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
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

Challenge

- 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 then 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 (Including use of complaint mechanisms)
- Promotion & enforcement
- Appropriate response to misconduct
- Risk assessment

Compliance Foundations

- 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.

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, procedures and education content
  - Structural → OSGs
  - Substantive → high risk areas
- Tell Management what needs to be done
- Monitor management performance
- Report to board and management on management execution

Role of Compliance Officer (Continued)

- Simplify complex, clarify ambiguous
- Take a position
- Respond to enforcement/legal changes
- Have the difficult conversations
- Revise/rework the Compliance Program
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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**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

**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

- **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

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

- 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 hospital 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
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.
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

Key Exceptions: personal services, office/equipment, rental, incidental benefit, non-monetary compensation, indirect compensation, compliance training, CME, and fair market value

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 coding/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
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  - 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)

• **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

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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!

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/devices/drives
  ➢ 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