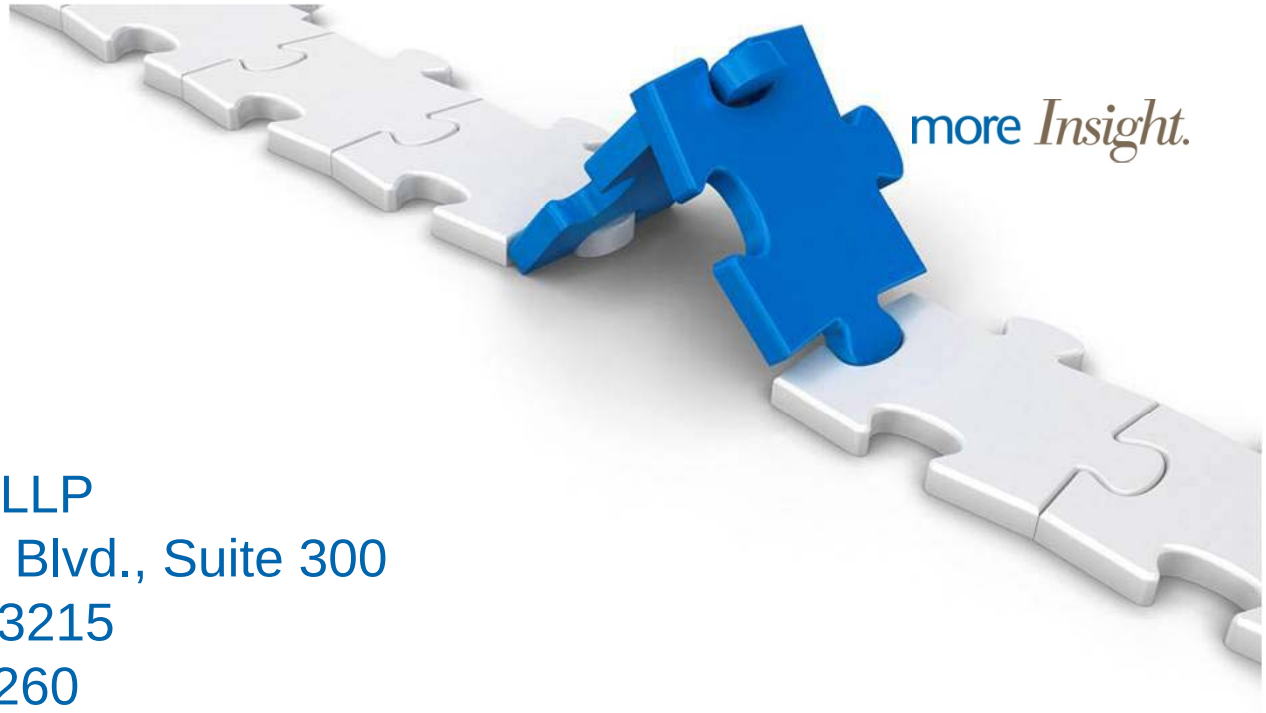
How to Survive a Government Audit

Lorman Educational Services

Independence, Ohio

Dinsmore



Presenter:

Thomas W. Hess
Dinsmore & Shohl LLP
191 W. Nationwide Blvd., Suite 300
Columbus, Ohio 43215
Phone: 614.227.4260
Fax: 614.628.6890
Email: thomas.hess@dinsmore.com

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

1. Federal Fraud and Abuse Laws:

a. Anti-Kickback Statute, Statutory Exceptions, Regulatory Safe Harbors

42 U.S.C. §1320a-7b

- Criminal statute
- Prohibits "knowingly and willfully" making false statements or representations of material fact in applying for benefits or payments under "Federal health care programs" (includes state health care programs funded in any part with Federal funds)
- Prohibits "knowingly and willfully" soliciting or receiving any "remuneration" (including any kickbacks, bribes or rebates) directly or indirectly, overly or covertly, "in cash or in kind," in exchange for referrals or in return for purchasing, leasing, ordering or arranging for or recommending the same if payment may be made in whole or in part under a Federal health care program

- Violations may result in a felony conviction with penalties including imprisonment for up to five years and a fine of up to $25,000
- The law has been interpreted to cover any arrangement where even "one purpose" of the remuneration was to induce referrals
- In addition, violation of the law may result in the imposition of civil monetary penalties of up to $50,000 per violation and exclusion from participation in federal health care programs.

b. False Claims Act

37 U.S.C. §3729 et seq.

- Originally enacted in 1863 as a response to widespread abuses by government contractors during the Civil War.
- Government agencies and private plaintiffs have made expanded use of the FCA since it was amended in 1986 to recover many times the government's losses for health care fraud.
- Civil statute that prohibits the knowing submission of false or fraudulent claims to the government for payment
- Civil penalty of not less than $5,500 and not more than $11,000 per claim plus treble (triple) damages
- Authorizes the filing of "qui tam" (whistleblower) lawsuits allowing private plaintiffs (usually former and sometimes current employees) to bring an action on behalf of the United States

b. False Claims Act (cont'd)

- Federal government is afforded an opportunity to intervene and prosecute the case
- The private plaintiffs (called "Relators") receive a share of any recovery of up to 30%
- An increasing area of focus of government investigations during recent years has been financial relationships between hospitals and physicians under AKS and Stark.
- To prove a *prima facie* case under the FCA:
  - Prove either (1) that a false claim (2) was presented by the defendant to the United States for payment or approval (3) with the defendant's knowledge that the claim was false
  - Or prove (1) that a false statement in support of a claim (2) was presented by the defendant to the United States for approval of a claim, (3) with the defendant's knowledge that the statement in support of the claim was false.

b. False Claims Act (cont'd)

- The FCA defines “knowing” and “knowingly” to mean “that a person, with respect to information (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information.”

c. Civil Monetary Penalties Law

42 U.S.C. §1320a-7a

- OIG may seek CMPs for a wide variety of conduct (42 CFR §1003.102), including:
  - False or fraudulent claims
  - AKS violation
  - Stark violation
- In most cases where OIG may seek CMPs, may also seek exclusion from participation in all Federal health care programs
- Most CMP demands are resolved through settlement with no decision made on the merits of the OIG's allegations

c. Civil Monetary Penalties Law (cont'd)

- OIG may seek different amounts of CMPs and assessments based on the type of violation at issue:
  - False or fraudulent claim = up to $10,000 for each item or service improperly claimed and an assessment of up to 3 times the amount improperly claimed
  - AKS violation = up to $50,000 for each improper act and an assessment of up to 3 times the amount at issue (regardless of whether some of the remuneration was for a lawful purpose)

d. HIPAA Criminal Statutes (Health Insurance Portability and Accountability Act of 1996)

42 U.S.C. §1320a-7c -- Health Care Fraud and Abuse Control Program

- HIPAA was, at the time it was enacted, one of the most comprehensive attempts to fight fraud in federal health care programs and expand the scope of health care fraud and abuse prevention
- Coordination of anti-fraud and abuse efforts at federal, state and local levels
- Program conducts investigations, audits, inspections, evaluations of health care providers
- A central fraud and abuse database was established for the reporting of final adverse actions (sanctions) against health care professionals, providers and suppliers

d. HIPAA Criminal Statutes (cont'd) (Health Insurance Portability and Accountability Act of 1996)

18 U.S.C. §1347 -- Health Care Fraud and Scheme

- Prohibits knowing and willful actions or attempts to: (1) execute a scheme to defraud any health care benefit program or (2) obtain by means of false representation any money or property of a health care benefit program
- Potential penalties include fines and imprisonment up to 10 years; up to 20 if serious bodily injury; up to life sentence if death

e. 18 U.S.C. §669 – Theft or Embezzlement in Connection with Health Care Benefit Program

- Prohibits knowing and willful embezzlement, stealing or otherwise without authority converting or intentionally misapplying money or property of a health care benefit program
- Potential penalties include fines and imprisonment up to 10 years; if less than $100 at issue, maximum imprisonment 1 year

f. 18 U.S.C. §1518 – Obstruction of Criminal Investigations of Health Care Offenses

- Anyone who willfully prevents, obstructs, misleads or delays or attempts to prevent the communication of information or records relating to a federal health care offense to a criminal investigator may face up to 5 years' imprisonment

g. 18 U.S.C. §1035 -- False Statements Relating to Health Care Matters

- Anyone who knowingly and willfully falsifies or conceals a material fact or makes a materially false, fictitious or fraudulent statement "in any matter involving a health care benefit program" may face fines and up to 5 years' imprisonment

h. State Laws

R.C. §4113.52 (Ohio Whistleblower Protection Act)

- An employee may report an employer for a violation of any state or federal statute or ordinance or regulation of a political subdivision that the employer has the authority to correct if the employee reasonably believes the violation is a criminal offense that is likely to cause an imminent risk of physical harm to persons or a hazard to public health or safety, a felony, or an improper solicitation for a contribution.
- Employee shall first notify supervisor orally and then file a written report with sufficient detail to identify and describe the violation.
- If employer does not correct or make a reasonable and good faith effort to correct within 24 hours after oral notification or receipt of the report, whichever is earlier, the employee may file a written report with the prosecuting authority, inspector general, or any other appropriate public official or agency with regulatory authority over the employer and the industry, trade or business in which the employer is engaged.

h. State Laws (cont'd)

R.C. §4113.52 (Ohio Whistleblower Protection Act)

- For certain more serious criminal activities, no report to the employer is required before reporting to authorities.
- An employee may similarly report an employee to the employer, but is not authorized to make the subsequent report to authorities under the statute.
- An employer may not take disciplinary or retaliatory action against an employee for making any report under this statute; reasonable good faith efforts to determine the accuracy of information as to reports are required.
- If the employee does not make reasonable good faith efforts to determine the accuracy of information, the employee may be subject to disciplinary action for reporting without a reasonable basis to do so.
- If the employer retaliates in violation of the statute, a claim for injunctive relief may be filed in Common Pleas Court by the employee if done within 180 days.
- If employee prevails in the action, may receive reinstatement, back pay, full fringe benefits, seniority, attorneys' fees, witness fees, expert fees, etc.

h. State Laws (cont'd)

R.C. §3999.22

- No person shall knowingly solicit, offer, pay, or receive any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual for the furnishing of health care services or goods for which whole or partial reimbursement is or may be made by a health care insurer, except as authorized by the health care or health insurance contract, policy or plan.
- Exceptions: deductibles or co-payments; discounts; bona fide payments within an entity or entities under common control; bona fide employees; lease, management or other business relationship;
- Criminal violation – 5th degree felony on first offense and 4th degree felony on each subsequent offense.

h. State Laws (cont'd)

R.C. §2913.40 (Medicaid Fraud)

- No person shall knowingly make or cause to be made a false or misleading statement or representation for use in obtaining reimbursement from Medicaid.
- No person, with purpose to commit fraud or knowing that the person is facilitating a fraud, shall do either of the following: (1) Contrary to the terms of the person's provider agreement, charge, solicit, accept, or receive for goods or services that the person provides under Medicaid any property, money, or other consideration in addition to the amount of reimbursement under Medicaid and the person's provider agreement for the goods or services and any cost-sharing expenses authorized by law. (2) Solicit, offer, or receive any remuneration, other than any cost-sharing expenses authorized law, in cash or in kind, including, but not limited to, a kickback or rebate, in connection with the furnishing of goods or services for which whole or partial reimbursement is or may be made under Medicaid.

h. State Laws (cont'd)

R.C. §2913.40 (Medicaid Fraud)

- No person, having submitted a claim for or provided goods or services under Medicaid, shall do either of the following for a period of at least six years after a reimbursement pursuant to that claim, or a reimbursement for those goods or services, is received under Medicaid: (1) Knowingly alter, falsify, destroy, conceal, or remove any records that are necessary to fully disclose the nature of all goods or services for which the claim was submitted, or for which reimbursement was received, by the person; (2) Knowingly alter, falsify, destroy, conceal, or remove any records that are necessary to disclose fully all income and expenditures upon which rates of reimbursement were based for the person.
- Medicaid fraud is a 1st degree misdemeanor.

h. State Laws (cont'd)

R.C. §2913.40 (Medicaid Fraud)

- If the value of property, services, or funds obtained is $500 or more and is less than $5,000, Medicaid fraud is a 5th degree felony.
- If the value of property, services, or funds obtained is $5,000 or more and less than $100,000, Medicaid fraud is a 4th degree felony.
- If the value of the property, services, or funds obtained is $100,000 or more, Medicaid fraud is a 3rd degree felony.
- If convicted, must pay cost of investigating and prosecuting case in addition to other penalties.

i. Intersection of FCA, AKS, Stark and CMPL

- Since the 1990s, the United States and qui tam plaintiffs ("Relators") have increasingly pursued remedies available under the FCA for alleged violations of AKS and Stark (in 1997, the CMPL was made applicable to the AKS).
- The theory is that claims for reimbursement are "tainted" by AKS/Stark violations and constitute "false claims" within the meaning of the FCA as a result of “false” certification of compliance with laws
- Health care continues to top the government's list of federal fraud investigation priorities, yielding the lion's share of recoveries in FCA cases in 2008
- $2.4 billion in FCA settlements and judgments in FY 2009

j. OIG Semiannual Report to Congress: Statistical Highlights

FY 2011

- Recover $5.2 Billion
- $627.8 Million in audit receivable
- $4.6 Billion exclusions from participation in federal health care programs
- 723 criminal actions
- 382 civil actions (FCA and unjust enrichment lawsuits in federal court; CMPL settlements; administrative recoveries re: provider self-disclosures)
- 2,662 in investigative receivables

k. Overview of Recent Enforcement Activities and Settlement Reported by OIG

- Allegan, Inc.
  - Misfunding
  - $600 Million
- Forest Pharmaceuticals, Inc.
  - Misfunding
  - $313 Million
- Omnicare
  - Charging more than it charges private insurances
  - $21 Million
- Novantis Pharmaceuticals Corp.
  - Off-labeling
  - $422.5 Million

k. Overview of Recent Enforcement Activities and Settlement Reported by OIG

- SB Pharmco Puerto Rico, Inc.
  - Distribution of adulterated drugs
  - $750 Million
- Christ Hospital
  - “Pay to Play”
  - $108 Million
- Detroit Medical Center
  - Improper relationships with referral physicians
  - $30 Million

2. Overview of Compliance

a. Discovery of a Healthcare Violation – The Dilemma

- Counsel representing a party or witness involved in a civil healthcare action, therefore, should never take the possibility or fact of a criminal investigation lightly. Allegations of a healthcare violation may surface during an internal investigation, routine audit, or through procedures established in a compliance plan.

b. Benefits of Voluntary Disclosure

- Voluntary disclosure may influence the broad range of discretion available to federal prosecutors.
- Voluntary disclosure is a good opportunity to demonstrate that the violation was an aberrant event.
- In evaluating the decision to disclose, it may be useful to consider the factors the government assesses under established voluntary disclosure plans.

b. Benefits of Voluntary Disclosure (cont'd)

The government considers:

1. Whether the disclosure was voluntary, timely, and complete;
2. The degree of disclosure;
3. The existence of a regular and comprehensive compliance program;
4. The pervasiveness of noncompliance;
5. Internal disciplinary actions; and
6. Subsequent compliance efforts.

- Another benefit of voluntary disclosure is the potential for reduction of criminal fines.

c. Costs of Voluntary Disclosure

- The most significant cost of disclosure is that voluntary disclosure may needlessly initiate a government investigation, which could lead to criminal liability, exclusion, administrative money penalties, or civil liability.
- Where the government already suspects improper conduct, disclosure may alert the government to a more serious problem than that currently under investigation.
- The government is not bound to forego prosecution simply because an entity voluntarily discloses a violation.
- Though disclosure may not lead to a criminal charge, it may provide or lead to enough evidence to support exclusion or other administrative action.

d. Is there a duty to disclose and refund overpayments?

- While there may be no duty to report mistakes or illegal behavior, if a provider becomes aware that it has received an overpayment, the provider has legal obligation to refund.
  1. The government can compel disclosure of information
     a. The OIG can subpoena documents
     b. The Attorney General can issue civil investigative demands (CID)
     c. Administrative Investigative Demands (AID)
     d. Search warrants

e. The Attorney-Client Privilege

1. Attorney-client privilege protects some communications and documents from disclosure.
   - The attorney-client privilege applies to confidential communications between lawyer and client, made for the purpose of obtaining legal advice of any kind, except if the protected is waived.
   - Its purpose is to encourage full and frank communications between attorneys and their clients and thereby promote broader public interests and the common good.
   - The attorney-client privilege protects confidential communications both to and from counsel.

e. The Attorney-Client Privilege (cont'd)

2. Attorney work product doctrine protects the notes, materials and mental process from disclosure.
   - The work product privilege is separate and distinct from the attorney-client privilege.
   - The work product privilege applies to any document prepared in anticipation of litigation by or for the attorney.
   - The Supreme Court has distinguished between two types of work product. "Fact" work product is the evidence or materials gathered by the attorney and it is given less protection. "Opinion" work product is the lawyer's mental impressions, opinions, and conclusions and is given almost absolute immunity from discovery.
   - In civil litigation, discovery of work product is governed by Rule 26 of the Federal Rules of Civil Procedure.

e. The Attorney-Client Privilege

3. If an internal review is conducted by an attorney, or under the direction of an attorney, then the attorney-client privilege and work product doctrine will apply to all conversations and correspondence produced by the review, unless there is a waiver.
4. Both the attorney-client and work product privileges can be waived by:
   - Disclosure of confidential information constitutes a waiver of the privilege.
   - Agreeing to allow the government to review an audit report may waive the privilege.
   - Disclosing part of an internal review.

f. Non-Privileged Reviews

1. Should be routine part of compliance program.
2. Reasonable “due diligence” standard.

g. External/Expert Reviews

1. Retain expert through counsel
2. Define the scope of the review
3. Securing unbiased reviews – prior work by reviewing expert
4. Dealing with expert findings

3. How Investigators Develop a Case

a. Government Tools

1. Civil Investigative Demands
2. Subpoenas
3. Search Warrants
4. Electronic Surveillance
5. Wiretapping

3. How Investigators Develop a Case

b. Human Sources Information

1. Competitors
2. Current employees and disgruntled former employees
3. Patients or families who have made inquiries or complaints
4. Targets or subjects of an investigation
5. Doctors and nurses who are dissatisfied with a provider's practices
6. Undercover agents who pose as employees or patients
7. Payors

4. Common Reasons for Inappropriate Documentation/Billing

a. Lack of knowledge of Federal and State laws and regulations
b. Ability to acknowledge functional weaknesses and vulnerabilities
c. Failure to provide appropriate service because of financial pressures which create the incentive to underutilize
d. Lack of oversight when using outside billing companies

5. Billing and Documentation Compliance Audit Tips

a. Focus on efforts on risk areas/past problematic activities
b. Should be performed with an element of SURPRISE!
c. Verify basic Medicare coverage criteria
d. Compare claim to supporting documentation

6. How to Conduct an Internal Investigation

a. Criteria to Consider

1. Define Scope and Criteria to Evaluate: Purpose, Pervasiveness and Procedures;
2. Professional Judgment;
3. Cost/Benefit;
4. Assign Resources (Multidisciplinary);
5. Private Investigators/Specialty Resources;
6. Outside Counsel and Consultants (Independence);
7. Respond to Third Party Inquiries (with a point person who log documents and maintains integrity & control);
8. Use your attorney-client privilege to maintain confidentiality;

6. How to Conduct an Internal Investigation

a. Criteria to Consider (cont'd)

9. Have an Analysis of the Results/Reporting;
10. Control Public Disclosures and Eliminate Fear of Retribution;
11. Use Interviews to develop a chronology and corroborate/document facts;
12. Have knowledgeable interviewers and sworn statements from witnesses;
13. Keep all original documents in their original form and in a secure place;
14. Be Objective – it's better that you find an issue first for damage control;
15. Elicit help from those who have clinical and analytical skills to search for billing compliance and medical necessity/quality of care;
16. Communicate all results to management, be sure to include a corrective action plan; and
17. Remember, it is important to control the process. Be proactive not reactive!

7. Scoring of Legal Liability Index

- Do you have written standards concerning the clinical **documentation**?
- Do you have written **standards of legal and ethical conduct**?
- Do you have written policies that promote your **commitment to compliance**?
- Have you designated a **chief compliance officer**?
- Do you offer **education and training programs**?
- Do you use **audits**?
- Do you have written policies for using **disciplinary actions**?

7. Scoring of Legal Liability Index

- Do you have written policies for **investigation and remediation**?
- Do you include adherence to compliance as an element in **evaluating**?
- Do you have written policies addressing the non-employment or retention of **sanctioned individuals**?
- Do you maintain a **hotline**?
- Do you have written policies and procedures to ensure all **records**?