



halleland
lewis nilan
& johnson

Compliance 202

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Cheryl Wagonhurst
Foley & Lardner LLP

Jenny O'Brien
Halleland Johnson Nilan and Lewis

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1

Recent Enforcement Activities and Trends



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Recent Enforcement Activities & Trends

- ✓ OIG Guidances, ie: supplemental hospital, pharma
- ✓ Revised Federal Sentencing Guidelines
- ✓ Sarbanes
- ✓ Quality Standards
- ✓ SEC
- ✓ NIH
- ✓ State Laws, ie: CA-SB1765, etc.
- ✓ Electronic Medical Record and HIPAA

Recent Focus of Medicare

- Increase the value
 - Improve the quality and value of care Medicare purchases
 - Quality + cost = value
- Control spending
- Promote accountability and care coordination
- Create better information and tools to use it (clinical and administrative)
- Set accurate prices

Key Areas of Impact

- Value Based Pricing & Transparency
 - Strengthen bond between quality and payment
 - Quality indicators for mandated reporting on Inpatients up from 10 to 21 for 2007
 - Currently only report expect tie to level of payment to come
 - For 2007 tie of Inpatient quality indicators to outpatient payments
 - Expect specific outpatient quality indicators for 2008
 - Quality, cost, payment data transparency
 - Stop paying hospitals for hospital acquired complications (2007 Present on Admission Reporting)
 - Anticipate implications for non-government payers

Key Areas of Impact

- New models for care coordination and payment to be developed and tested.
 - Expect shift in physician resources to support greater coordination of care.
 - May focus on “spell of illness” payment versus fee for service
 - Watch for incentives to manage chronic care needs more effectively (new systems, new businesses/products that partner with physicians)
 - Models being utilized in Medicare Advantage Plans could be mandated for traditional Medicare

Key Areas of Impact

- Need to Improve Accuracy of Prices
 - Must improve data integrity
 - Implications for charging, coding, billing, documentation
 - Could create greater administrative burden for providers
- Improve Payment for Outpatient Therapies
 - Spending on PT/OT/ST has doubled since 2000
 - No data to explain why- increase in patient need or just increase in services provided
 - Expect greater focus on patient outcomes
 - New assessment, risk and outcomes measurement tools
 - New payment options e.g. bundled payment based upon condition
 - Could see payments tied by quality levels or outcomes

Key Areas of Impact

- New technology
 - Electronic records
 - Diagnostic tools, devices, etc.
- New forms, mandates (UB-04, Revised 1500, NPI, Administrative Simplification, etc.)
- Competitive Acquisition for DME, regional providers, capped rental, beneficiary equipment ownership

What does all this mean to you?

- Expect greater intersections with Quality, Risk, Compliance and Legal

What does all this mean to you?

- Expect greater intersections with Quality, Risk, Compliance and Legal



Additional Areas of Focus

- State Attorney General:
 - Charged with protecting the public interest, attorney's general are initiating increasingly aggressive demands for public accountability from private not-for-profit (501(c)(3)) institutions
- AG Legal Basis:
 - Authority to investigate charitable organizations
 - Private inurement
 - Charitable Trusts
 - IRS tax issues



Recent Compliance Guidance



Recent Compliance Guidance

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



OIG Supplemental Guidance

- Compliance Officer should be member of Senior Management and supported by Compliance Committee
 - Allowing Compliance to be subordinate to Senior Management may compromise the independence and objectivity
 - Although Compliance should be independent, a multi-disciplinary team approach is needed



OIG Compliance Guidance (cont'd)

- Compliance Officer's Duties may include:
 - Developing and implementing policies
 - Overseeing and monitoring program implementation
 - Coordinating internal audits
 - Investigating reports of noncompliance
 - Serving as a resource on substantive issues
 - Reporting directly to the board and senior management on compliance matters



OIG Compliance Guidance (cont'd)

- Key responsibility: investigation and coordination of organization's response to compliance failures



OIG-AHLA Corporate Compliance Resource

- Directors have a duty to exercise reasonable diligence in overseeing the compliance function
- Board should know structure of program and who are the key employees responsible for its implementation and operation
- Board should receive regular reports



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
- Compliance personnel shall be given adequate resources, appropriate authority and direct access to board

Sentencing Guidelines

- Place responsibility on Boards and Executives for oversight and management of Compliance Program
- Specific individuals within the organization shall be delegated operational responsibility for the program and these individuals shall report to high level personnel and to the board on the effectiveness of the program
- Bottom line: someone at the top must own responsibility for the compliance function

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

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



Industry Standard

- What do we know?
 - HCCA 8th Annual Survey (2006)
 - Compliance Officers:
 - 64% report to CEO/President
 - 65% had a stand alone department
 - 71% are officer or senior management level
 - 71% are also responsible for Privacy
 - 96% provide compliance updates to the Board
 - 54% report quarterly

Industry Standard

- 92% of Programs have compliance committees
 - Responsibilities include planning, disposition of investigations, disposition of audits, reporting to the governing board, self disclosures, enforcement authority
 - 74% of Compliance Officer's chair the org. compliance committee
 - Committee is made up of CFO/Finance, Administration, Billing, HR, CO, Legal, Operations, CEO, Physician Leader
 - Less frequently includes HIM, RM, clinical department head, Nursing, Audit, IS, QA, Lab, Board Member, other, Physicians

Industry Standard (cont'd)

- HCCA survey (cont'd)
 - Major focus areas for compliance programs:
 - 1) Auditing and Monitoring
 - 2) Education and Training
 - 3) Conducting effectiveness evaluations
 - 4) New/revised regulations/policies/procedures
 - 5) Employee Awareness
 - 6) Risk Assessments
 - 7) HIPAA

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What about You?

- How does the relationship of your Compliance Officer to Senior Management compare with these standards
 - Member of Senior Management?
 - Meets with senior management periodically?
 - Reports to CEO
 - Has access to Board?
 - Other?

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What about your organization?

- How does your CO's duties compare to the standards and industry practice?



COMMUNICATING COMPLIANCE TO THE BOARD OF DIRECTORS

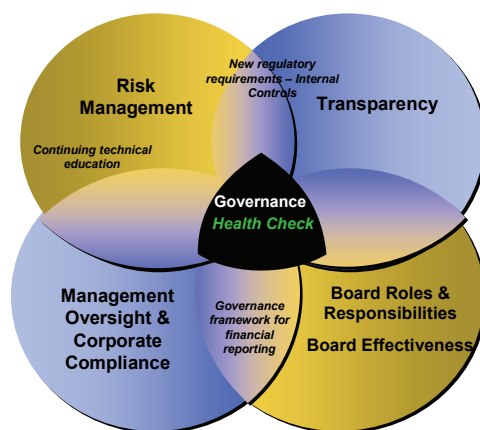


Relationship between the Board and the Compliance Officer

- Compliance Guidance, Sentencing Guidelines, Corporate Compliance Resource and Sarbanes Oxley all emphasize the governing body's responsibility to exercise oversight of the compliance program



Evolution of Corporate Governance Focus



- Top priorities for Governance include:
- Corporate governance health check to assess audit committee and board effectiveness
- Financial reporting governance framework
- Board effectiveness
- Continuing technical education
- Ethics services
- *New regulatory requirements - internal control*



Key Questions Boards Should be Asking

- ✓ **How is the board structured to oversee compliance issues?**
- ✓ **How is the compliance program organized and who are the key employees responsible for its implementation and operation?**
- ✓ **How does the compliance reporting system work?**
- ✓ **How frequently does the Board receive reports about compliance issues?**

Source: HHS OIG/AHLA

Board 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

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



INTERNAL INVESTIGATIONS



Internal Investigations

“An inevitable consequence of an effective compliance program is the identification of practices that warrant an internal investigation, and when appropriate, disclosure to the government.”

HHS Office of Inspector General



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Common Practical Challenges

- Risk of creating report cards without A's and B's
- “Bad Paper”
 - Internal and external resources document things in an unfortunate manner
- Privilege Issues
 - Established too late
 - Could be waived, voluntarily or involuntarily
- Stakeholder Exclusion
 - Independence and fairness of investigation
- Repayments and Disclosures
 - How far do you go ...



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Internal Investigations

- Triggers—Becoming aware of a problem
 - Discovery of faulty billing advice
 - Inquiries by third party payors
 - Increase in denied claims
 - Government investigation
 - Whistle-blower actions
 - Statistics

Internal Investigations

- Prioritizing multiple compliance issues
 - Could the issue have a significant impact on the business bottom line?
 - Does the issue present credible evidence of ongoing misconduct that may violate the law & should be reported immediately?
 - Has the organization established (and followed) its own standards for the amount of time allotted to address incoming compliance concerns?

Internal Investigations

38

- Factual due diligence
 - Staffing – *who should the review team include?*
 - Claims process analysis
 - Interviews
 - System reviews
 - Determination of Resolution



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39

WHEN TO INVOLVE LEGAL COUNSEL



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When to Involve Legal Counsel

- Privileges
 - What is a “privilege”?
 - Rule of evidence barring communications from admission in legal proceeding
 - Examples: marital communications privilege, patient-physician privilege & psychotherapist-patient privilege
 - Corporate clients
 - No 5th Amendment rights against self-incrimination for corporations – makes attorney-client privilege especially important

When to Involve Legal Counsel

- Privileges (cont'd)
 - Policy
 - Encourage full and frank communication between an attorney and his or her client
 - This communication is generally more important than the need for evidence in litigation
 - Whose privilege is it?
 - The client holds the privilege (not the attorney)
 - The corporate client (and not its employees or agents) holds the privilege

When to Involve Legal Counsel

- Practical considerations
 - How to decide whether to bring an internal investigation under privilege
 - Ordinary-course auditing and monitoring vs. privileged audits and investigations
 - Risk analysis
 - Varies by organization, risk area and potential exposure to organization

When to Involve Legal Counsel

- Practical considerations (cont'd)
 - Timing is everything
 - Get attorney involved with investigation early
 - Attorney can assist client in evaluating risk of conducting investigation outside of privilege
 - Attorney should render advice after non-lawyer advisor delivers work product

When to Involve Legal Counsel

- Practical considerations (cont'd)
 - Attorney should control & personally supervise investigation
 - Attorney should retain and personally supervise consultants & non-attorneys
 - Just copying attorney on correspondence probably doesn't do it
 - NOTE: Communications with non-privileged persons (i) are not protected by privilege and (ii) may destroy otherwise privileged conversations



DISCLOSURE TO OUTSIDE ENTITIES



Disclosure to Outside Entities

- Has a violation of law occurred?
 - Material violation
 - Substantial overpayment
 - Improper payment
 - Violation of statute, regulation or agency directive
 - Provision of items or services of a substandard quality



Disclosure to Outside Entities

- Obligation to disclose
 - Knowledge of events & intent = crucial factors
 - 42 U.S.C. § 1320a-7b(a)(3)
 - No obligation to admit to receiving an overpayment &/or submitting an improper charge



Disclosure to Outside Entities

- How far back should you go?
 - The OIG suggests
 - Using “reasonable and calculated benchmarks” to assist in determining the parameters of an internal investigation
 - Taking a “reasonable” approach that can be “justified under the circumstances”
 - Expanding the inquiry if the initial review suggests existence of a broader problem

Disclosure to Outside Entities

- How far back should you go? (cont'd)
 - General time period for reopening of Medicare claims is 4 years
 - FCA statute of limitations
 - 6 years – after date of violation
 - 3 years – after date when material facts are known or should have been known by the government, but in no event more than 10 years after the date on which the violation occurred
 - Fact specific stopping points
 - Change in computer systems
 - Change in personnel

Disclosure to Outside Entities

- Potential risks & benefits
 - Favorable treatment
 - Less rigorous CIA
 - Resolve exclusion remedy
 - Minimize potential disruption
 - Minimize excessive damages
 - Preclude whistle-blower action by requesting Contractor or OIG to “investigate” disclosed facts
 - Other considerations

Disclosure to Outside Entities

- Where to report?
 - To Program Contractors
 - Matters exclusively involving overpayments or errors that do not suggest a violation of law has occurred
 - Issue = Contractor demands for OIG-style disclosure for routine billing errors
 - To the OIG
 - If in the provider’s reasonable assessment the matter(s) is potentially violative of federal, civil or criminal laws

Disclosure to Outside Entities

- Where to report ? (cont'd)
 - To the DOJ
 - Main Justice v. USAO
 - Civil v. Criminal Divisions
 - Local politics
 - USAO priorities



Disclosure to Outside Entities

- Reporting—Timing issues
 - The OIG on prompt reporting

Demonstrates the entity's "good faith and willingness to work with governmental authorities to correct and remedy the problem"

"Will be considered a mitigating factor in determining administrative sanctions"



Disclosure to Outside Entities

- Reporting—Timing issues
 - Disclosure within 60 days after—
 - Determining credible evidence of a violation
 - Identifying an overpayment
 - Disclosure within 30 days of—
 - The time the violation was initially detected
 - May limit risk to double damages under the FCA

CASE STUDIES

Case Studies

- How far back do you go to self report?
 - Routine audit discovers that a hospital coder, who is a long-term employee, has been inaccurately coding procedures



Case Studies

- How and to whom should this be reported?
 - A physician's ownership in a clinical laboratory is identified during a routine screening after several years of referrals and billing



Case Studies

- Can you “safely” employ excluded individuals?
 - A hospital wants to find a way to accommodate a senior employee whose exclusion status is discovered during a routine cost report audit by the FI



PROGRAM EFFECTIVENESS

What is the OIG looking for?



CMS Project for Effectiveness of Hospital Compliance Programs⁶⁰

- Announced May 2004
 - Six N.E. states, D.C., DE, MD, NJ, NY, PA, VA, WV
 - Focus on acute-care hospitals and academic medical centers with a minimum of 100 beds for 18 months
 - Inpatient at least 30% of revenue
 - Medicare at least 25% of revenue
 - 15-20 participants
- “Evaluate effectiveness of voluntary compliance programs”
 - Identify best practices and how to apply them
- Look at developing incentives to encourage providers with an effective compliance program
 - Expedited appeals
 - Enhanced claims data
 - Better interaction with contractors, more interaction with CMS

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61

CMS Pilot Project (cont'd)

- 2 site visits
- CMS will develop list of indicators to come up with a quantifiable measure of the provider's effectiveness
- Outcome measures based on, e.g., Medicare claims rejection, overall error rates
- Educational incentive through enhanced claims data in report-card format

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Analyzing Effectiveness Internally

- Organization
 - Culture
- Governance and Senior Management
 - Commitment
- Structure and Processes
 - Internal Controls
- Assessment and Enhancement
 - Auditing and Monitoring



Organizational Culture

- Values and rewards:
 - Compliance
 - Prevention
 - Detection
 - Resolution
- Code of Ethics/Conduct
- Core Values
- Compliance as part of annual performance review



Governance and 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

Governance and Senior Management *Documented Effectiveness*

- Demonstrate and document efforts to get it right the first time through
 - Evaluation of new business ventures for potential risk
 - Proper delegation of authority and accountability
 - Timely response to newly developed rules and regulations
 - Systematic testing of internal control systems tested

Enforcement of Disciplinary Standards

- Standards well-publicized
- Consistently enforced
- Exclusion lists checked
- Emphasis on non-retaliation



Effectiveness Reviewed Annually

- Assess compliance with 7 elements
- Billing and coding error rates
- Refunds
- Internal or external audit results
- Employee awareness of compliance program
- Hotline calls and other referrals
- Number of investigations and outcomes
- Responses to issues
- Consistent enforcement and discipline



QUESTIONS?



Appendix

Questions to Ask in Assessing the Seven Elements of an Effective Compliance Program



Elements of an effective compliance plan ⁷⁰

- Establishment of compliance standards and procedures
- Appointment of a compliance officer or committee
- Exercise of due care in the delegation of discretionary authority
- Employee education and compliance training
- On-going monitoring and reporting systems
- Consistent and continuous enforcement of compliance standards
- Response to offenses; prevention of reoccurrences

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Assessing the Seven Elements ⁷¹

1. Designation of Compliance Officer and Compliance Committee

Key questions :

- Is there a compliance officer who is well-qualified, a member of senior management, and who is supported by a Compliance Committee?
- Is there a clear mission statement?
- Are there sufficient resources available?
- Is there an appropriate relationship between the compliance officer and general counsel?

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Assessing the Seven Elements

1. Designation of Compliance Officer and Compliance Committee

Key questions (cont'd) :

- Is there an active compliance committee?
- Is the committee comprised of trained representatives of each relevant functional department, and members of senior management?
- Are ad hoc groups or task forces utilized?



Assessing the Seven Elements

Key questions: (cont'd)

- Does the compliance officer have access to:
 - Governing body?
 - Senior management?
 - Legal counsel?
- Does the compliance officer have good internal working relationships?
- Does the compliance officer make regular report to the governing body?



Assessing the Seven Elements

2. Development of Compliance Policies and Procedures, Including Standards of Conduct

Key questions :

Have standards of conduct been distributed to:

- Governing body?
- All officers?
- All managers?
- Employees?
- Contractors?
- Medical Staff?

Assessing the Seven Elements

Key questions (cont'd):

Are policies and procedures:

- Clearly written?
- Relevant to day-to-day responsibilities?
- Readily available to those who need them?
- Re-evaluated on a regular basis?
- Is compliance with policies and procedures monitored?

Assessing the Seven Elements

Key questions (cont'd):

Does the hospital have risk assessment tools that evaluate:

- Federal health care program requirements?
- OIG CPGs?
- Work plans?
- Special Advisory Bulletins?
- Special Fraud Alerts?

Assessing the Seven Elements

3. Developing Open Lines of Communication

Key questions:

- Has the hospital fostered an organizational culture that:
 - Encourages open communication?
 - Prevents retaliation?
- Hotline:
 - Has one been established?
 - Is it publicized?
 - Are calls logged and tracked for trends?
 - Do callers receive feedback?

Assessing the Seven Elements

Key questions (cont'd):

- Are all potential fraud and abuse issues investigated?
- Are results of internal investigations routinely reported to governing body?
- Is the governing body actively engaged in pursuing appropriate remedies to institutional or recurring problems?
- How are
 - Compliance program activities communicated within the organization?
 - How frequently?

Assessing the Seven Elements

4. Appropriate Training and Education

Key questions :

- Does the hospital have qualified trainers?
- Do the trainers:
 - Conduct annual compliance training?
 - Including general and specific training?
- Is training evaluated for effectiveness?
- Has hospital
 - Kept current on changes in Federal health care program requirements?
 - Adapted training and education accordingly?

Assessing the Seven Elements

Key questions (cont'd):

- Is education and training curriculum developed considering the following:
 - Results of audits and investigations?
 - Results of previous training and education activities?
 - Hotline reports received?
 - OIG/CMS communications?
- Has hospital evaluated effectiveness of training and education utilizing appropriate methods?

Assessing the Seven Elements

Key questions (cont'd):

- Has the governing body been provided with appropriate training?
- Are training and education activities well documented?
- Are there attendance requirements?

Assessing the Seven Elements

Key questions (cont'd) :

- Has hospital evaluated error rates based on annual audit results?
- Is there an ongoing effort to uncover hidden weaknesses and deficiencies?
- Do audits include a review of clinical documentation?

Assessing the Seven Elements

5. Internal Monitoring and Auditing

Key questions :

- Is an annual audit plan developed?
- Does the audit plan include:
 - Assessment of billing systems?
 - Claims accuracy?
 - Root cause analysis of errors?
- Is audit staff qualified and appropriately certified?
- Are resources available for unscheduled reviews as requested by the compliance officer?

Assessing the Seven Elements

6. Response to Detected Deficiencies

Key questions :

- Does the hospital have in place a process for promptly responding to detected deficiencies?
- Are all deficiencies thoroughly and promptly investigated?
- Are corrective action plans developed?
- Is corrective action taken verified after implementation?
- When identified, are overpayments promptly re-paid and disclosed appropriately?

Assessing the Seven Elements

7. Enforcement of Disciplinary Standards

Key questions :

- Are disciplinary standards well publicized?
- Are disciplinary standards consistently enforced and documented?
- Are employees, contractors and medical staff checked routinely against government sanction list?

Assessing the Seven Elements

“In Sum, while no single factor is conclusive of an effective compliance program, the preceding seven areas form a useful starting point for developing and maintaining an effective compliance program.”



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