HOW EFFECTIVE COMPLIANCE PROGRAMS ADDRESS FALSE CLAIMS/WHISTLEBLOWER ISSUES

James G. Sheehan
Chief Integrity Officer/Executive Deputy Commissioner
New York City Human Resources Administration
Sheehanj@hra.nyc.gov

NYC HUMAN RESOURCES ADMINISTRATION
• Largest US social services agency
• 3 million Medicaid enrollees
• Extensive data mining and analytic capacity
• National leader in improper payment detection

USUAL DISCLAIMERS
• A complaint is an allegation.
• Settlement of a case is not an admission of liability.
• Citation of an opinion for educational purposes here does not necessarily represent agreement with the court’s reasoning or result.
• Past results do not guarantee future performance.
GOALS OF THIS PRESENTATION

• REVIEW CURRENT LAW AND CASES GOVERNING FALSE CLAIMS AND WHISTLEBLOWER PROVISIONS
• WHY DO INSIDERS FILE WHISTLEBLOWER COMPLAINTS—WHAT HAPPENS WHEN THEY DO
• REVIEW LAW ADDRESSING COMPLIANCE PROGRAMS AND THEIR RELATIONSHIPS WITH FALSE CLAIMS CASES
• PRACTICAL ADVICE FOR REDUCING ORGANIZATIONAL EXPOSURE FROM WHISTLEBLOWER CASES THROUGH EFFECTIVE COMPLIANCE PROGRAMS

GOALS OF THIS PRESENTATION

• “Discourage litigation. Persuade your neighbors to compromise whenever you can. As a peacemaker the lawyer has superior opportunity of being a good man. There will still be business enough.”
  —Abraham Lincoln

• Address employee and stakeholder concerns before they become qui tam cases.
• Build processes to show you have done so.

THE NEW CLIMATE

• “Calling Out The Frauds
• Schneiderman’s law has positioned New York as a national destination for whistleblowers to bring more, higher-quality claims and the hefty payouts that often come with them, according to several experts in the Medicaid fraud-prosecution field.”
• February 19, 2011 · The Capital
• (posted on ericschneiderman.com)
THE NEW CLIMATE

• SUPPORT AND ENCOURAGEMENT OF WHISTLEBLOWER CASES BY LEADING PROSECUTORS
  – SOUTHERN DISTRICT OF NEW YORK
  – (appointment of Heidi Wendel in 2011 as head of Civil Frauds unit)
  – DISTRICT OF NEW JERSEY
• EXPANSIONS OF QUI TAM STATUTES

THE NEW CLIMATE

• Whistleblower Web sites
• Whistleblower support organizations
• How-to books, checklists, advice
• Twitter and Blog
• Leaks and disclosures
• New technologies empower individuals in dealing with organizations
• Assume transparency

MORE CASES

• As of the end of 2012, there were more than 1200 federal qui tam cases under investigation with no decision yet as to whether DOJ will intervene.
• Of these cases, over 800 involve healthcare fraud, many against multiple defendants.
**U.S. ex rel. Hutcheson v. Blackstone**  
(1st Cir. 2011)

- Blackstone “caused” hospitals (“unwittingly”) to submit materially “false or fraudulent” claims because the claims did not meet a “a material precondition” for payment.
- Alleged kickbacks to hospital physicians “would have been capable of influencing Medicare’s decision whether to pay the claims had it been aware of them.”
- A submitting entity’s representation about its own legal compliance can incorporate an implied representation concerning the behavior of non-submitting entities.

**CURRENT HOSPITAL ISSUES - CARDIOLOGY**

- 1/4/2013-$4.4 million settlement-EMH Regional Medical Center, Ohio-unnecessary angioplasty and stent procedures
- Former catheterization lab manager accused hospital of doing procedures on patients with insufficient blockage-received $661,000 award

**CONFESS, CALCULATE, AND PAY- DOJ REQUEST**

- In August 2012, the US Department of Justice (“DOJ”) sent an email to hospitals nationwide asking them to conduct self-audits to identify Medicare fraud involving implantable defibrillators and calculate potential penalties under the False Claims.
### IMPLANTABLE DEFIBRILLATORS-CONFESS, CALCULATE, AND PAY-STANDARDS

- Whether there was a medical need for the hospital to violate CMS rules;
- Whether the patient was harmed;
- If the hospital was aware or had a statistical pattern of implanting the devices against CMS guidelines; and
- If the hospital has an established compliance program

### CONFESS, CALCULATE, AND PAY- DOJ REQUEST

- What should a compliance officer do with this request?
- 6402 report, refund, explain duty
- Whistleblower qui tam risk
- Do NOT take responsibility for this on your own
- Consult counsel
- Advise compliance committee and governing board

### THE MOST IMPORTANT INTEGRITY PROVISIONS OF ACA

- MANDATORY REPORTING, REPAYMENT, AND EXPLANATION OF OVERPAYMENTS BY "PERSONS"
- "KNOWING" RETENTION OF OVERPAYMENT BEYOND 60 DAYS IS A FALSE CLAIM (invokes penalties and whistleblower provisions)
- MANDATORY COMPLIANCE PLANS (first in nursing homes, later in other providers) which will include mandatory reporting of overpayments, mandatory review and follow up-
- Will CMS impose ACA’s compliance requirements?
A TALE OF TWO CASES AND COMING ATTRACTIONS

• WHISTLEBLOWER SUSAN LESTER, RN, AND THE EVIL DR. FITTIS
• DAVID TREMOGLIE AND BUSTLETON GUIDANCE CENTER
• MAXIM HEALTH CARE 2011 (investigation begun in 2004 after filed whistleblower case)
• HEALTH CARE INVESTIGATIONS AFTER 2010-COMPLIANCE, REPORTING, PAYMENT SUSPENSION

SUSAN LESTER AND DR. FITTIS

• Whistleblower
• Subject
• Fraud Victim
• Compliance responsibilities
• “for money”

DOCTOR TREMOGLIE

• Fraud
• Abuse
• Improper Payments
• Risk of patient harm
• Role of private regulators
### MAXIM HOME HEALTH-2011-THE NEW MODEL HEALTH CASE
- Maxim Healthcare Services, company with 360 offices nationwide offering home health care services, agrees to pay about $150 million to settle civil and criminal charges -false billings to Medicaid and the Department of Veterans Affairs (no Medicare)
- nine current and former Maxim employees have pleaded guilty since 2009 to felony charges

### RICHARD WEST-PATIENT - MAXIM WHISTLEBLOWER
- "I'm on oxygen, I wasn't getting the nursing care I needed and services were being cut back because of me being over the so-called spending limit. There were times I thought I would die."
- After checking his own medical records, he discovered the company providing him with nursing care appeared to have overbilled Medicaid for hundreds of hours for people who were never there.

### MAXIM CONSPIRACY TO DEFRAUD-criminal information
- "Maxim emphasized sales goals at the expense of clinical and compliance responsibilities"
- During the relevant time period, Maxim did not have in place “appropriate training and compliance programs to prevent and identify fraudulent conduct.”
- “Relevant time period” before ACA.
KYPHOPLASTY QUI TAM

- Hospitals overcharged Medicare between 2000 and 2008 when performing kyphoplasty, a minimally-invasive procedure used to treat certain spinal fractures that often are due to osteoporosis. In many cases, the procedure can be performed safely as a less costly outpatient procedure, but the government contends that the hospitals performed the procedure on an in-patient basis in order to increase their Medicare billings.
- Qui tam filed in 2008 in Buffalo by Craig Patrick and Charles Bates, both employed by Medtronic
- "These settlements show the continuing commitment by the U.S. Attorney's Office to investigate and recover any improper billings for kyphoplasty procedures which the hospitals inappropriately classified as inpatient, rather than outpatient," said William J. Hochul Jr., U.S. Attorney for the Western District of New York
- Recoveries: 27 hospitals plus Medtronic

MEDLINE-KICKBACKS TO HOSPITALS

- March 2011-$85 million settlement of whistleblower case
- Alleged kickbacks to HCA and other firms to purchase supplies
- Kickbacks allegedly disguised "as rebates, junkets, expensive gifts, and charitable donations"
- Case declined by DOJ

KICKBACKS

- $241 million settlement between California AG and state's largest Medicaid lab provider, Quest Diagnostics (May 2011)
- Whistleblower was a competitor-filed suit against 7 lab companies alleging labs offered below cost pricing to induce referrals of higher priced Medicaid tests
- USA ex rel. Wilkins v. United Health (3d Cir. 2011) "compliance with AKS is clearly a condition of payment"
USA ex rel. Donigian v. St. Jude Medical

- St. Jude Medical Inc. has agreed to pay the United States $16 million to resolve allegations that the company used post-market studies and a registry to pay kickbacks to induce physicians to implant the company’s pacemakers and defibrillators, the Justice Department announced today.
- Post-market studies are intended to assess the clinical performance of a medical device or drug after that device or drug has been approved by the Food and Drug Administration. Registries are collections of data maintained by a device manufacturer concerning its products that have been sold and implanted in patients.
- The United States contends that St. Jude used three post-market studies and a device registry as vehicles to pay participating physicians kickbacks to induce them to implant St. Jude pacemakers and defibrillators. Although St. Jude collected data and information from participating physicians, it is alleged that the company knowingly and intentionally used the studies and registry as a means of increasing its device sales by paying certain physicians to select St. Jude pacemakers and implantable cardioverter defibrillators (ICDs) for their patients. In each case, St. Jude paid each participating physician a fee that ranged up to $2,000 per patient. The United States alleges that St. Jude solicited physicians for the studies in order to retain their business and/or convert their business from a competitor’s product.
- DOJ press release, January 20, 2011

THE MAY, 2009 FERA Amendments to the False Claims Act (FCA)

1. Expand FCA liability to indirect recipients of federal and state funds
2. Expand FCA liability for the improper retention of overpayments, even where there is no “knowing” false claim
3. Add a materiality requirement to the FCA, defining it broadly
4. Expand protections for whistleblowers to include contractors as well as employees
5. Expand the statute of limitations

ADDITIONAL PROVISIONS OF 2010 NEW YORK FERA ACT

- Establishing anti-blacklisting protections against whistleblowers, so company “Y” cannot refuse to hire a qualified worker because he or she reported company “X” for fraud;
- Clarification that whistleblowers who use the Freedom of Information Act are not barred from suing a contractor for fraud because he or she created a public disclosure of information; and
- The first-in-the-nation ban on employers from suing employees who provide evidence of fraud to law enforcement in a False Claims Act case.

Took effect August 27, 2010

http://assembly.state.ny.us/law/?default_fld=&bn=A11568P%09%09&Text
FCA ISSUES OF THE 2010 AFFORDABLE CARE ACT (ACA)

- Claim induced by a kickback is a false claim.
- Section 6402 obligation to report, refund, and explain identified overpayments (combined with 2009 FERA False Claims liability) for anyone who knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money.
- NY SSL §363-d(2)(g) and 18 NYCRR Part 521 obligation to repay improper payments.

THE FCA ELEMENTS

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.
THE FCA ELEMENTS

- (1) the terms “knowing” and “knowingly”—(A) mean that a person, with respect to information—(i) has actual knowledge of the information;
- (ii) acts in deliberate ignorance of the truth or falsity of the information; or
- (iii) acts in reckless disregard of the truth or falsity of the information; and
- (B) require no proof of specific intent to defraud;

THE KEY ISSUE

- WHAT DOES “KNOWINGLY” MEAN FOR AN ORGANIZATION?
- Employee in scope of duties
- “Reckless disregard”
- “Deliberate ignorance”
- Compliance process is an effective defense to “knowingly”—both in interpreting requirements and responding to employee concerns
- “the appropriate test is whether the defendant’s actions were ‘reasonable and prudent’ under the circumstances.” S. Rep. No. 99-345, at 21 (1986)

THE FCA WHISTLEBLOWER PROCESS

- Complaint and Disclosure Statement filed under seal
- Attorney General (state and/or federal) leads investigation
- State or feds intervene or decline; “relator” may proceed whether or not government intervenes
- Average time under seal exceeds two years
WHY DO INSIDERS FILE WHISTLEBLOWER COMPLAINTS—WHAT HAPPENS WHEN THEY DO

- Whistle-Blowers’ Experiences in Fraud Litigation against Pharmaceutical Companies

- "...the triggering event for most (16 of 22) insiders was a career change — starting at a new company (10 of 16) or being promoted to a new position (6 of 16)."
- "a large proportion (11 of 26) of the relators refused to participate in the corporate actions that led to the suit."
- Nearly all (18 of 22) insiders first tried to fix matters internally by talking to their superiors, filing an internal complaint, or both.

- "Although the relators in this sample all ended up using the qui tam mechanism, only six specifically intended to do so."
- The others fell into the qui tam process after seeking lawyers for other reasons (e.g., unfair employment practices), or after being encouraged to file suit by family or friends.
- Several relators (5 of 26) reported fears that the fraudulent behavior would be discovered and would result in legal consequences for them.
WHY DO INSIDERS FILE
WHISTLEBLOWER COMPLAINTS—WHAT HAPPENS WHEN THEY DO

- The experience of being involved in troubling corporate behavior and a qui tam case had substantial and long-lasting effects for nearly all of the insiders, although no similar problems were reported by any of the four outsiders.
- For at least eight insiders, the financial consequences were reportedly devastating. One said, "I just wasn't able to get a job. It went longer and longer..."
- Six relators (all insiders) reported divorces, severe marital strain, or other family conflicts during this time.
- Thirteen relators reported having stress-related health problems, including shingles, psoriasis, autoimmune disorders, panic attacks, asthma, insomnia, temporomandibular joint disorder, migraine headaches, and generalized anxiety.

WHY DO INSIDERS FILE
WHISTLEBLOWER COMPLAINTS—WHAT HAPPENS WHEN THEY DO

- A majority perceived their net recovery to be small relative to the time they spent on the case and the disruption and damage to their careers. After settlement, none of the 4 outsiders changed jobs, but only 2 of the 22 insiders remained employed in the pharmaceutical industry. One ruefully reported that he "should have taken the bribe" (Relator 7), and another noted that if she "stayed and took stock options" she "would've been worth a lot more" (Relator 4). The prevailing sentiment was that the payoff had not been worth the personal cost.

WHY DO INSIDERS FILE
WHISTLEBLOWER COMPLAINTS—WHAT HAPPENS WHEN THEY DO

- Relators offered a range of advice for others who might find themselves in similar situations. Some offered strategic suggestions, such as hiring an experienced personal attorney, and many suggested a need to mentally prepare for a process more protracted, stressful, and conflict-ridden, and less financially rewarding, than prospective whistleblowers might expect.
FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• Plaintiffs have sufficiently alleged that Medco submitted its false claims ‘knowingly’. At the very least, the Government has claimed that Medco’s compliance programs were either non-existent or insufficient, in satisfaction of the “reckless” requirements of 3729(b).”

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 146. Medco Health acted knowingly, as that term is used in the False Claims Act, 31 U.S.C. § 3729, that is, with reckless disregard or deliberate ignorance of the truth or falsity of information it submitted to the United States and its contractors in support of its claims.
• 147. This reckless disregard or deliberate ignorance arose from the following actions and course of conduct by Medco.
• USA v. Medco Health Solutions-Complaint of United States filed 9/29/03

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 a. Medco Health’s board members and officers failed to satisfy their obligation to assure “that information and reporting systems exist in the organization that are reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board, each within its scope, to reach informed judgments concerning the corporation’s compliance with the law. . . .” In Re Caremark 698 A.2d 959, 969 (Del. Ch. 1996).
• 147 b. Medco Health failed to implement a corporate compliance program which satisfied the requirements of proper corporate practice and Delaware law.

• 147 c. The compliance program in place at relevant times was not reasonably capable of reducing the prospect of misconduct. Most employees were either entirely unaware of the existence of such a program, or were not familiar with its details.

• 147 d. There were no specific high-level personnel within Medco with direct responsibility for overseeing compliance, with direct access to the CEO and board of directors.
FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 f. There were no regular reports to the board concerning internal investigations.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 g. There was no effective, timely communication to employees about the program.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 h. There were no effective methods of monitoring, auditing, or reporting on compliance.
FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 i. There was no effective anonymous hotline.
• 147 j. There was no effective protection of whistleblowers.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 k. There was no consistent enforcement through corrective actions; rather, certain management, supervisors, and employees who engaged in illegal activities were rewarded with substantial severance packages in return for protecting more senior executives, and agreeing not to report violations to outside investigators.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 l. There were no systems to assure reasonable steps to respond to reported offenses, including detection of violations and investigation of violations.
FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 m. Such reporting of violations as did occur was false and misleading, and designed to hide the extent of the violations, the effect on patients, the role of senior executives in the violations, and the need for further investigation of violations.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 n. There was no effective code of ethics as that term is used in SEC Release Nos. 33-8177 and 34-47235.

• o. There was inadequate due diligence to support the representation under 18 U.S.C. § 1350 set forth in the May 14, 2003 certification by a Medco Health board member that "any fraud, whether or not material, that involves management" had been disclosed. (Sarbanes-Oxley Act representation required of chief financial officer)

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

• 147 e. There was no compliance officer within MedcoHealth with responsibility for independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations. Rather, it was the practice to assign responsibility for investigations to executives within whose area of responsibility the alleged wrongdoing occurred.
EFFECTIVE COMPLIANCE AND FALSE CLAIMS

• Use the Medco allegations as a road map:
  • “information and reporting systems exist in the organization that are reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board, each within its scope, to reach informed judgments concerning the corporation’s compliance with the law…”

EFFECTIVE COMPLIANCE AND FALSE CLAIMS

• Use the requirements of 18 NYCRR 521 as a road map
• Use the COMPLIANCE PROGRAM ASSESSMENT TOOL (available at www.OMIG.ny.gov) as a road map
• Use the OIG compliance guidance as a road map: oig.hhs.gov/fraud/complianceresources.asp

EFFECTIVE COMPLIANCE-SENTENCING GUIDELINES

1. the organization exercises due diligence to prevent and detect inappropriate conduct by the Medicaid provider;
2. the organization promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; and
3. the compliance program is reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting improper conduct.

Failure to prevent or detect specific offenses does not necessarily mean that the program is not generally effective in preventing and detecting such conduct.

Federal Sentencing Guidelines most recent amendment effective 11/1/2010 Section B52.1(a)
DO FEDERAL ACQUISITION REGULATIONS CREATE FCA LIABILITY?

- Does not cover Medicare A Hospitals Medicare B providers
- Medicare Advantage subcontractors, Part D plans, VA and Tricare plans?

More Current FCA cases in NY

- United States v. Huron Consulting 2011 WL 253259 (SDNY 1/24/11)—relaxed pleading requirement for Rule 9(b) "when a plaintiff is not in a position to know specific facts until after discovery"
- United States v. Dialysis Clinic 2011 WL 167246 (NDNY 1/19/2011) analysis of distinction between conditions of participation and conditions of payment for Medicare and Medicaid for False Claims purposes; applying Mikes v. Straus 274 F. 3d 687 (2d Cir. 2001)

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