed by you

Is your Board and senior/relevant management personnel sufficiently informed, involved, and willing to sign the required CIA certifications regarding compliance oversight?
  • (“in compliance with all applicable Federal health care program requirements”)

Measuring Compliance Against Recent CIAs

Perform annual risk assessment and internal review?

1. Identify and prioritize risks.
2. Develop internal audit work plans related to the identified risk areas.
3. Implement the internal audit work plans.
4. Develop corrective action plans in response to the results of any audits performed.
5. Track the implementation of the corrective action plans in order to assess the effectiveness of such plans.
Best Practices

• Is there a Gold standard? What about Platinum? Titanium?!  
• We are health care companies. We exist to provide excellent quality patient care and/or health care goods and services.  
  • Good Compliance programs should further that purpose.  
• Having a robust hotline, open to all, is not a bad thing.  
  • Remember, facts uncovered in investigation are typically not privileged.  
• Self-disclosures can be good. (Well, “good” compared to a *qui tam!*  
  • Decide to whom you will disclose. (CMS vs. OIG vs. DOJ/USAO)  
  • Choose and follow the appropriate protocol – and provide full disclosure.  
• Nobody’s perfect. But just like the AKS, it’s all about intent ....  

QUESTIONS?