Introduction to Healthcare Risk Areas & Compliance

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Overview

Part I.
• The ethics and compliance challenge
• The compliance impact of healthcare reform
• The “risk tolerance” dilemma

Part II.
• Compliance program foundations
• Building adequate controls

Part III.
• Key risks areas for hospitals and physicians
Challenge

Workforce Ethics

Ethics Perception:_____________

Ethics Reality

- Cheating
- Stealing
- Resumes
- Reporting
- Character/Competence assessment

Challenge

- Aggressive Enforcement Climate
- Fraud
- Embezzlement
- Culture/Tone at the top
- Controls
Challenge

Business activities outside normal control processes
- Separate entities
- Medical staff accounts
- Inadequate segregation of duties

Management Pressure Areas
- Financial Performance
- Overtime
- Meal/break period penalties
- Productivity
- Quality

• Communication
  Sloppy, inappropriate e-mails, memos, letters, voice mails, telephone conversations, etc.
  
  Your statements/words/communications will be used against you in enforcement actions!!
Challenge

• Healthcare is most complex, highly regulated segment of U.S. economy

• Mayo CEO (2002): More than 200,000 pages of laws, regulations, standards, etc.

• Complex, confusing and counterintuitive laws and rules

• Thousands of material changes each year

Health Reform Impact

Reform is precarious politically
Reform ‘Sold’ to public as mechanism to
  ➢ Cover uninsured
  ➢ Control costs
‘Savings’ predicated significantly on increasing fraud/abuse recoveries by a factor of 8 to 10
Providers (hospital/doctors) largely excluded from healthcare reform and cost control discussions
Healthcare Reform Impact

**Numerous changes to substantive laws**
- Modest relief in some areas (Stark)
- Explosion of new/changed laws and rules

**Increased enforcement risk**
- Lower burden of proof for Government
- Increased fines/penalties
- New crimes/standards

**Significantly expanded enforcement**
- Bounty hunters (RAC, ZPICs, MACs, MICs, etc.)
- Increased funding for FBI, OIG, MFCUs, etc.

Risk Tolerance

**Risk tolerance question is difficult.**
- Risk is not always clear
- Do we put greater weight on criminal rather than civil risk
- Do we consider ‘enforcement’ probability
- How do we factor in reputation exposure
- Risk to different parties may be unequal

Make sure you fully understand the risk before you accept the risk!
Compliance Foundations

Organization Sentencing Guidelines
- Outlines minimally required components of an “effective compliance and ethics program”

Basic Elements
- Policies & procedures
- High-level oversight
- Screening
- Education
- Monitoring & auditing
- Complaint mechanisms
- Promotion & enforcement
- Appropriate response to misconduct
- Risk assessment

Compliance Foundation

• OIG Compliance Program Guidance
  - Hospital
  - Hospice
  - DME
  - Nursing Facilities
  - Small Physician Practices
  - Billing Companies
  - Pharmaceuticals
  - Ambulance
  - Home Health
  - Medicare + Choice
  - Clinical Lab

• Corporate Integrity Agreements

• Deferred Prosecution Agreements
Compliance Foundations

**Role of the Board**

- Define scope of the program
- Align incentives
- Approve key policies and procedures
- Require periodic, substantive reporting by management
- Ask questions!!

**Tip:** Add compliance expertise to board or appropriate committee.

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Compliance Foundations

**Role of Management**

- Actively promote/support program
- Ensure implementation of program
- Create culture that permits questions
- Hold subordinates accountable

**Tip:** It’s management’s job to implement the program and ensure compliance. The role of the compliance officer is to ensure management has the tools & resources.
Role of Compliance Officer

• Design (and redesign) program with input from management (operations), employees, peers and experts

• Develop policies and procedures
  ➢ Structural → OSGs
  ➢ Substantive → high risk areas

• Develop/acquire educational programs applicable to targeted job functions

Role of Compliance Officer (Continued)

• Simplify complex, clarify ambiguous
• Respond to environmental changes
• Monitor and report on execution
• Have the difficult conversations
Compliance Foundations

**Role of Employees**

- Participate in program – complete education, follow P & Ps
- Seek advice when there are questions
- Bring issues of non-compliance to attention of appropriate people
  - Internal
  - Anonymous
- Cooperate in investigating/fixing identified problems

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Compliance Foundations

**Keep the Program Simple**

- Tackle highest risks first
- Give management/employees clear direction
  - Ambiguity paralyzes
  - Specificity enables accountability
- Work within limits of organization’s resources
Compliance Foundations

• **Align Incentives**
  • Incentive compensation
  • Transparency
  • Performance evaluation
  • Recognition
  • Keeping promises

Compliance Foundations

• **Properly Positioned Compliance Officer**
  • Reports to board (committee) and/or CEO
  • Regular executive sessions
  • Reasonable severance package
  • Minimize conflicting responsibilities
  • Educated compliance officer
Compliance Foundations

Specific, Measurable Objectives

• **Structural (program operation)**
  
  - P & Ps - orientation to program and P&Ps; development or review of P&Ps, adherence to P&Ps
  
  - High Level Oversight – Board Oversight, Sr. Mgmt participation in meetings, audit exit conferences, compliance meetings, compliance officer member of Sr. Management, etc
  
  - Education - completion of compliance and ethics education, completion of job specific education programs, ethics scenario discussions in staff meetings, etc
  
  - Screening – background checks, exclusion checks

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Compliance Foundations

Specific, Measurable Objectives

• **Structural (program operation) (continued)**
  
  - Investigation/Reporting - documentation of employee complaints and hotline calls, prompt investigation and response to complaints/hotline calls
  
  - Monitoring/Auditing - completion of audit/monitoring activities, scores on audits (accuracy of process), completion of reports, tracking & submission of data, etc
  
  - Remediation – correction of identified mistakes (refunds, data/reporting errors, etc), completion of corrective action plans (training, P&P development/modification, implementation of new/different control processes, etc)
Compliance Foundations

- **Substantive**
  - **General**
    - tax, FLSA, environmental, antitrust, etc.
  - **Healthcare Specific**
    - anti-kickback, Stark, false claim, (including documentation, medical necessity, coding & billing, quality of care standards), licensure & certification, HIPAA, tax-exemption (charity care, billing & collection, intermediate sanctions, lobbying and political activity, loss of bond tax-exemption)

**Tip:** Develop a compliance scorecard for key business unit executives that addresses structural components and key substantive risks. These objectives must be specific, objectively measurable and will be most effective if it has a material impact on the performance evaluation and/or incentive compensation process. See attached example

Compliance Foundations

Management & Board Reporting – Written Reports

**Written Reports** – purpose is to inform, report and educate

- Issues
- Investigations (internal & external)
- Annual work plan progress
- Key metrics
- Recent developments
Compliance Foundations

Management & Board Reporting – Oral Reports

Oral Reports

- Highlight
  - New investigations/issues
  - New reports/tools
  - Key messages
- Respond to management/board questions
- Ask management/board if they have questions

Compliance Foundations

Management & Board Reporting – Minutes

Purpose: To reflect topics, deliberations and actions in meeting and demonstrate that participants are effectively fulfilling their role

- Outline
  - General topic area
  - Issues
  - Questions/deliberations
  - Action

See Corporate Minute-Taking: A General Counsel’s Guide by Michael Peregrine & Russ Hayman
Controls

- **Culture**
  - Management example
  - Management action

- **Control Process**
  - Management has an obligation to ensure
    1) effective control processes in place and
    2) control processes are being followed

**TRUST IS NOT AN INTERNAL CONTROL!!**

(TIP: Education does not change behavior! Carefully review audit reports for remediation plans that call for “Education”)

Risk Areas: Anti-Kickback/Stark

**Anti-kickback/Stark**

- Purpose of these laws is to prevent payments/ incentives to physicians designed to induce referrals/or impact clinical judgment.

- Risk area for both CHW and individual employees.

- **Basic Rules**
  1. Never offer anything of value to induce referrals
  2. Never pay/rent to a physician without signed, written agreement
Risk Areas: Anti-Kickback/Stark (Continued)

**Anti-Kickback Laws**

- Prohibit payments intended to induce referrals.
- Statute is violated only if there is intent to influence (induce) referrals.
- Includes *safe harbors*, which permit arrangements which might otherwise be improper. An arrangement may be permissible, even if it does not fit in a safe harbor.
- Statute contains both civil and criminal penalties.

**Stark Laws**

- Prohibit referrals where a financial relationship exists (unless covered by an exception).
- Contains *exceptions* permitting referrals—provided all applicable requirements are met—that would otherwise be illegal.
- An arrangement does not comply with the law if it doesn’t meet all exception requirements.
- Violation of the Stark laws carries civil penalties (*billing prohibitions* and fines). Failure to repay triggers false claims and possible criminal liability.
Risk Areas: Anti-Kickback/Stark (Continued)

**Safe Harbors/Exceptions:** Are specific requirements related to each safe harbor/exception. Must meet technical requirements and generally must include:

- written and signed agreement
- minimum term of one-year
- fair market value compensation/payment
- compensation set in advance
- Must not take into account value or volume of referrals

Risk Area: Incorrect Claims

- Providers have an obligation to deliver, code and bill services in a manner consistent with applicable laws/rules.

- Whistleblower laws provide incentives to individuals to report improper behavior and billing inaccuracies.

- Government devoting extensive resources to identifying incorrect billing (RACs, ZPICs, MACs, MICs, etc.)
Risk Area: Incorrect Claims (Continued)

- **Key vulnerabilities**
  - Inadequate clinical documentation
  - Inadequate clinical documentation
  - Inadequate clinical documentation
  - Conditions of Participation
  - National/Local Coverage Determinations
  - Medical necessity
  - Correct patient status (IP, OP, Observation)
  - Quality
  - Coding (approaching 50,000 codes)
  - Technical billing requirements (thousands)

Risk Area: Incorrect Claims (Continued)

- **Penalties**
  - Refunds
  - Treble damages
  - Fines of $5,500 - $11,000 per claim, adjusted for inflation
  - Permissive exclusion
  - Prison and mandatory exclusion
Risk Area: Quality

Increasing importance

- **Technology** – more access to data
- **Transparency** – increasing public reporting of hospital and physician data. However, be aware of the data limits.

  - Bad data = bad
  - Good data = ?

- **Payment tied to quality**
- **Risk exposure** – physicians, hospital, hospital management & boards

Risk Area: Quality (Continued)

Key Issues

- **Medical Necessity** – generally driven by timely, accurate, legible documentation. Management & physicians must understand payer criteria – RAC audits

- **Effective Case Management/ Utilization Review Function**
  - Case Management competence
  - Early review of all Medicare admits
  - Notices to patients when cases don’t meet criteria
  - Notice to physician of cases not meeting criteria
  - Effective UR Committee
  - Credentialing element related to appropriate admits
Risk Area: Quality (Continued)

- Consistent adherence to Standard of Care/Protocols
- Avoiding “never events” & hospital acquired infections
- ‘Conditions of Participation’ Compliance

**Tip:** “Public” reporting of quality data by physician and department will improve results.

*Transparency changes behavior!*

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**Risk Area: Quality (Continued)**

**Consistent credentialing/re-credentialing**
- Verification of licensure, CV/application info, sanctions and exclusion check
- Analysis of admitting/practice patterns and outcomes

**Effective Peer Review**
- Prompt, independent investigation
- Comprehensive documentation
- Appropriate corrective action
- Monitoring corrective action plans
- Consistent, transparent board reporting
Risk Areas: Privacy & Data Security (HIPPA)

• Privacy and Security violations pose increasing risks at both federal and state level

• Issues (Risks)
  ➢ Loss/theft of unencrypted data
  ➢ Snooping/unauthorized data access
  ➢ Cameras capturing PHI
  ➢ Social Media
  ➢ Failure to timely report

• Penalties
  ➢ Fines & possible criminal sentencing

Risk Area: Tax Exemption Issues

• Intense scrutiny by Federal, state and local governments and agencies, consumer groups, unions and press

• Areas of concern
  ➢ Charity care and community benefit
  ➢ Pricing
  ➢ Collection activity
  ➢ Balance sheet
  ➢ Joint venture and management agreements, particularly with for-profits
  ➢ Executive compensation and benefits
QUESTIONS?

Thank You