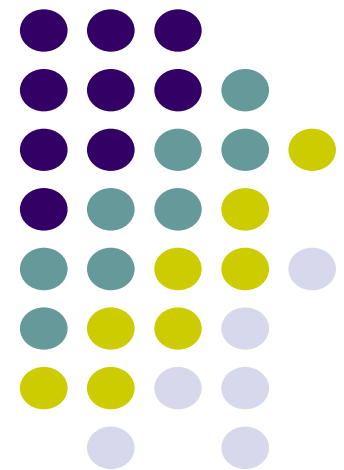
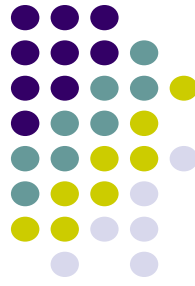


**HCCA Physician Practice
Compliance Conference**
San Francisco, CA

**Understanding Focus of
Enforcement in
Physician Practice Settings**

Stephen A. Morreale, D.P.A., CHC
Compliance & Risk Dynamics
HHS-IG/Chief Investigations (Ret.)

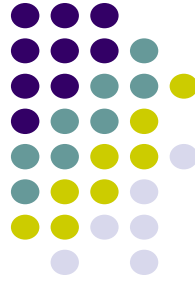




Session Overview

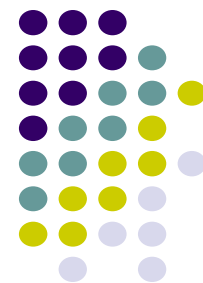
- Road to Practice Scrutiny
 - How will they have time to look at my practice?
- Quality of Care: Using FCA
- Relators and Prevention Strategies
 - Who steps forward?
- Keeping issues and complaints internal
- Conducting thorough internal inquiries
- Handling Official Requests for Records

Medical Service Providers

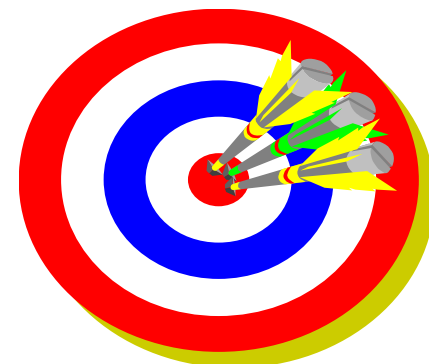


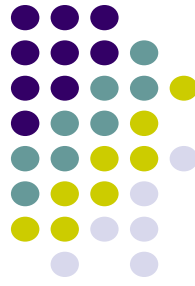
- What factors can trigger a look from investigators?
- What actions can occur?
- Can Quality of Care trigger FCA charges?
- What is the state vs. federal exposure for actions/inaction?

Recent Enforcement Activities & Trends



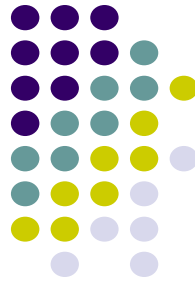
- ✓ OIG Guidance, ie: , Physician practice, supplemental hospital, pharma, Part D
- ✓ Revised Federal Sentencing Guidelines
- ✓ Deficit Reduction Act
- ✓ Sarbanes-Oxley
- ✓ Quality Standards
- ✓ SEC
- ✓ NIH
- ✓ State Laws & Regulations
- ✓ State IG





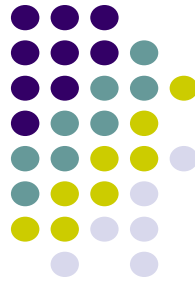
Federal Health Programs

- Contract with Medicare and Medicaid
 - Many strings attached
- Powerful and serious sanctions or consequences for non-compliance, if violation found
- Similar to IRS actions
- Exclusion potential



CMS Cost Estimates

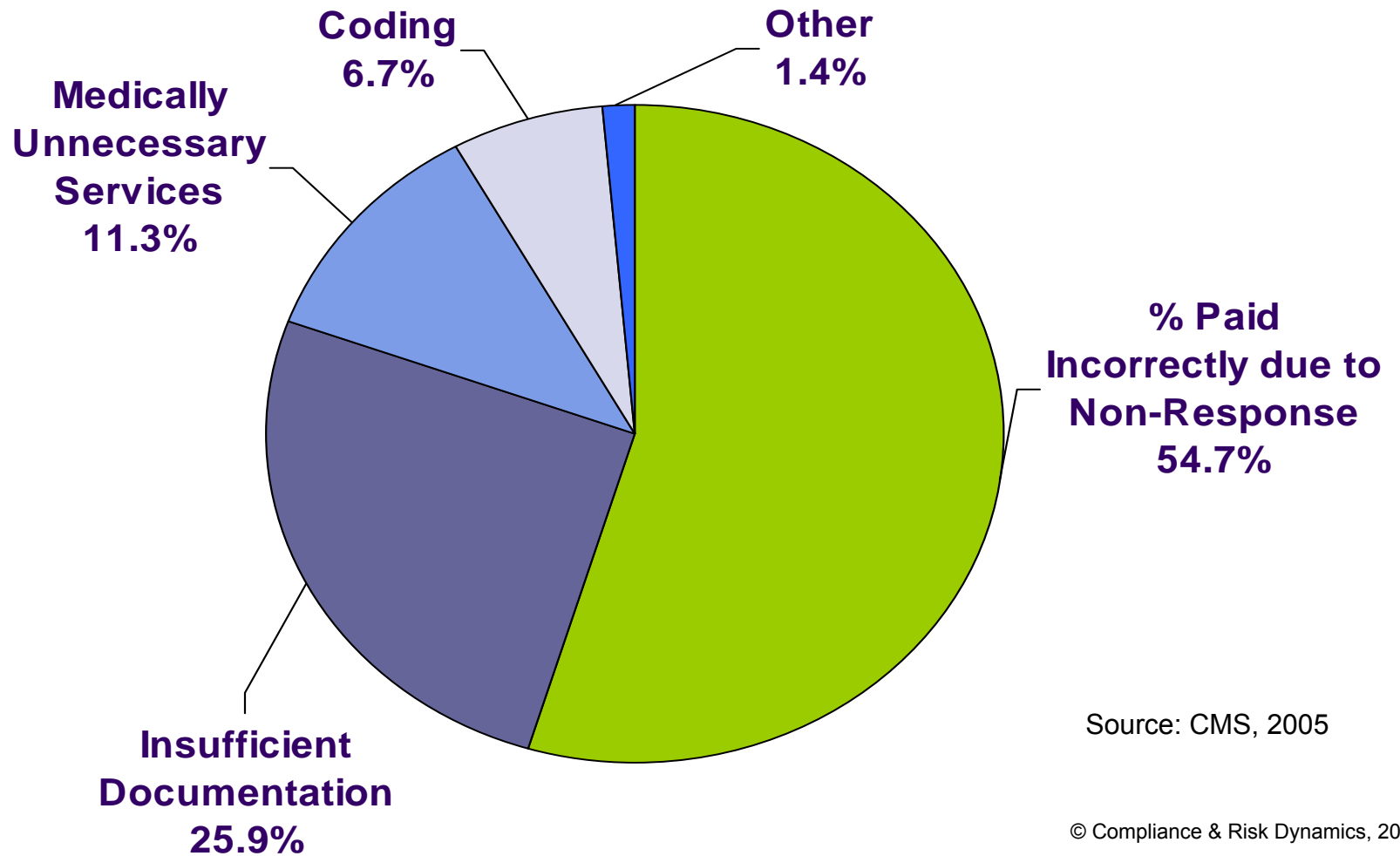
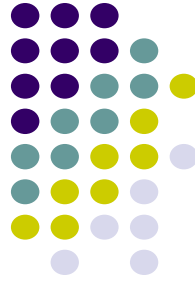
- In 1965 split was 25% Gov vs. 75% private
- 2004 USG paid 46% of \$1.8 Trillion in Medical expenses
- By 2014-Medical payments rise to \$3.6 Trillion USG will pay nearly 50% --totaling \$1.8 Trillion
- Will account for nearly 19% of GDP in 2014.



Medicare Expenditures

- Average organization see 6% loss of revenues through fraud schemes
- HHS-OIG found that 6.3% of 2001 claims were improperly billed, lacked documentation or were fraudulent
- Estimated \$12.1 billion loss
- NHCAA estimates of 2003 HC expenditures—3% fraud = \$51 billion per year

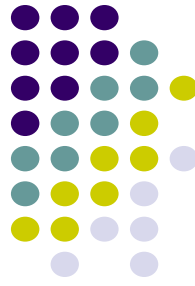
Causes of Errors*



Source: CMS, 2005

© Compliance & Risk Dynamics, 2005

* Values are unadjusted

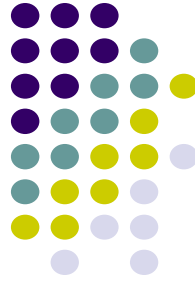


Part D-Medicare Drug Benefit

- MEDIC units being formed— PSC's for Rx Benefit
- Beneficiaries pay \$35 for discount Rx card
 - Pay for first \$250 of drug costs
 - Medicare picks up 75% of next \$2k in expenses
 - From \$2100 to \$5,000 beneficiary liable
 - Over \$5,100 USG pays 95%
 - Gap insurance rising
- Expected USG outlay — \$534 to 720 Billion

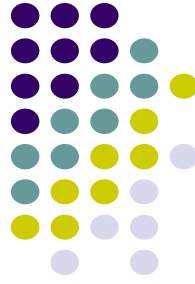
Source: CMS Report 2005

Importance of people in Compliance



- People can make or break organization
- Can represent your best compliance program
- Focus on:
 - Staff
 - Patients
 - Patient's families
 - Vendors

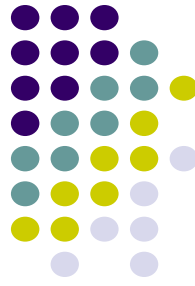
Importance of People

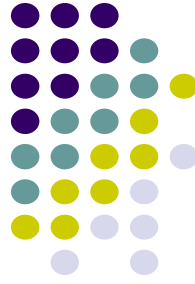


- Don't let external reporting be only outlet
- Let people know who will listen to complaints/issues
- Get back to complainant with action taken
- Use Hotline Service

Anatomy of a Relator

- Disgruntled employee
- Has raised issue inside organization
- Feel they have been ignored

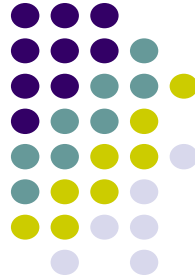




Who are Relators?

- Employees: Former and Current
- Partners
- Competitors
- Vendors
- Nurses
- Compliance Officers
- Auditors

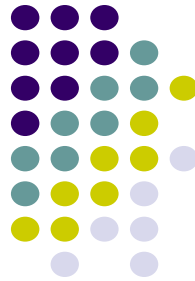
Focus: Billing Consultants



- Bad advice?
- Focus shifts from practice to billing consultant

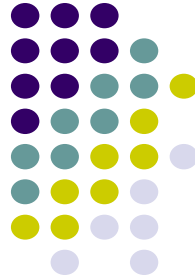
Focus: Rebate Issues

- Rebates for prescribing
- Rebates occur after payment
- Can be seen as inducement
- When



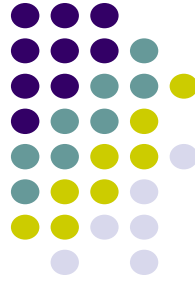
Focus: Stark Issues

- Financial relationships
- Improper referrals

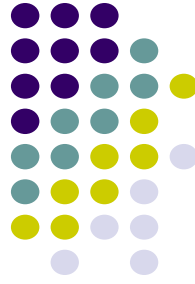


Issues of Ethics & Principles

- Patient complaints
- Patient family complaints
- Clinical staff complaints

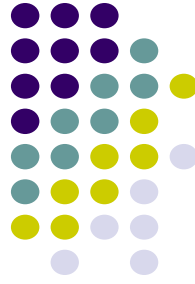


Electronic Medical Records



- Need Standards
- Audit trail
 - Who issued diag?
 - Who wrote Rx?

Hotline

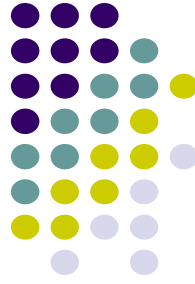


- Important to offer and market availability
- Take calls seriously
- Call to hotline are often last internal attempt to rectify
- Callers watch for reaction/action
- If none, external notification may be next



Possible Flash Points

- Proactive Approach through Compliance Reviews
- Handling Official Visits Appropriately
 - Establish Policy and Protocol
 - Train personnel at all levels.



How Fraud Reports Arrive

- Confidential Reporting Mechanism
 - Over ½ issues identified through tips not audits
 - Review of 508 recent occupational fraud losses
 - 60% from employees
 - 20% from customers
 - 16% from vendors
 - 13% anonymous

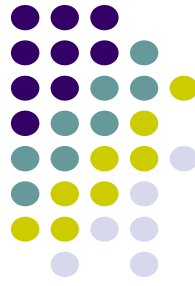
Source: ACFE 2004 Report on Occupational Fraud and Abuse



Erroneous vs. Fraudulent

- OIG does not disparage medical professionals
- No civil or criminal liability for errors or negligence
- Errors and mistakes should be reported immediately
 - Carrier
 - CMS
 - OIG-Self disclosure

Emerging Focus Areas

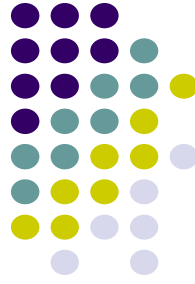


- Quality of care
 - Standard of care enforcement actions
 - Administrative sanctions
 - Civil monetary penalties
 - Termination of provider agreement
 - Provider exclusion



Quality of Care

- Neglect leading to injury or death
- Fraud from over-billing/Up-coding
- Group Treatment/Podiatry
- Medical Review without Visit
- Medically unnecessary procedures
- Proper credentialing of personnel

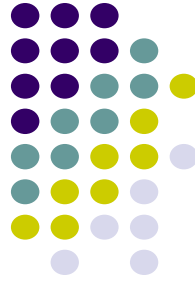




Potential Hot Spots in Quality

- Adverse Events
- Research
- Documentation, ie: reflects services provided
- Adhering to Safety Requirements
- Corrective Action Plan follow up
- Quality Measures defined by your organization

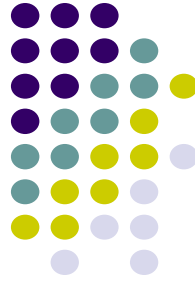
Quality of Care Investigations



- CT Skilled Nursing Facility
 - Lack of proper wound care
 - State Surveyors give warning
 - SNF makes no significant changes
 - PT admitted to ER
 - ER complains on condition of PT
 - MFCU and OI sent to ER
 - PT dies of sepsis

View of Oversight Entities

- Lack of care
- Do not meet minimum standards
- Will often rise to False Claims Charges





Recent Compliance Guidance

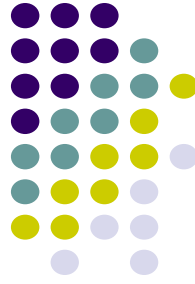
- Federal Agencies have issued 3 important documents relating to the structure and operation of Compliance Programs:
 - OIG Draft Supplemental Compliance Guidance for Hospitals
 - Corporate Compliance: A Resource for Health Care Boards of Directors, published by OIG and AHLA
 - Recent revisions to the Federal Sentencing Guidelines

Compliance Officer Concerns

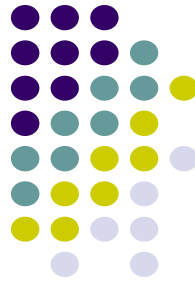


- Federal Sentencing Guidelines
- Enterprise Risk Management
- Role of CO
- Managing Compliance vs. Doing Compliance
- Measuring Compliance Program Effectiveness
- CO Role in Revenue Cycle Management
- SOX and CO

OIG Corporate Integrity Agreements



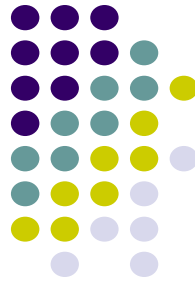
- In a CIA:
 - Compliance Officer (CO) must be a member of Senior Management
 - CO reports to board at least quarterly
 - CO has access to the board at any time
 - CO not subordinate to General Counsel or to the Chief Financial Officer
 - Now developing Corporate Compliance Certification (CCA)



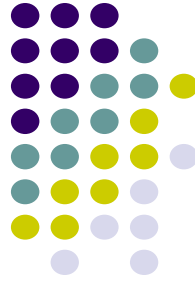
Sarbanes-Oxley Compared

- SOX requires a public company to have an audit committee that oversees its financial reporting and financial auditing functions
 - Committee of the board of directors
 - Independent of management
 - Must be able to engage counsel and advisers
 - Must be funded to the extent the audit committee determines is appropriate

Sarbanes-Oxley Compared



- CEO and CFO are responsible for establishing, maintaining, and regularly evaluating internal controls for financial reporting and public disclosure purposes—must certify this in SEC reports
- CEO and CFO must disclose any deficiencies in controls and any fraud to the audit committee and the outside auditor



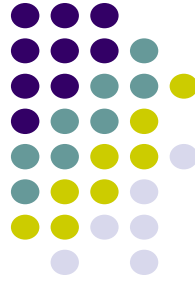
What Fraud?

- Billing for more expensive services at a higher service fee than was actually provided.
- Falsifying CMN's, plans of treatment, and medical records to justify payment.
- Billing for services not furnished.
- Soliciting, offering, or receiving a kickback.
- Billing separately for services that should be included in a single service fee.
- Misrepresenting the diagnosis to justify payment.



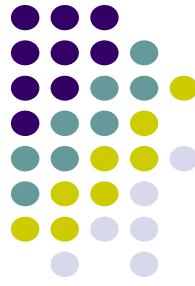
Flash Points

- Inducements-Important Focal Point
- Anti-Kickback
 - OIG Compliance Guidance for Pharma
 - AMA Guidelines
 - PhRMA Guidance
 - Part D!
 - Recent Settlements & Investigations
- SOX Requirements



How Fraud Reports Arrive

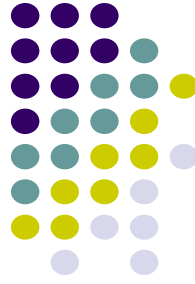
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Erroneous vs. Fraudulent

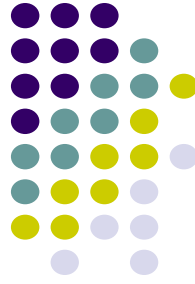
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- Errors and mistakes should be reported immediately
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 - CMS
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Enforcement Roles - Overview

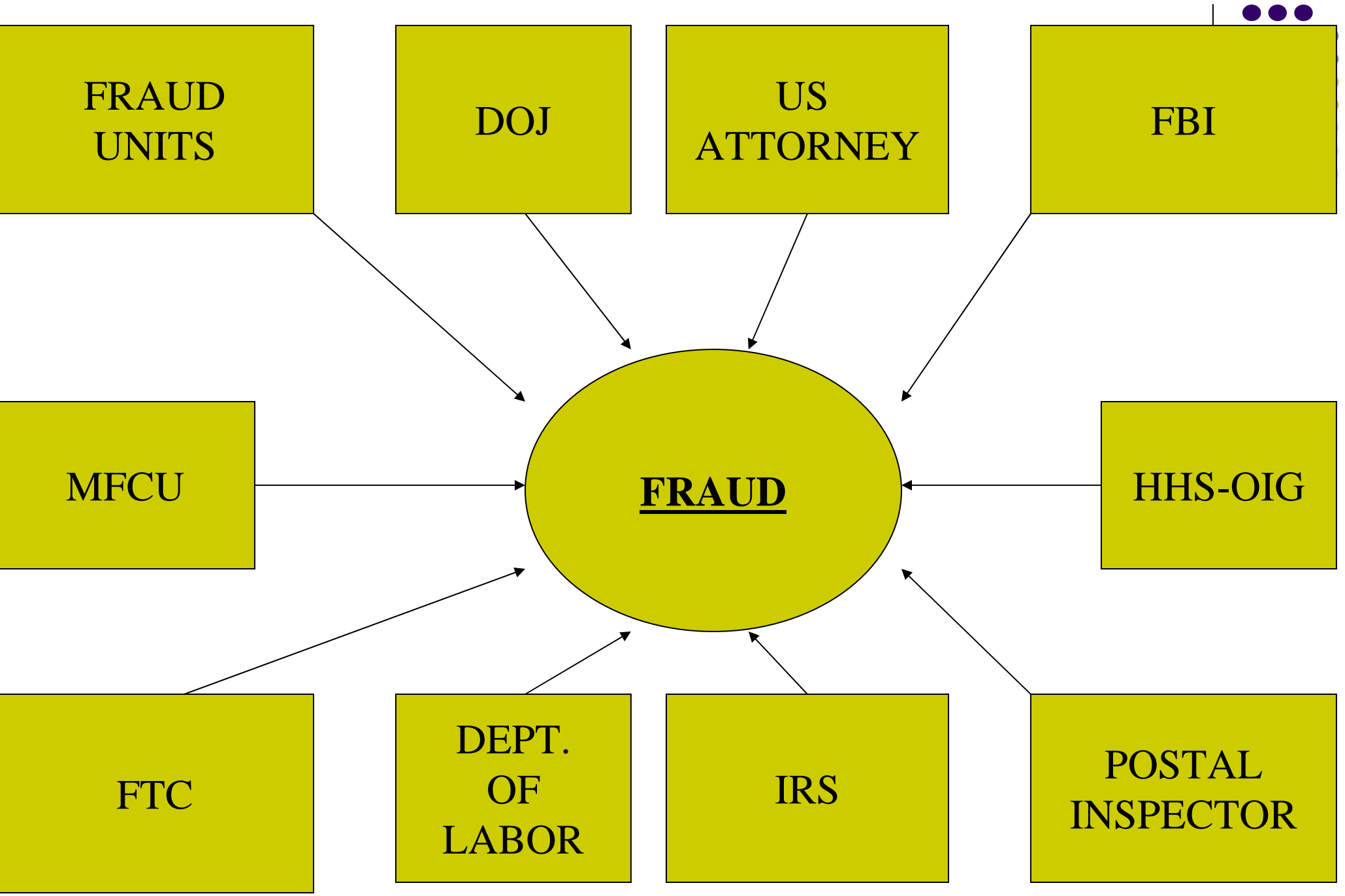


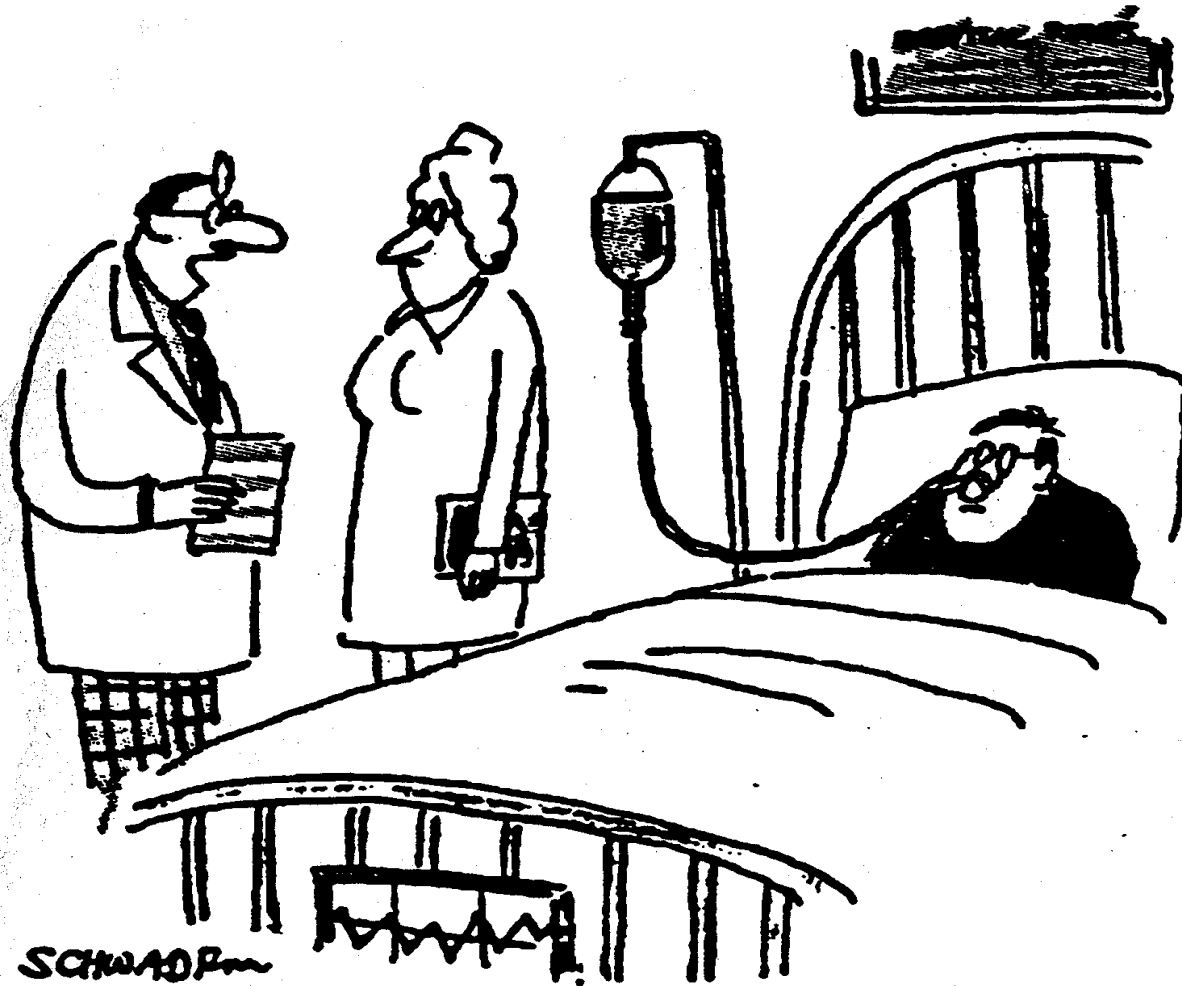
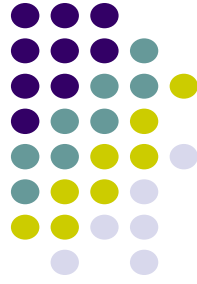
- Federal Government
- State Agencies
- Accreditation Agencies

False Claims Act



- How does this relate to quality?
- Areas of focus for FCA actions
- Corrective actions to resolve issues



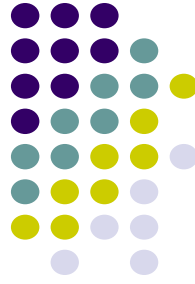


**“No, no! We attach the IV to the patient’s wrist,
nurse. We only *bill* them through the nose.”**

REPRINTED WITH PERMISSION

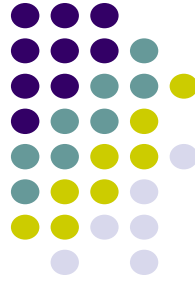
ABA 1993

© Compliance & Risk Dynamics, 2005



Common Provider Fraud

- Billing for non-rendered services
- Upcoding
- Performing medically unnecessary services for revenue generation
- Misrepresenting non-covered treatments as medically necessary covered services: i.e. Tummy tucks billed as lumpectomies.



Fraudulent Practices

Billing for more expensive services at a higher service fee than was actually provided.

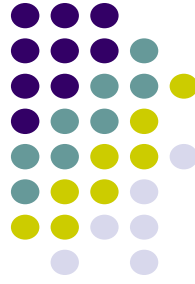
Falsifying certificates of medical necessity, plans of treatment, and medical records to justify payment.

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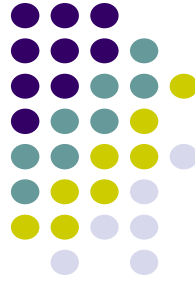
Misrepresenting the diagnosis to justify payment.



Where is My Investigation?

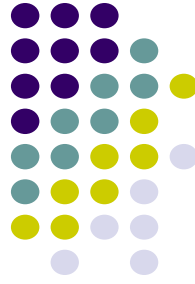
- State v. Federal
- Civil v. Criminal
- Administrative v. Formal
- Erroneous v. Fraudulent

Health Care False Statements (18 USC 1035)



Prohibits knowingly and willfully falsifying or concealing any material fact or making materially false or fraudulent statement or representation in connection with the delivery of or payment for health care services or benefits.

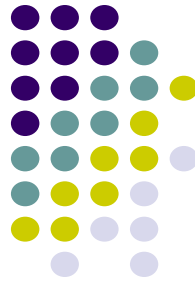
Civil False Claims Act (31 USC 3729-33)



The False Claims Act imposes civil liability for knowingly presenting or causing to be presented a false or fraudulent claim to the United States for payment or approval. It also prohibits knowingly using a false record or statement to get a false or fraudulent claim paid or approved, and conspiring to defraud the government by getting a false or fraudulent claim allowed or paid.. Also provides for an action by a private citizen as a *qui tam* action, on behalf of the government.

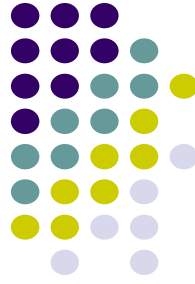
Civil Monetary Penalties Act

42 USC 1320a-7a(a); 42 CFR 1003.110



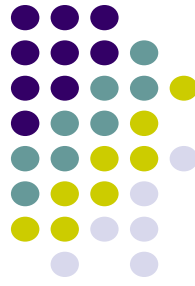
The Civil Monetary Penalties Act (CMP) allows the OIG to initiate administrative proceedings against any person who knowingly presents an improperly filed claim or engages in other specifically prohibited conduct. Here, knowledge and intent includes a person who acts in deliberate ignorance of the truth or falsity of information or who acts with reckless disregard of the truth or falsity of information.

Program Exclusion (42 USC 1320a-7)



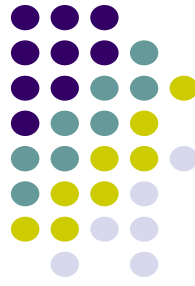
Exclusion by OIG of health care providers who receive criminal or civil sanction. For the period of exclusion, an excluded person or entity can not be an enrolled Medicaid or Medicare provider or furnish services or items to a beneficiary until reinstated.

How Prepare Organization for an Investigation?



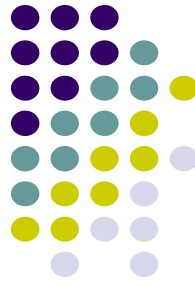
- Designate an individual to respond to official inquiries from government agents.
- Control flow of information from employees to agents.
- Advise employees to obtain agent's identification and agency affiliation so that they can be verified by the provider.

How Prepare Organization for an Investigation?

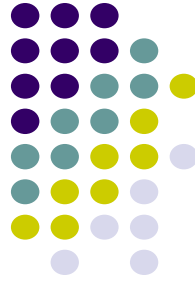


- Retain critical records, hardware, software, etc. that agents will take but are needed by the physician to operate his/her practice.
- Advise employees that they are not obligated to speak with government agents, but are not prohibited from doing so, either.

How Prepare Organization for an Investigation?

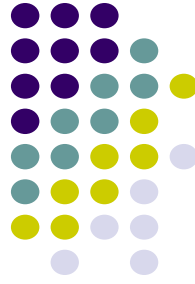


- Provider should inform employees that they do not have to talk with agents until they consult with the corporate compliance officer or legal counsel.
- Advise employees that if they choose to speak with government officials, the employee may dictate the conditions of the interview.



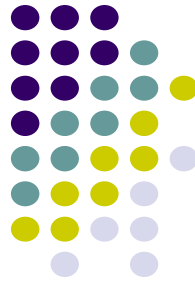
Where Is My Employer?

- Internal Compliance Plan
- Compliance Officer
- General Counsel
- Right To Indemnification
- Right To Representation
- Right To Whistleblower Protection
- Right To Separate Counsel
- Protections (Licensing Boards, Adverse Actions)



“Erroneous” vs. “Fraudulent”

- OIG does not disparage medical professionals
- No civil or criminal liability for errors or negligence
- Errors and mistakes should be reported immediately



Headlines on Health Care

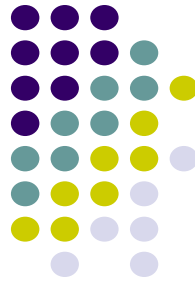
- RAND Study Shows Correct Care Given Less Than 60% of Time
 - Journal of Health Affairs May/June 2004
- Health South Executive Pleads Guilty
- Cooperating in Investigations Can Minimize Penalties in Health Fraud Cases, Official Says
 - Health Care Fraud Report/BNA - 3/19/03



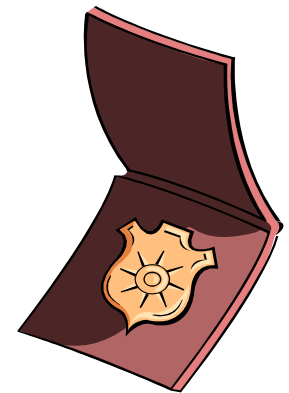
Headlines in Health Care

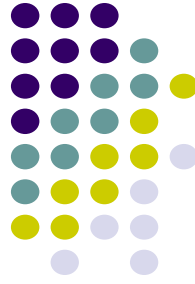
- Adult diapers billed as expensive prosthetic devices
- Nursing Home Charged in Medicare Fraud
- Norwalk Doctor Who Defrauded Medicaid Program and Insurance Companies Sentenced
- 11 Die in Hartford Nursing Home Fire
- The Pill: Professors Safety Tests Were Faked
- Hospital Drug-Error Trends Continue

Miscellaneous Investigations



- Dr. xxx-Excessive Billing
 - Calculated 364 days of Billing
 - Usually 20 hours of duty
 - Some billing days totaling 30 hours
- Dr. xxx-False Diagnoses/Research
 - \$7m Medicare billing over 3 years
 - 25 patients/Mix of blood to support diagnosis
- Dr. xxx – ENT Allergy Testing/Unnecessary Surgery
- Self-Administered Drugs
- Teaching Hospital Grant Fraud

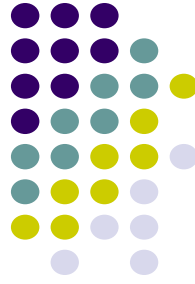




Common Provider Fraud

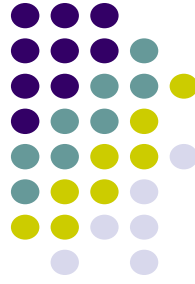
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- Upcoding
- Performing medically unnecessary services for revenue generation
- Misrepresenting non-covered treatments as medically necessary covered services: i.e. Tummy tucks billed as lumpectomies.

Misc. Investigations



- Identity Fraud - R.Ph.
 - 20 years false credentials
- Nursing Home Embezzlement
- Dr. xxx-Suspended Optometrist
 - Providing/billing for services/Arrested
- PT/OT Home Visits-Up coding/Over billing

Duty of Care Concept



- Duty of care involves determining whether the directors acted
 - ✓ In good faith
 - ✓ With the level of care that an ordinarily prudent person would in like circumstances
 - ✓ In a manner that they reasonably believe is in the best interest of the corporation

Source: HHS-OIG/AHLA

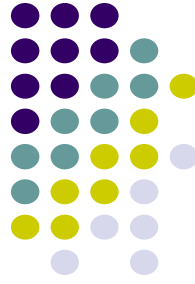
Management Obligations to Duty of Care



- **Decision-making function**
 - Applying duty of care principles to a specific decision or board action
- **Oversight function**
 - Applying duty of care principles with respect to the general activity in overseeing the day-to-day business activities of the corporation

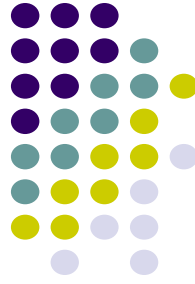
Source: HHS OIG/AHLA

Emerging Focus Areas



- Hospital billing and collection practices
 - Discounting charges
- Contract arrangements





Governance & Senior Management

- Emphasized by OIG
 - Supplemental Compliance Guidance for Hospitals
 - Board Educational Resource
- How Measured?
 - Formal commitment to compliance
 - Active involvement
 - Allocation of resources
 - Empowerment of compliance professionals

Audit Emphasis: Specific Risk Areas



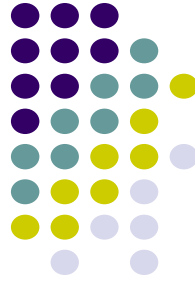
- OIG Workplan
- OIG Semiannual Report
- Relevant Compliance Guidance
- LMRPs
- Program requirements
- Specific risk areas for provider's industry segment



Responses to Potential Non-Compliance



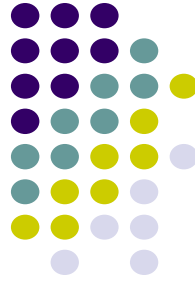
- Document responses to issues
- Investigate as appropriate
 - Internal and external resources as warranted
- Corrective action plans developed and enacted
- Refund of all identified overpayments



US Sentencing Guidelines

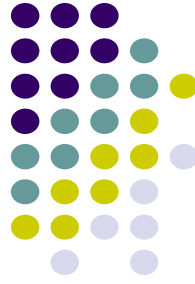
- Revision of Guidelines started about the time that the Enron scandal broke
- Sentencing Guidelines development influenced by desire to make corporate boards more responsible for the compliance function
- The influence of the Sarbanes-Oxley debate is evident

Sentencing Guidelines



- Guidelines are used in determining the appropriate sentence for a corporate defendant
- Are also viewed as important guidance concerning the essential elements of an effective compliance program
- Play an important role in the development of best practices

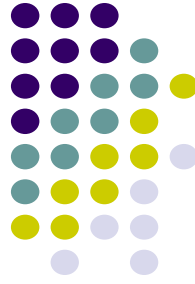
Sentencing Guidelines



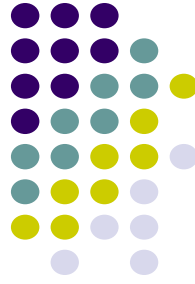
- Place responsibility on Boards and Executives for oversight and management of Compliance Program
- “High-level personnel” who have substantial control over the organization must be responsible and accountable for the program
 - Need not handle day to day operations
- Specific individuals within the organization shall be delegated operational responsibility for the program

Sentencing Guidelines

- High level personnel shall be knowledgeable about the content and operation of the program and must ensure that the organization's program is effective
- Bottom line: someone at the top must own responsibility for the compliance function



Contact Information



Dr. Steve Morreale
Compliance & Risk Dynamics

smorreale@compliancedynamics.net

508-624-7053 Office

www.compliancedynamics.net