10 TOP COMPLIANCE ISSUES FOR 2016

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A little about us . . .

- Charities Bureau for NY Attorney General Eric Schneiderman
- Regulation and Support of New York's Non-Profit sector-1.2 million employees, 80,000 registered organizations

New York State Attorney General
Eric T. Schneiderman

"OUR JOB AS A REGULATOR ISN'T JUST TO GO OUT AND CATCH BAD GUYS, IT'S ALSO TO HELP THE GOOD GUYS CONDUCT THEIR BUSINESS EFFICIENTLY AND EFFECTIVELY."

USUAL DISCLAIMERS

- A complaint or an indictment is an allegation. A press release is an opinion.
- Citation of an opinion or settlement for educational purposes here does not necessarily represent agreement with the court's reasoning or result, or Government's theory of the case.

GOALS OF THIS PRESENTATION

- TOP TEN-CURRENT LAW, RULES, CASES, SETTLEMENTS
- ADVICE FOR REDUCING ORGANIZATIONAL EXPOSURE

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;**
- Liability for retaliation against whistleblowers-double back pay plus interest

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

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.**

10) Tools of compliance or potential adverse action?

- January 2012 warning letter regarding the phone call with Alexander;
- February 2012 warning letter regarding Plaintiff's corporate credit card;
- negative mid-year performance review;
- PIP (performance improvement plan)

DiFiore v CSL Bearing (ED Pa 3/17/16)

- "The cumulative impact of retaliatory acts may become actionable even though the actions would be de minimis if considered in isolation."
- FCA anti-retaliation provision
- "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment"

9)HIPAA/HITECH

- **United States ex rel. Sheldon v. Kettering Health Network (6th Circuit March 17, 2016) False Claims Act (FCA) relating to a data breach. Kettering's "attestation of compliance [with the HITECH Act] is not rendered false by virtue of individual breaches. . ."**
- **OCR (Office of Civil Rights) has taken down its page listing specific cases, but still pursuing them-penalties and corrective actions.**

8)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

8) DOJ ICD CONFESSION PROJECT

- October 30, 2015: 70 settlements involving 457 hospitals in 43 states for more than $250 million related to implantable cardioverter defibrillators(ICD) implanted in Medicare patients in violation of Medicare coverage requirements
- "While recognizing and respecting physician judgment, the department will hold accountable hospitals and health systems . . ."

7) Stark/FCA settlements-2015-16

- Adventist Health System - $115 million,
- North Broward Hospital District - $69.5 million
- Columbus Regional Healthcare System and Dr. Andrew Pippas for $25 million plus contingent payments up to an additional $10 million.
- Tri-City Medical Center- $3.2 million-97 financial arrangements with physicians and physician groups

6) Billing for Dead People

- 1/16-Nashville (Tenn.) Pharmacy Services -$7.8 million –billed Medicare and TennCare for medications for dead patients.

5) Following Directions

- Medical Reimbursement Systems- $500,000 settlement - Firm complied with physician group's request to certify to TRICARE that services were rendered in a qualifying HPSA to obtain 10% bonus when they were not.

4) Statistical Sampling

- Using statistical sampling to prove **liability** and damages. United States ex rel. Martin et al. v. Life Care Centers of Am., Inc., No. 1:08-cv-251 (E.D. Tenn. Sept. 29, 2014). "courts now consider mathematical and statistical methods [to be] well recognized as reliable and acceptable evidence in determining adjudicative facts."

3)THE MOST IMPORTANT INTEGRITY PROVISION 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)

3) Final 60 Day rule

- February 12, 2016-Final 60 day rule to report, refund, explain overpayments (42 C.F.R. § 401.305)
- the 60-day clock does not start to tick while the provider is conducting its "reasonable diligence" investigation
- six-month time frame as a "benchmark" for how long the reasonable diligence should take
- Six year look back period

2) Government Knowledge of Non-Compliance

- UNITED STATES OF AMERICA, ex rel. SPAY v. CVS CAREMARK CORPORATION (E.D. Pa. 2015)
- "with respect to . . . false physician identifiers, the government was well aware of the use of such identifiers and, while not happy with the practice, condoned their use as a way of ensuring that valid prescriptions were filled during the early roll-out stages of Medicare Part D. . ."

1)Implied certification

- some individuals who provided the services did not have the certifications required by the regulations
- Is a claim "false" if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment?
- Universal Health Services v. Escobar (1st Cir. 2015) argued in Supreme Court April 17, 2016

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
- Interconnections-liability for others' conduct

PROGRAM INSTRUCTION-NO DOCUMENTATION OF "FACE-TO-FACE" PHYSICIAN ASSESSMENT

- ResCare Iowa Inc. has agreed to pay $5.63 million to the United States and the state of Iowa to resolve allegations that it violated the False Claims Act by submitting false home healthcare billings to the Medicare and Medicaid programs
- "The rules of both Medicare and the state of Iowa's Medicaid program require an independent physician to certify that home healthcare services are medically necessary and to order the specific type and amount of healthcare services to be provided by the home health agency. Additionally, since 2011, Medicare and Iowa Medicaid rules require these independent physicians to perform an in-person "face-to-face" assessment of each patient before the home health agency can bill the government for any home healthcare services. The settlement resolves allegations that between 2009 and 2014, ResCare Iowa billed the government for services provided to Medicare and Medicaid patients in Iowa without documenting compliance with these requirements."
- USDOJ February 2015

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.**

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
- Failure to have NY required "effective compliance program" can be basis for reckless disregard
- "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).

EFFECTIVE COMPLIANCE AND FALSE CLAIMS

- "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. . ." USA v. Medco Complaint, 2004

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

NEW YORK ATTORNEY GENERAL

- http://www.ag.ny.gov/
- http://www.ag.ny.gov/feature/whistleblowers-new-york-false-claims-act (whistleblower instructions)
- http://www.ag.ny.gov/whistleblowers/procedural-regulations-false-claims-act (procedural regulations)