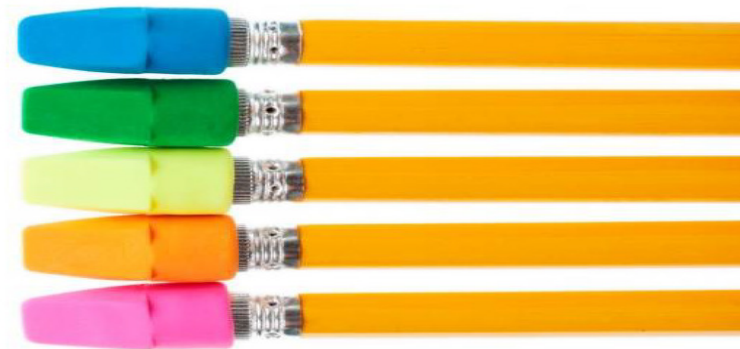


Fraud and Abuse 2016: Game-Changing Trends and Cases (and How to Protect Your Organization)

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- Review key fraud and abuse provisions, and discuss ever-more heightened government scrutiny for healthcare providers and payers
- Identify key indicators and measure progress along the journey of compliance and delineate how you know when you get to “mission accomplished”
- Share practical implementation recommendations for preparing for and responding to a government inquiry



Polling Question #1

- What is your role in your organization?
 1. In-House Legal
 2. In-House Compliance
 3. Outside Counsel
 4. Other

Part I: Enforcement

■ Health Care Statutes

- CMP: 42 U.S.C. § 1320a-7a
- False Claims: 31 U.S.C. § 3729
- False Statements and Kickbacks: 42 U.S.C. § 1320a-7b
- Stark Law: 42 U.S.C. § 1395nn
- Health Care Fraud: 18 U.S.C. § 1347



■ Other Criminal Statutes

- Mail and Wire Fraud: 18 U.S.C. §§ 1341 and 1343
- Material False Statement in Matter Within Jurisdiction of United States: 18 U.S.C. § 1001
- False, Fictitious or Fraudulent Claims: 18 U.S.C. § 287
- Obstruction of an “Official Proceeding” / Altering Records: 18 U.S.C. § 1512(c)

The Key Players Agree: Health Care Fraud and False Claims Act Will Remain a Priority



- DOJ AAG: Today, I want to announce that we will be stepping up our use of one tool, and that is the fine work done by all of you in investigating and filing cases under the False Claims Act. Through our Fraud Section, we will be committing more resources to this vital area, so that we can move swiftly and effectively to combat major fraud involving government programs.

(9/17/2014 Remarks of DOJ Criminal Division AAG Leslie Caldwell at the Taxpayers Against Fraud Education Fund Conference)



- HHS Inspector General: “We continue our two-pronged attack on alleged fraudulent corporate behavior. Our investigations expose wrongdoing and our Corporate Integrity Agreements monitor companies’ compliance with controls designed to prevent future problems.”

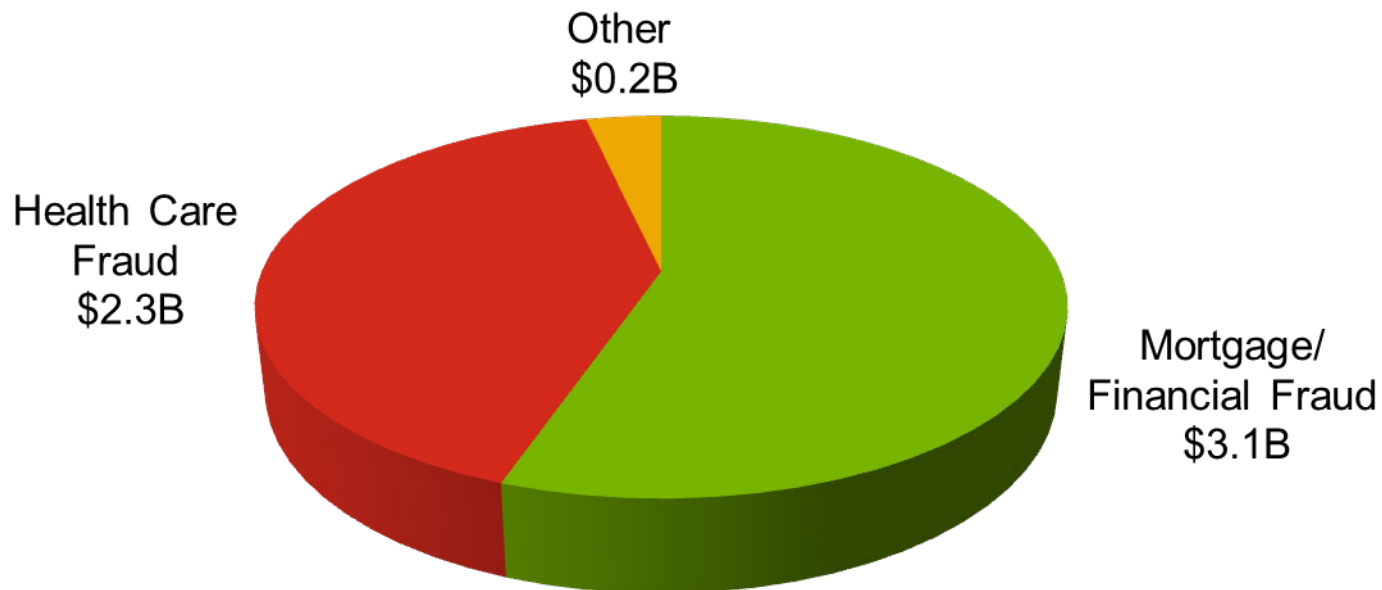
(Remarks of Daniel Levinson in 12/19/12 Press Release, “Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY.; Pays \$762 Million to Resolve Criminal Liability and False Claims Act Allegations”)

Follow the Money:

Health Care at the Heart of Department of Justice's FCA Success

6

- In fiscal year 2014, the Department of Justice recovered over **\$5.6 billion** in settlements and judgments under the False Claims Act – a new record for a single year. Of that, **\$2.3 billion came from health care cases.**



Source: Press Release, DOJ Office of Public Affairs, 11/20/2014

- 2014 was the **5th straight year** that DOJ recovered more than **\$2 billion** in health care fraud cases
- DOJ recovered **\$14.5 billion** in health care fraud cases between 2009 and 2014
- In June 2015, DOJ announced the largest health care fraud “takedown” in history
 - \$712 million in false billings
 - criminal charges against 243 individuals around the country, including 46 doctors
- False claims included those based on off-label marketing, kickbacks, Stark, up-coding, double billing, violations of Medicare staffing regulations, and lack of medical necessity

- Civil False Claims:

- *Knowingly* presenting or *causing to be presented a false claim for payment or approval*;
- *Knowingly* making, using, or causing to be made or used a false record or statement *material to a false or fraudulent claim*;
- *Knowingly* making, using, or causing to be made or used a false record to avoid, or decrease an *obligation* to pay or transmit property to the Government.
 - » 31 U.S.C. § 3729(a)
- “Knowingly” includes “reckless disregard” or “deliberate indifference”
 - » 31 U.S.C. § 3729(b)

- Criminal False Claims:

- Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, *any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent*, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title. 18 U.S.C. 287
- In connection with the *delivery of or payment for any Healthcare program benefits, items, or services, knowingly and willfully*
 - » *falsifies, conceals, or covers up* by any trick, scheme, or device a material fact; or
 - » makes any *materially false, fictitious, or fraudulent statements or representations*; or
 - » makes or uses any *materially false writing or document* knowing the same to contain any materially false, fictitious, or fraudulent statement or entry. 18 U.S.C. § 1035

Polling Question #2

- What type of organization do you work for?
 1. Pharmaceutical company
 2. Medical device company
 3. Hospital/health care provider
 4. Insurer/payer
 5. Managed care organization
 6. Other

- **Violations of Anti-Kickback Statute**
- **Omnicare, Inc.** (June 2014): Omnicare agreed to pay \$125 million civil settlement to resolve a FCA case based on alleged AKS violations arising out of discounts to skilled nursing facilities.
- **PharMerica Corp.** (Oct. 2015): PharMerica, a pharmaceutical services provider, agreed to pay \$9.25 million to settle FCA claims arising out of alleged receipt of kickbacks in the form of rebates, educational grants and other financial support from pharmaceutical company.
- **Tuomey Health Care System** (October 2015): Tuomey agrees to pay \$72 million to settle FCA case arising out of unlawful financial arrangements with physicians, after the Fourth Circuit affirmed a \$237 million jury verdict.
- **Novartis AG** (October 2015): Novartis agrees to pay \$392 million to settle FCA case alleging that Novartis violated the AKS by providing financial incentives to specialty pharmacies for promoting their drugs.
- AKS cases are brought under theory of “implied certification” – no affirmative false statement required, as long as the submitted claims imply compliance with federal regulations.
 - » Standard: The “FCA plaintiff ... must show that the contractor withheld information about its noncompliance with material contractual requirements.” *United States v. Science Applications Int’l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010).

- AKS: Specific Intent Not Required

- Under Affordable Care Act, “a person need not have actual knowledge of [the Anti-Kickback Statute] or specific intent to commit a violation of that section” for conviction
 - » ACA § 6402(f)(2)
- Resolves a Circuit Split
 - » Prior to passage of the ACA, the AKS was understood by most courts to have an elevated standard of proof with respect to intent, requiring the defendant to know that their acts are “unjustifiable” and/or “wrongful” and allowing a “good faith” defense. See *U.S. v. Jain*, 93 F.3d 436 (8th Cir. 1996).
 - » Some courts interpreted the AKS as requiring government to prove defendant had actual knowledge of the AKS’s prohibition on kickbacks for conviction. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995).
 - » Under new provision, “good faith” defense has been narrowed.

- **Johnson & Johnson** (November 2013): J&J subsidiary pleads guilty and agrees to pay \$2.2 billion to resolve criminal FDCA charges and civil FCA claims relating to off-label promotion of Risperdal, Invega, and Natrecor.
- **CareFusion** (January 2014): CareFusion agrees to pay \$40.1 million to civilly settle FCA case involving off-label promotion, and kickbacks.
- **Endo Pharmaceutical** (February 2014): Endo enters into a deferred prosecution agreement and agrees to pay \$192 million to resolve criminal charges and civil FCA case arising out of off-label promotion.

- Courts have provided some relief in the off-label marketing cases:

- *U.S. v. Caronia* (2d. Cir. 2012):
 - 2d Circuit overturns criminal conviction on First Amendment grounds where sales rep made truthful statements regarding off-label benefits.

- *Amarin v. FDA* (S.D.N.Y. August 2015):
 - Based on *Caronia*, district court grants, on First Amendment grounds, a preliminary injunction permitting Amarin to engage in truthful off-label marketing of Vascepa.

- DOJ Deputy Assistant General (2013): DOJ will take “an especially hard look” at violations of current good manufacturing practices (“cGMPs”).
- **GlaxoSmithKline** (October 2010): GSK pays \$750 million to resolve criminal charges and FCA case arising out of violations of cGMPs. Resolution includes \$600 million to resolve FCA claims, and \$150 million to resolve criminal charges.
- **Ranbaxy** (May 2013): Ranbaxy subsidiary pleaded guilty to felony charges, paying \$150 million in criminal fines, and \$350 million to settle FCA claims, arising out of its failure to comply with cGMPs.

- But courts have pushed back on this as well.
 - United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694 (4th Cir. 2014): Fourth Circuit holds that violations of GMPs do not give rise to FCA claims because mere regulatory non-compliance does not render the claims false
 - United States ex rel. Campie v. Gilead Sci., Inc., 2015 U.S. Dist. LEXIS 1635 (N.D. Cal. 2015): district court holds that false statements regarding regulatory violations during drug approval process does not give rise to FCA claims.
 - United States ex rel. Petratos v. Genentech, Inc., 2015 U.S. Dist. LEXIS 146525 (D.N.J. 2015): district court holds that “submissions to the FDA to get [drug] approved are not claims for payment” under the FCA.

Trends in Fraud and Abuse Prosecutions: Questioning Medical Judgment

■ Enforcement Actions Challenging Judgment of Hospitals and Doctors

- February 2012: Fourteen hospitals agree to pay \$12 million to civilly settle allegations that they chose to conduct kyphoplasty spinal fracture treatment as an inpatient instead of an outpatient procedure, resulting in larger and unnecessary bills to Medicare. *U.S. ex rel. Patrick v. Greenville Hosp. Sys.* (W.D.N.Y., 2011)
- March 2013: Court denies defendant's motion to dismiss in FCA action brought against Illinois teaching hospital whose "overlapping surgical schedules" allegedly ran afoul of Medicare Part B requirement that attending physician be "immediately available" during simultaneous surgeries or have an equivalent "back-up" physician on hand. *U.S. ex rel Goldberg v. Rush Univ. Med. Ctr.*, 04-cv-4584 (N.D. Ill. 2013)
- May 2014: physician criminally charged with billing for incision/drainage surgical procedures that either were not performed, or were billed as though they were performed in an operating room when they were not. *United States v. Ahmed*, No. 14-cr-277 (E.D.N.Y. 2014).
- October 2015: physician and pharmacy owners criminally charged with prescribing and providing medically unnecessary prescriptions for expensive pharmaceuticals. *United States v. Lerner*, No. 15-cr-20511 (E.D. Mich. 2015):

Trends in Fraud and Abuse Prosecutions: FCA Cases Against Managed Care Plans

- United States ex rel. José R. Valdez v. Aveta, Inc., et al., Case No. 15-cv-01140 (D.P.R.)
 - Whistleblower alleges that managed care plans “knowingly overstated, and/or concealed and failed to correct their overstatements of, risk adjustment scores.”
- United States ex rel. Olivia Graves v. Plaza Medical Centers Corp., Humana, Inc., et al., Case No. 10-civ-23382 (S.D. Fl.).
 - Allegation that plan knew or should have known that the number of patients being diagnosed with diabetes and related conditions increased when a new doctor took over a practice, and thus inflated capitation payments.

- Courts of Appeals nationwide allow courts to base treble damages on the full amount received by the defendant, not the amount the government was overcharged.
- U.S. ex rel. Feldman v. Von Gorp, 697 F.3d 78 (2d Cir. 2012): a teaching hospital received a research grant for a fellowship program, but did not conduct the program in the manner promised in its application. Finding that the hospital's false claims deprived a more worthy applicant from the funds, the Second Circuit allowed treble damages based on the total grant, not the amount of the grant less the value of the fellowship, as proposed by defendant.
 - Hospital described proposed AIDS research program in NIH grant application. Actual executed program deviated from application: different “key personnel”; curriculum changed; and grant money was used to study diseases other than HIV/AIDS.
 - Second Circuit reasoned that total grant was appropriate measure of damages because due to the defendant's alleged misstatement, “the government has entirely lost its opportunity to award the grant money to a recipient who would have used the money as the government intended.”

- *Feldman* case mimics definition of “loss” in Federal Sentencing Guidelines
 - Under Federal Sentencing Guidelines, heightened sentencing for defendants convicted of a “Federal health care offense involving a Government health care program” over \$1 million (2 levels), \$7 million (3 levels) or \$20 million (4 levels). See USSG § 2B.1.1.
 - “Loss” defined as “greater of actual loss or intended loss.” Commentary to Guidelines § 2B.1.1 at § 3.
 - “In a case in which the defendant is convicted of a Federal health care offense, the aggregate dollar amount of fraudulent bills submitted to the ... program shall constitute prima facie evidence of the amount of the intended loss.” Commentary to Guidelines § 2B.1.1 at § 3(f)(viii) (emphasis added).

- In 2010, Congress mandated that HHS identify fraud using predictive modeling.
 - § 4241 of Small Business Jobs Act
- Program is intended to determine whether claims are legitimate *in advance*.
- Is also being used retroactively build FCA and criminal cases.



Real Time Claims Streaming to Build Profiles and Create Risk Scores

As of June 30, 2011, CMS is streaming all Medicare FFS claims through its predictive modeling technology. As each claim streams through the predictive modeling system, the system builds profiles of providers, networks, billing patterns, and beneficiary utilization. These profiles enable CMS to create risk scores to estimate the likelihood of fraud and flag potentially fraudulent claims and billing patterns.

Risk scores enable CMS to quickly identify unusual billing activity and flag claims for more thorough review prior to releasing payment. The system automatically prioritizes claims, providers, beneficiaries, and networks that are generating the most alerts and highest risk scores. CMS is leveraging the benefits of its new high-tech system to complement, not replace, the expertise of its experienced analysts:

■ “Responsible Corporate Officer Doctrine”

- “[A] corporate agent, through whose act, default or omission the corporation committed a crime in violation of the [FDCA] may be held criminally liable for the wrongdoing of the corporation whether or not the crime required consciousness of wrongdoing by the agent.” *U.S. v. Park*, 421 U.S. 658, 670 (1975)

- DOJ: The Yates Memo (September 2015)
 - Focuses on “accountability from the individuals who perpetrated the wrongdoing.”
 - In order to qualify for cooperation credit, companies must provide DOJ with relevant facts pertaining to individual culpability.
 - Criminal and civil investigations should focus on individuals from inception,
 - Criminal and civil government attorneys should be in routine contact with each other during investigations
 - Absent “extraordinary circumstances”, DOJ will not release individuals as part of settlements with companies.
 - Corporate cases should not be resolved without a clear plan to resolve related individual cases
 - Civil attorneys should evaluate whether to bring suit against an individual based on considerations beyond that individual’s ability to pay.

Enforcement Trends: Use of “Responsible Corporate Officer” Doctrine to Exclude Individuals

- If a company is convicted or pleads to a federal health care crime HHS has authority to exclude any individual:
 - (i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know . . . of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or
 - (ii) who is an officer or managing employee . . . of such an entity.
 - » 42 U.S.C. § 1320a-7(b)(15)(A)(i)
- HHS’s position
 - No due process necessary to exclude RCO once entity is sanctioned
 - Evidence that owner, officer, or managing employee knew or should have known creates presumption of exclusion which may be overcome only by “significant factors”
 - » 2010 Guidance for Implementing Permissive Exclusion Authority

- Wire Fraud:

- U.S. v. Harkonen, No. 11-10209 (9th Cir., March 4, 2013):

- » CEO of pharmaceutical manufacturer prosecuted for transmitting – through a company press release – false and misleading information on the effectiveness of off-label treatment and the results of a Phase III drug trial.
 - » Jury convicted on charge of wire fraud, but acquitted on misbranding charge.
 - » Ninth Circuit rejected CEO's appeal, ruling that falsity of press release rendered First Amendment defense inapplicable.

- U.S. v. Carter, No. 14-cr-0002 (M.D. La. 2014):

- » Pharmacy owner criminally charged with health care fraud and wire fraud for billing Medicare Part D plans for recycled/expired pharmaceuticals.

- ACA § 6402(d)(1) governs payments from Medicare or Medicaid:
 - If a person has received an overpayment, the person shall:
 - (a) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
 - (b) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- ACA § 6402(d)(3)
 - Any overpayment retained by a person after the deadline [of 60 days from the date overpayment was identified] for reporting and returning the overpayment is an *obligation* for purposes of [False Claims Act].
- Intent at the time claim was submitted is irrelevant.
- Liability may exist even where company is unaware of overpayment, if company shows “reckless disregard” or “deliberate ignorance” of the mistake.

- How many self-disclosures or refunds to the government has your organization made in 2015?
 1. None
 2. 1-3
 3. 4-6
 4. 7-10
 5. More than 10
 6. Don't know

- Examples of potential overpayment would be receiving payments due to claims for:
 - Incorrect provider payee
 - Services not rendered
 - Payment made by primary insurance
 - Servicing person lacked required license of certification
 - Service inconsistent with physician order
 - Inpatient procedures billed as outpatient
 - Readmissions
 - Duplicate payments
- Query whether a reckless or deliberate failure to identify poor medical services after full payment received could qualify as an FCA violation under the ACA.

- ***U.S. ex rel. Kane v. Continuum Health Partners***, No. 11 Civ. 2325, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015)
 - Potential Sea Change for Providers

- New York federal judge rules that the 60-day clock starts running when a provider becomes aware of a “potential” overpayment
 - At the end of 60 days, the payment has been “withheld” and gives rise to FCA liability

- Creates a strong incentive for whistleblowers to file on day 61 because of the First-to-File Rule

- But there are potential defenses: if the provider is conducting a good faith investigation, the repayment arguably isn’t being “improperly” withheld

- ACA significantly heightens False Claims Act exposure for insurers operating on Exchanges:
 - “Payments made by, through, or in connection with the Exchange are subject to the False Claims Act to the extent that those payments include Federal Funds.”
 - Participating health insurance issuers must comply with ACA’s eligibility requirements “as a material condition of an issuer’s entitlement to receive payments including premium tax credits and cost-sharing reductions.”
 - Damages for FCA violations committed in connection with a payment received via the Exchange include civil penalties (\$5,000 up to \$11,000) plus “not less than three times and not more than six times the amount of damages which the Government sustains.”

Part II: Compliance

- Has your organization been the subject of a government healthcare related audit or investigation over the past 2 years that resulted in substantial recoveries?
 1. Yes
 2. No
 3. I don't know

1. MICs, RACs, ZPICs, etc., audits
2. Conflicts of Interest/Aggregate Spend
3. Increased Anti-Kickback and Stark Enforcement
4. Credentialing/Exclusions
5. Merger/Affiliation Due Diligence
6. Governance
7. HIPAA/Hi-Tech
8. Compliance Regulations / Effectiveness Reviews
9. ACA § 6402(d) – Self-Disclosures
10. Whistleblower actions



Can you answer:

1. What did you do to prevent / detect? and
 2. How could you **NOT** have known?
- Keep in mind regulators/prosecutors always have 20/20 hindsight
 - “Your actions speak so loudly, I can not hear what you are saying” ~ Ralph Waldo Emerson

The Current State of Mandated Compliance

- CORPORATE INTEGRITY AGREEMENTS (US HHS-OIG)--early 1990s
- MANDATED COMPLIANCE DISCLOSURES FOR NON-PROFITS ON IRS 990 (2008) (not required to have compliance standards on conflicts, disclosure, etc.--only to report whether you do)
- MANDATED COMPLIANCE PROGRAMS FOR MEDICARE ADVANTAGE AND PART D (CMS-2009) (72 FR 68700 and program memos)
- MANDATED COMPLIANCE PROGRAMS FOR FEDERAL CONTRACTORS (2009) (FAR 52.203-13) (reporting of “significant overpayment(s)” on the contract)
- MANDATED “EFFECTIVE” COMPLIANCE PROGRAMS FOR NY MEDICAID PROVIDERS-(New York OMIG 2009) (18 NYCRR 521)
- MANDATED REPAYMENT OF MEDICARE AND MEDICAID OVERPAYMENTS (PPACA Section 6402 (2010))
- MANDATED COMPLIANCE PROGRAMS FOR NURSING HOMES AND SOME OTHER HEALTH PROVIDERS--Patient Protection and Affordable Care Act Sections 6102, 6401 (2013 for nursing homes)

Mandatory compliance - §6401(7)(A)

Patient Protection and Affordable Care Act (ACA)

- As a condition of enrollment:

...shall have in operation a compliance and ethics program that has been reasonably designed, implemented and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations AND in promoting quality of care consistent with regulations developed by the Secretary, working jointly with the HHS OIG.

- Still waiting regulations

- Could you convince:

- USAO/DOJ
- OIG?
- MFCU?
- OMIG?

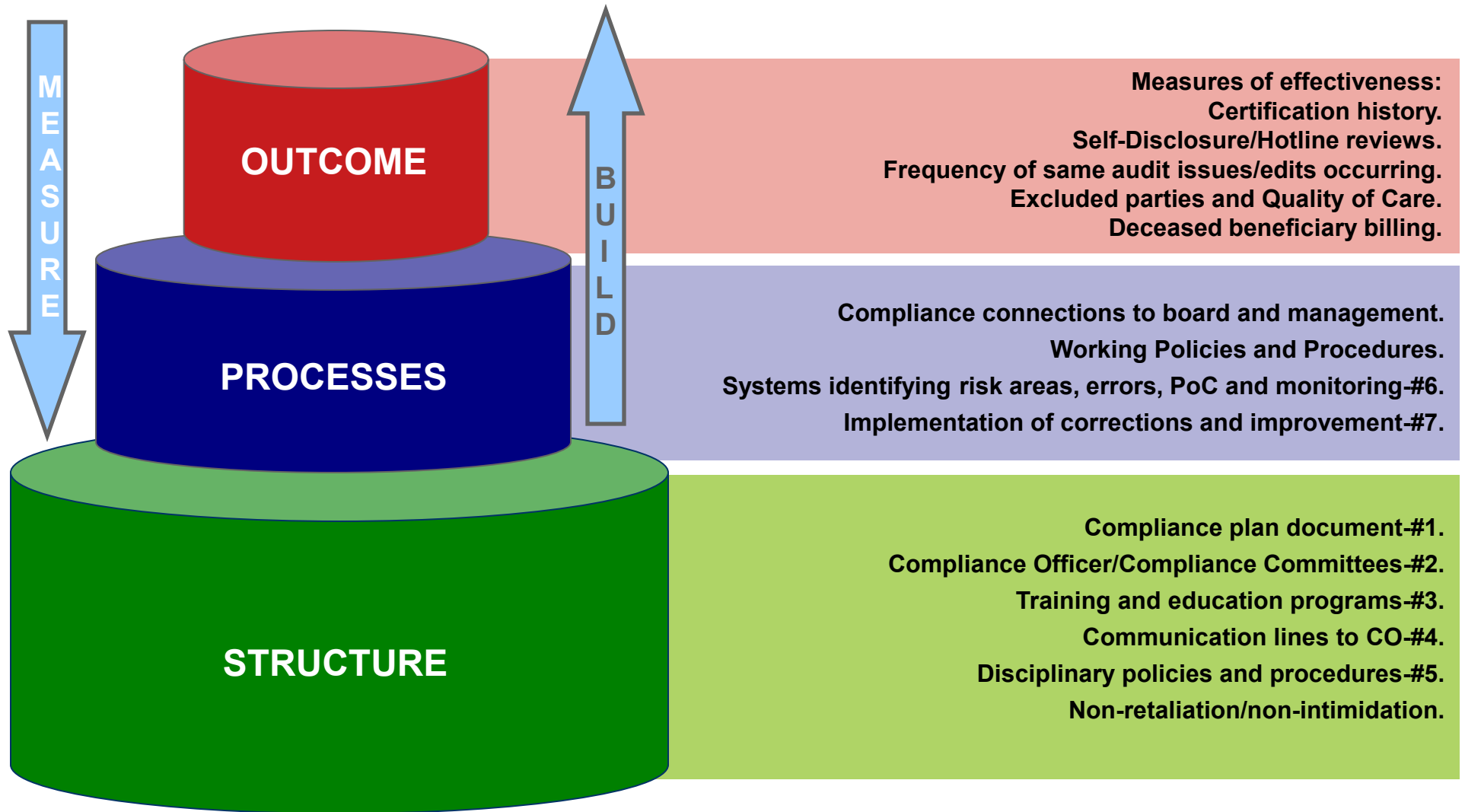


- November 2015: DOJ Criminal Fraud Section hires compliance consultant to assist prosecutors in assessing corporate compliance program

What does a Successful Compliance Program Look Like?

- We have a hotline and a code of conduct.
- We have the above AND we did some training and sometimes the CO gets to see the CEO.
- We have the above, AND a lot of policies and some communications about compliance . . . CO reports to the CEO and occasionally even gets to hear about board meetings.
- We have the above AND there is an active compliance committee that is made up of key decision makers who are actively engaged and address important compliance issues in a timely manner . . . The CO also reports to the BOD.
- The organization has a well-documented and executed seven-element program that achieves, focuses on, and measures outcomes . . . The CO has the support of the C-suite and the BOD, and there is clear accountability for compliance throughout the organization . . . The CO is viewed as a strategic business partner, and the majority of management understands the breadth of the compliance program and their obligation to support it.

How to Build and Measure a Compliance Program for Effectiveness



Mandatory Accountable Care Organization (ACO) Compliance Plan Elements

- Designated compliance official who is ***not legal counsel*** to the ACO and reports directly to the ACO's governing body
- Compliance training for ACO as well as its participants and providers/suppliers
- Annual Certification of Compliance
- **MUST *report probable violations of law*** to an appropriate law enforcement agency

42 C.F.R. § 425.300

- Will look similar to processes utilized by managed care and ACOs of their downstream entities and participants respectively.
- Will likely be some combination of contractual obligations, monitoring and attestations of compliance.
- Focus will likely be less on claims and more on communication, accuracy of reporting, adherence to implementation plan, and distribution of funding.

Element 1- Policies and Procedures

- Communication and access
- Application to multiple entities
- Inconsistencies across providers
- Monitoring implementation and adherence

Element 2 – Compliance Officer / Committee

- Serving more than one organization
- CO Reporting Structure (Executives and Board)
- Composition and participation of Compliance Committee

Element 3 – Training / Education

- Duplication of information, efforts
- Training specific to policies and risks
- Need to distinguish from existing focus / practices
- Evidence of completion

Element 4 – Communication / Reporting

- Adequate efforts to publicize reporting options
- Communication of types of issues to report
- Coordination of hotlines and referrals to other departments

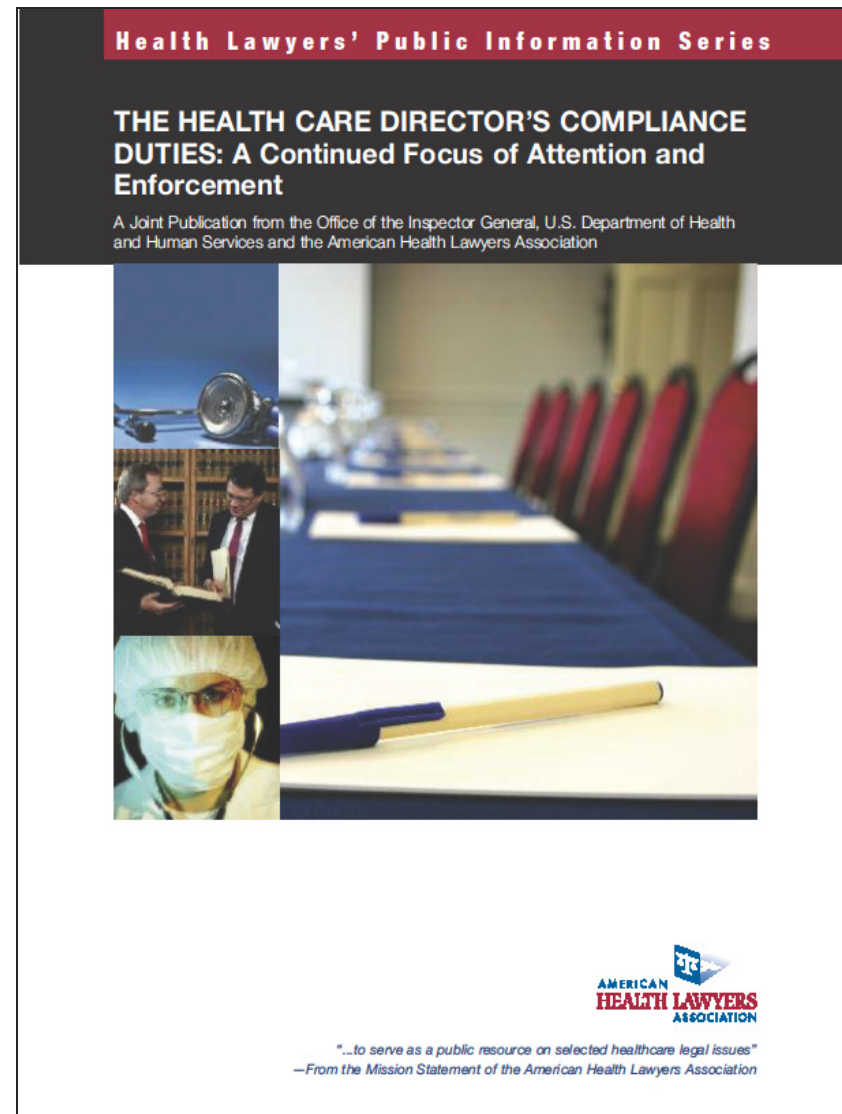
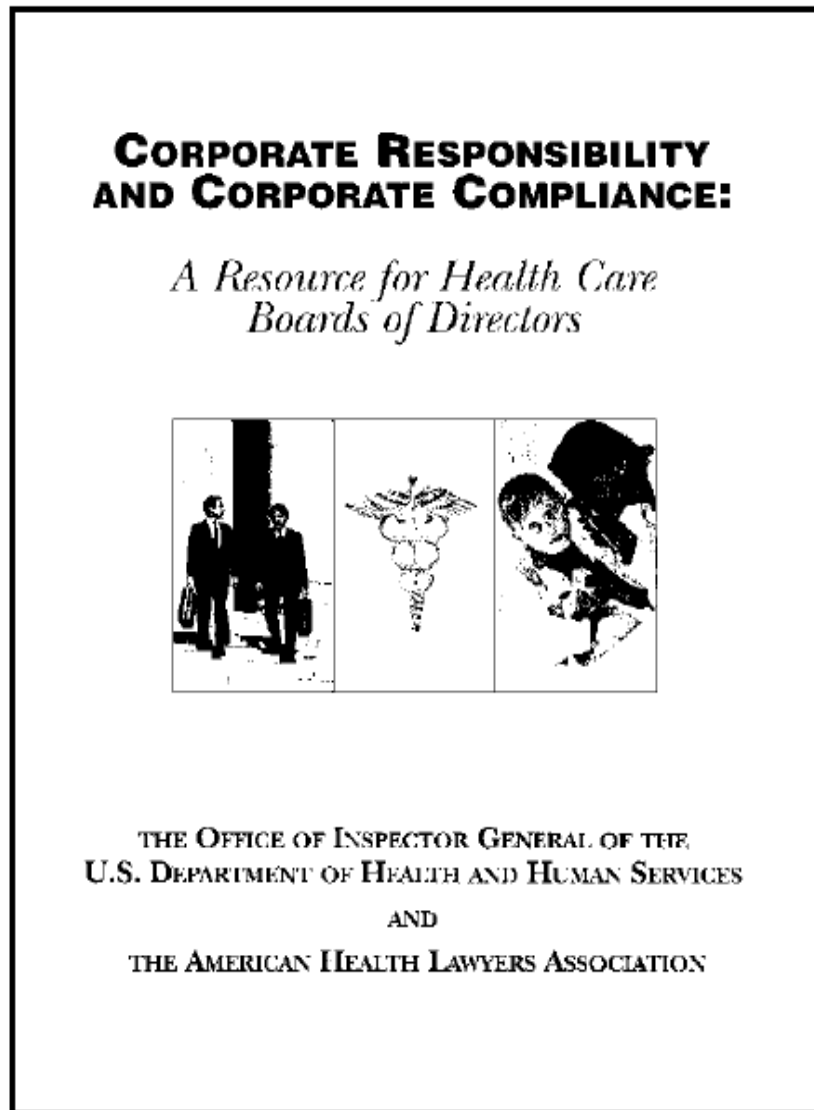
Element 5 - Discipline

- Relationships include more than just employment making enforcement difficult
- Coordination
- Auditing of disciplinary actions

Elements 6 & 7 – Risk Identification, Monitoring and Follow-up

- Coordination across participants and partners
- Access to information
- Timely communication and follow-up
- Who owns process and reporting requirements
- Impact on failure to report/disclose

- Develop culture, tone at the top, share accountability
- Credible Compliance Officer with adequate resources and direct access to the Board and Executive Team
- Require reporting of concerns
- Build compliance into operations
 - “Active” monitoring and internal auditing efforts built into department operations
 - Consider including predictive modeling?
 - » Pros and Cons
 - » Use in high-risk areas only?
- Address issues and track information
 - Inquiries/complaints/repayments



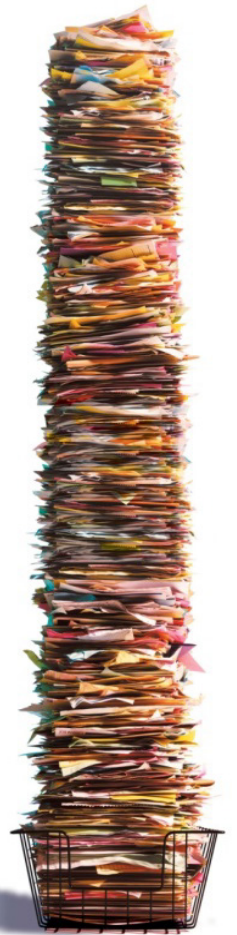
- Assume limited knowledge, time and resources, too much information, competing priorities, overcrowded agendas
- Make the connections—How does C&E program impact the bottom line? Operational efficiencies? Competitive advantage? Strategy and business decision support? Ability to prepare for emerging issues? Ability to contract/new business opportunities & increased revenue potential?
- Ensure they understand the environmental risks and how they affect scope of the C&E program responsibilities vs. management responsibilities
- Don't report on activities; report on key issues and outcomes
- Identify trends, use operational data—where we are, where we are headed...

Considerations of Fraud

INQUIRY	RESPONSE
a. What are your views on fraud?	
b. Do you have any knowledge of actual, alleged or suspected fraud affecting the organization?	
c. How does the Board exercise oversight of fraud risk assessment and controls established to address fraud risk?	
d. Is the organization in compliance with laws and regulations that may have a material effect on the financial statements?	
d. Has the organization's service organization reported, or is otherwise aware of, any fraud, noncompliance with laws and regulations, or uncorrected misstatements at the service organization affecting the organization's financial statements?	
Signature:	
Name & Title	, Chairman of the Board
Date:	

- Has your organization undergone an external compliance program effectiveness review in the last 18 months?
 1. Yes
 2. No
 3. I don't know

- Compliance program supporting documentation
 - Compliance policies, plans and other documents that describe the entity's approach to managing the compliance program
 - Documentation describing operational functions that interact with the compliance program
 - Compliance committee and Board resolutions, agendas, and minutes that describe their roles in overseeing compliance
 - Compliance training and communications regarding compliance
 - Hotline information, logs and following up email searches and interviews when appropriate
 - Compliance risk assessments and documented follow-through
 - Compliance auditing/monitoring reports, trends and corrective action plans
 - Summaries of incidents self-reporting, disclosures,
 - Evidence of enforcing compliance standards



Organizational Influences

- Culture
- Structure and Resources
- Competing Objectives



Outside Influences

- Government surveys, audits, investigations
- Whistleblowers
- Changing rules
- Mergers/acquisitions

- Handling a Criminal Case or FCA Case Where the Government Has Intervened
 - Document Hold
 - Internal Investigation
 - Upjohn Warnings
 - Consider Counsel for Certain Employees
 - Privilege Waiver Issues When Cooperating

- Handling an FCA Case Where the Government Has Not Intervened
 - Document Hold
 - Obtain USAO filings under seal

- Motion to Dismiss
 - Public Disclosure Bar
 - 9(b)/12(b)
 - Causation



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Memberships and Activities

- Former Member, Board of Directors, NY Council of Defense Lawyers
- Member, Board of Editors, Business Crimes Bulletin
- Member, Board of Directors and Co-Chair, Foreign & International Law Committee, NY County Lawyers Association
- Former Member, Criminal Law Committee, Association of the Bar of the City of New York
- Former Member, National Association of Criminal Defense Lawyers
- Member, New York Women's Criminal Defense Group

Experience

- Represented multiple pharmaceutical, medical device and health care companies and providers in criminal and civil FCA, off-label and kickback cases
- **See Website:** <http://www.manatt.com/JacquelineWolff>

Focus Areas

- Foreign Corrupt Practices Act (FCPA) Violations
- Healthcare Fraud
- Securities Fraud
- Food, Drug & Cosmetic Act (FDCA) Violations
- Tax Crimes
- Corporate Immigration Crimes
- Other regulatory-based violations



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Experience

- Former federal prosecutor
- Former Member of DOJ/HHS Health Care Fraud Prevention and Enforcement Action Team and Health Care Fraud Strike Force
- Represented insurers, providers, pharmaceutical and medical device companies, and individuals in a wide range of criminal and civil government investigations and commercial litigation
- **See Website: <https://www.manatt.com/Arunabha-Bhoumik>**

Focus areas

- Corporate Investigations & White Collar Defense
- False Claims Act litigation
- Health Care Fraud
- Securities Fraud
- Commercial Litigation



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Memberships and Activities

- Co-Chair – NYS Bar Association Health Law Section Committee on Fraud, Abuse and Compliance
- HCCA – Board Member, CHC
- Frequent speaker/author on compliance-related topics

Experience

- First Deputy – NYS OMIG
- Interim Compliance/Privacy Officer – Yale-New Haven Health
- Compliance Officer – Northeast Health

Focus Areas

- Compliance and privacy program assessment and assistance
- Internal investigations
- OIG/CMS /OMIG /MFCU – audit / investigation /exclusion defense, negotiation, and settlements
- Self-disclosures
- Board of Directors, senior management and staff training