HOW EFFECTIVE COMPLIANCE PROGRAMS ADDRESS FALSE CLAIMS/ WHISTLEBLOWER ISSUES

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Public Health Law §32 –

Medicaid IG functions/duties/responsibilities

17. to conduct educational programs for medical assistance program providers, vendors, contractors and recipients designed to limit fraud and abuse within the medical assistance program.

- These programs will be scheduled as needed by the provider community. Your feedback on this program, and suggestions for new topics, are appreciated.

USUAL DISCLAIMERS

- A complaint is an allegation.
- Settlement of a case is not an admission of liability.
- Citation of an opinion by OMIG 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 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 Jan. 4, 2011, there were 1,341 federal *qui tam* cases under investigation with no decision yet as to whether DOJ will intervene. (letter from DOJ to Senators Charles Grassley and Patrick Leahy)
- Of these cases, 885 involve healthcare fraud.
- Examples of current cases on next slides.

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 out-patient 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

KICKBACK AND STARK VIOLATIONS AS FCA CASES

- **BALTIMORE, November 9, 2010 --** St. Joseph Medical Center has agreed to pay $22 million in a settlement involving unnecessary stents implanted in several patients.
- The lawsuit against the hospital said it paid an unlawful amount of money when it entered into a series of professional services contracts with a cardiology group called MidAtlantic Cardiovascular Associates.
- The settlement resolves the lawsuit that alleged the hospital violated the Anti-Kickback Act, Stark Law and the False Claims Act by making illegal payments to MACVA in return for patient referrals insured by federal health care programs for cardiac procedures.
- Medically unnecessary stents implanted in patients between January 2008 and May 2009 by Dr. Mark Midei, a one-time partner in MACVA who was later employed by SJMC
- (from WBALTV.com)

United States ex rel. Kevin N. Colquitt v. Abbott Laboratories et al., Civ. Action No. 3-06-CV-1769 (N.D. Tex.)

- “AARP Texas announced today that AARP attorneys have joined as co-counsel (with *qui tam* firms) in a whistleblower case challenging several medical device makers' allegedly illegal, off-label marketing of metal biliary stents wrongfully placed in older patients to treat vascular disease. The involvement of AARP's attorneys supports the organization's ongoing efforts to address health care fraud, a major contributing factor for escalating health care costs.”
- AARP press release, 10/12/2010

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 defibrillator 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.

Governor David Paterson signed into law on August 13, 2010; took effect August 27, 2010

http://assembly.state.ny.us/leg/?default_fld=&bn=A11568%09%09&Text=Y

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;**

THE FCA ELEMENTS

- **(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)
- Reliance on a reasonable interpretation of an ambiguous requirement can preclude the finding of "reckless disregard" under 31 U.S.C. § 3729(b)(3). *United States ex rel. K & R Partnership v. Massachusetts Housing Finance Agency*, 530 F.3d 980 (D.C. Cir. 2008).

THE FCA WHISTLEBLOWER PROCESS

- Complaint and Disclosure Statement filed under seal
- OMIG advised by AG of state filings; sometimes of federal filings
- Attorney General (state and/or federal) leads investigation
- By statute, OMIG consulted on state intervention decision
- 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**
- A. S. Kesselheim,et al.
- N Engl J Med 2010; 362:1832-1839May 13, 2010

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

- " . . . 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.

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

- “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

- *United States v. Merck-Medco Managed Care, L.L.C., 336 F.Supp.2d 430, 440-41 (E.D.Pa. 2004).*
- *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).

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

- 147 b. Medco Health failed to implement a corporate compliance program which satisfied the requirements of proper corporate practice and Delaware law.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

- 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.

FALSE CLAIMS ACT AND COMPLIANCE PROGRAMS

- 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 8B2.1(a)

DO FEDERAL ACQUISITION REGULATIONS CREATE FCA LIABILITY?

- 48 C.F.R. §§ 9.406-2, 9.407-2 and 52.203-13- Mandatory Disclosure for Federal Contractors-also requires compliance and ethics programs for certain contractors, and reporting violations of criminal law and false claims.
- Does not cover Medicare A Hospitals Medicare B providers
- Medicare Advantage subcontractors, Part D plans, VA and Tricare plans?

Current FCA cases

- Liburd v. Bronx Lebanon 2010 WL 1508267 (2d Cir. 4/16/2010)-summary judgment for defendant on retaliation claim.
- Frazier v. Iasis Healthcare 2010 WL 3190641 (9th Cir. 8/12/10) –chief compliance officer given third chance to plead FCA complaint alleging “an illegal kickback scheme violating “Stark or Anti-Kickback”
- United States v. Campbell 2010 WL 43013 (1/4/2011)-Stark violations-*mens rea* requirement-not suitable for summary judgment for plaintiff

Current FCA cases

- 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) discussion of original source doctrine where OMIG issued an audit report on the defendant provider; an 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)
- United States v. Christi Sulzbach 2010 WL 1531492 (SD FL. 4/16/2010)-false certifications by general counsel of compliance with applicable federal program requirements (Stark requirements). Case barred by statute of limitations.

www.omig.ny.gov

- Compliance Alerts
- Over 2000 provider audit reports, detailing findings in specific industry
- Annual work plans
- New York excluded provider list
- Self-Disclosure protocol
- Corporate Integrity Agreements
- Listserv
- Link to sites for all 18 states which currently publish their state exclusion lists
- Follow us on Twitter