COMPLIANCE AUDIO/WEB CONFERENCES

Health Care Compliance Association (HCCA)

Whistleblower Claims in Healthcare

I. Compliance Perspective
September 25 2008

II. Enforcement Perspective
October 8, 2008

Increasing Exposure to Whistleblower Controversy - The Compliance Disconnect

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Why Whistleblower and False Claims Act Cases Will Continue to Focus on Healthcare Organizations

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JUSTICE DEPARTMENT RECOVERS $2 BILLION FOR FRAUD AGAINST THE GOVERNMENT IN FY 2007; MORE THAN $20 BILLION SINCE 1986

WASHINGTON -- The United States obtained $2 billion in settlements and judgments in the fiscal year ending September 30, 2007, pursuing allegations of fraud against the federal government, the Justice Department announced today. This brings total recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, to more than $20 billion.

"This year's outstanding recoveries in civil fraud cases demonstrate this administration's unwavering commitment to root out fraud against the government and to ensure that citizens' tax dollars are well spent," said Peter D. Keisler, Acting Attorney General and Assistant Attorney General for the Civil Division. "It also attests to the fortitude of whistleblowers who report fraud and the tireless efforts of the civil servants who investigate and prosecute these cases."

A Few Notable Whistleblower and FCA Settlements and Judgments

•CoxHealth	$60 million	July 2008
•Merck & Co.	$650 million	February 2008
•St. Joseph's Hospital	$26 million	December 2007
•Amerigroup Illinois*	$344 million	March 2007
•Schering-Plough	$435 million	August 2006
•Tenet Healthcare	$900 million	June 2006
•Saint Barnabas	$265 million	June 2006
•Serono	$567 million	October 2005

*In July, 2008, Amerigroup settled the FCA judgment for $225 million and a Corporate Integrity Agreement.

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The Primary Reasons Healthcare Organizations Remain Exposed to Whistleblower and Enforcement Controversy

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1. The Program is Not Focused on Heading Off Claims

- Paper and process do not establish effective compliance.
- Programs don't really address the threat of whistleblower claims and won't pass muster in the event of a problem.
- The significant enforcement cases you are reading about don't involve issues noted in the OIG Work Plan!!
- Focus on the enforcer's key question: "Why didn't your compliance program identify and head off this problem?"

2. Programs Are Not Operated As Adopted or Written

- Compliance programs fail to operate in conformance with what is adopted in writing.
- "Shelf" compliance programs serve to aggravate whistleblower claims and FCA liability.
- Programs must be living and breathing--not policies and procedures that sit and gather dust.
- Failure to operate adopted compliance programs create governance issues and risk aggravated sanctions.
- It is better to have no compliance program than to ignore the one you have held out as in force.

3. The Program is Not "Effective" Absent Ongoing Assessment

- Ongoing assessment of risks should drive compliance focus to true priority enforcement areas.
- The prevention or detection of wrongdoing is all that pays dividends with enforcement authorities.
- Compliance assessments demand time and resources that fail to compete well as business priorities.
- Lack of updating to address evolving compliance standards and risks will guarantee dictated and onerous terms in the event of enforcement.
- You have no idea whether the program is working and management and employees "get it" without assessments.

4. The Hotline Is Not Advertised or Used Sufficiently

- Effective compliance demands hotlines and other tools used by employees to report concerns and problems.
- Enforcement exposes failures to advertise the existence of the hotline or efforts to stress their importance to the commitment to compliance.
- The level of use of hotlines is a barometer of the effective functioning of the compliance program.
- Enforcement authorities will evaluate hotline usage in the event of a problem or whistleblower claim.
- It is essential to identify and fix hotline performance issues.

5. Compliance Education is Inadequate and Dull

- Compliance education at all levels must include tailored and meaningful messages dealing with real issues.
- Many programs fail to adequately communicate the basics never mind the False Claims Act or other compliance risks.
- Training and education using interactive case studies can improve understanding and increase internal reporting.
- Prosecutors and other external speakers can help convey the commitment to compliance and reasons it matters.

6. Employees Are Not Comfortable Reporting Compliance Concerns

- Employees do not view the commitment to compliance as sincere or their managers as genuinely receptive to reported concerns.
- Surveys find managers perceive their employees as committed to compliance and unafraid to report or disclose problems.
- Enforcement authorities cynically dismiss compliance programs as disconnected from corporate reality.
- Convince employees that they are truly encouraged to report matters and will be protected (and even rewarded).
- Without employee input and assistance, no organization can protect its interests in identifying and fixing compliance related problems.

7. Compliance is an Aspirational Goal- Not a Business Priority

- Compliance and ethics is not a business priority—widely seen as a matter for the lawyers.
- The "tone at the top" is usually absent or insufficient and real compliance oversight is lacking.
- You need better and ongoing messaging about the importance of compliance and commitment to doing the right thing.
- Making compliance a performance review matter serves to reinforce the commitment and culture.
- Employee rewards and recognition also help to convey compliance commitment.

8. The Program Does Not Reflect Compliance Standards Set Forth in Major Enforcement Settlements

- Programs remain static in the face of dictated compliance measures driven by regulatory enforcement including FCA cases.
- Settlements set the bar for related industry participants and reinforce or establish the terms and conditions for "effective" compliance.
- Enforcement trends, regulatory guidance, and whistleblower and FCA case settlements should help define the focus of compliance.
- Evaluation of dictated compliance settlement terms includes developing the case to distinguish your organizational approach.

9. The Organization Fails to Properly Handle or Respond to Internal Reports

- Employee reported concerns or complaints are routinely mishandled and lead to whistleblower and enforcement controversy.
- Organizations are unprepared and ill-equipped to conduct assessments and respond in a way that deters whistleblowers and FCA exposure.
- Understand the common failings in internal responses to reported compliance problems including use of self-disclosure.
- Do not dismiss anonymous reports.
- Sensitize managers to the dynamic associated with internal reporting by employees.

10. The Compliance Effort Fails to Understand the Employee Reporting Dynamic

- Employees question the organization's commitment to compliance.
- Compliance assessments reveal employees do not truly feel welcome or encouraged to report problems.
- Government enforcers find that employees are routinely "stonewalled" or "ignored" when raising concerns which ripen into FCA actions.
- Most managers lack education and training to understand how incredibly hard it is for employees to make reports.

11. Organizations Are Not Prepared to Handle Internal Investigations

- Competent investigation of reported compliance problems is a must to protect the organization and reduce exposure to FCA liability.
- Advance planning for handling reported compliance problems is a developing better practice.
- Few organizations correctly evaluate the assistance needed to assess the potential liability, necessary corrective actions, and potential enforcement response.
- Improper internal investigation has the effect of aggravating the problem.
- Compliance Officer and inside counsel are essential but may also need protective distance.

12. Organizations Routinely Discount "Disgruntled Employees"

- The common and openly stated view is that compliance reports are the product of "disgruntled employees."
- The phrase suggests an unsupported effort to demean employee whistleblower reports and disregard for compliance.
- Focus on the substance of the reported conduct and prepare to address the substance of the complaint or concern.
- U.S. Attorneys and other enforcement authorities can and will properly evaluate motivations and credibility of whistleblowers.

13. The Compliance Program Fails to Protect Whistleblowers

- Employees that elect to become whistleblowers or bring information forward must be protected.
- Training and education is needed to convey the prohibitation on retaliation as part of the culture of compliance.
- Protection is particularly important when whistleblowers are internally identified or suspected.
- Dismissals of whistleblowers run substantial risks and must be handled without aggravating exposure to liability.

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Locke Lord Bissell & Liddell LLP Healthcare, Compliance and Investigations Practices

The development of compliance programs that meet requirements established by the Sentencing Commission, OIG, DOJ and other concerned enforcement authorities, is critical to a strategic plan to reduce exposure to claims under the False Claims Act and other fraud and abuse laws. The attorneys at LLB&L are experienced and well qualified to assist in this critically important area.

LLB&L offers invaluable insights to regulatory enforcement authorities' views on effective compliance and assists healthcare organizations in structuring their programs to meet evolving requirements. The firm also defends challenges to compliance programs including administrative, civil, criminal and qui tam whistleblower actions around the country.

Please call Patrick S. Coffey at 312.443.1802 (pcoffey@lockelord.com) or contact the Locke Lord Bissell & Liddell attorney with whom you work.