Conducting a Compliance Audit or Review – Key Issues

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Do you have an effective compliance program?
- Competitive advantages
- Establish reputational advantages
- Address auditor concerns
- Avoids fear that can chill creativity
- Reduces likelihood of legal violations
- Avoids compliance hurdles to transactions
- May reduce penalties/avoid CIA in the event of a Government investigation
- Minimizes institutional risk and avoids adverse PR

Challenges to Establishing an Effective Compliance Program
- Limited resources
- Ineffective and infrequent compliance education
- Embedding compliance within the business culture
- Getting the business to “own” compliance
- Tone at the middle/manager buy in
- Inadequate commitment to auditing/internal reviews
- Lack of clear communications channels
Typical Compliance Pitfalls

- Policies too complicated and theoretical
- Lack of policies in relevant and applicable risk areas (e.g., non-monetary compensation; response to government inquiries; bundled contracts)
- Inadequate internal controls to ensure policies are followed
- Early involvement of Legal/Compliance when issues or need for guidance arise
- Failure to involve the business in compliance policy development, implementation and education

Recent Legal Changes

- Sunshine Act
- Updated Foreign Corrupt Practices Act (FCPA) guidance
- False Claims Act (FCA) changes
- 60-day rule for reporting and refunding identified overpayments
- HITECH Act

Need for Compliance “Gap” Analysis

- Health care reforms create new compliance risks for health care providers and life science companies
- Statutory changes provide new tools and additional resources to investigate and prosecute health care fraud & abuse, while making violations easier to prove
- Increased focus on physician relationships
- Advent of RAC, HEAT and other audit and enforcement initiatives
Legal Areas to Consider
- State and Federal False Claims Acts
- Billing, Coding and Documentation Requirements
- Anti-Kickback Statute
- Stark Act
- Licensing and Medicare/Medicaid Requirements
- Tax Exemption Considerations
- FCPA
- FDA
- Sunshine Act

Areas of Compliance Review
- Compliance program infrastructure
- Channels for communicating compliance issues and seeking guidance
- Compliance education
- Auditing/monitoring function
- Billing/coding function coding
- Licensing requirements

Areas of Compliance Review (cont’d)
- Medicare/Medicaid participation, payment and performance standards
- Medical record documentation
- Marketing
- FCPA issues
- Physician financial relationships
- Interplay among quality, UM, billing and compliance functions
Road Map for Compliance Review

- Step 1: Kickoff teleconference to define project scope, objectives and content/timing of deliverables.
- Step 2: Issue work plan and information request.
- Step 3: Review compliance plan, policies and other documents provided in response to information request.
- Step 4: Conduct focus group interviews of key client Compliance and Legal representatives and leadership.
- Step 5: Deliver draft report identifying gaps from regulatory/best practice standards and recommendations to fill gaps.
- Step 6: Vet preliminary report with Compliance and Legal.
- Step 7: Revise report and draft executive summary.
- Step 8: Present findings and recommendations to Board or Audit Committee.

Questions to Consider

- Does the organization have an effective compliance function that:
  - Minimizes enterprise risk by promoting compliance with applicable legal parameters?
  - Enables the organization to proactively identify and address any compliance issues that arise?
- Is there reason to believe that the organization faces material compliance exposure in any regulatory risk area?

Elements of an Effective Compliance Plan

- Written standards of conduct, policies and procedures that promote the health system’s commitment to compliance.
- Designation of a Compliance Officer and other appropriate compliance infrastructure.
- Training and education.
- Effective lines of communication.
- Auditing and monitoring.
- Enforcement of disciplinary standards through well publicized guidelines.
- Prompt and appropriate response to suspected non-compliance.
Key Recommendations

- Establish communication protocols and policies to consistently address the billing/compliance implications of quality and regulatory issues in a manner that minimizes both False Claims Act and malpractice exposure
- Upgrade policies, tools and educational programs on physician transactions to arm leaders with knowledge of what they can do, as well as what they cannot do
- Require business ownership of all policies
- Develop internal controls to guard against violation of scope of practice and scope of authority parameters
- Develop contract tracking mechanisms

Key Recommendations

- Institute a “rapid response protocol” to address Government inquiries
- Develop and implement an annual compliance education plan identifying the curriculum, target audience, format and teaching methodology for programs that proactively focus on topics that minimize enterprise risk
- Create more effective channels of communication to assure awareness of compliance policy changes, legal developments and potential compliance issues
- Make sure that sound auditing/monitoring plan and investigation protocols are in place to address all risk areas
  - Shift from retrospective to concurrent auditing in known risk areas

Gap Analysis Follow Up

- Identify and prioritize recommendations for implementation
- Develop work plan to effectuate recommendations
- Solicit leadership team input on recommendations and work plan
- Implement work plan, including policy, protocol, and process revisions to improve compliance plan effectiveness
- Educate workforce on compliance program changes
Steps to Compliance – Written Standards of Conduct, Policies and Procedures

- Document compliance expectations
- Aligned with regulatory guidance
- Code of Conduct
- Compliance program documents
- Up-to-date policies and procedures addressing risk areas
- Proof of distribution to employees and FDRs
- Employee/contractor certifications/acknowledgements
- Vendor credentialing and certifications
- Policy or statement of non-intimidation and non-retaliation
- Establish schedule for and track periodic updates

Steps to Compliance – Oversight/ Appropriate Compliance Infrastructure

- Compliance Committee charters, agendas and minutes
- Updates to CEO on program status and issues
- Periodic Board updates, agendas and minutes.
- Ability for Compliance Officer to make in-person reports to CEO and Board
- Org Charts to demonstrate reporting structure
- Job descriptions
- Be ready to answer auditor questions when interviewed

Steps to Compliance – Training and Education

- Annual compliance education plan/curriculum
  - All employees educated within 30 days of hire and at least annually thereafter
- Retain training materials, agendas, sign-in sheets
  - Use and document scenario-based training whenever practicable
- Methods to track completion and follow-up
  - Track all training
    - Job-specific
    - Ad-hoc training/coaching
    - Third party conferences
    - Completion of electronic modules
- Document methods to determine effectiveness of training (e.g., tests, surveys, post-training discussions)
- Compliance training as a documented element of performance reviews
Steps to Compliance – Create Open Communication Channels

- Multiple, well-publicized communication channels available to employees, Board and FDRs
  - Anonymous reporting option available
  - Reporting channels posted in employee areas and on intranet
- Code of Conduct requires reporting of concerns
  - Code also encourages employees/contractors to seek compliance guidance prior to taking action when they are unclear on compliance parameters
- System to track reports and follow-up
- Policy or statement of non-retaliation
- Email, newsletters, and other forms of information exchange on compliance issues and developments
- Compliance officer feedback to management on compliance risk areas

Steps to Compliance – Auditing and Monitoring

- Risk assessments
- Annual work plans and progress tracking
- Auditing and monitoring results shared with Compliance Officer, CEO, Board, Compliance Committee and key managers
- Work plans for follow up on adverse audit results
- Annual audit of compliance program effectiveness
- Monthly review of sanctions and exclusions
- Data analysis to identify fraud, waste and abuse
- List of auditing and monitoring activities, frequency, systems used
- Process to audit and monitor FDRs
- Document coordination with other areas (Internal Audit, Compliance, Business owners, Special Investigation Unit, etc.)

Steps to Compliance – Enforcement

- Policies and procedures have clear, specific disciplinary standards
- Timely and consistent enforcement
- Provide examples of non-compliant conduct
- Retention of records
- Track so it can be trended or reported
- Management team accountability for foreseeable compliance failures of subordinates
Steps to Compliance – Rapid Response to Suspected Non-Compliance

- Investigation protocols
- Document holds
- Investigation steps are logged and well documented
  - Retain documentation of interviews and documents reviewed
  - Segregate privileged materials
- Identify root cause of issues
- Corrective action plans designed to correct and prevent future occurrences
- Assessments of corrective action plan effectiveness/lack of repeat issues
- Policy revisions and education to prevent recurrence of non-compliant behavior
- Reports to government authorities when required or deemed appropriate
- Referrals to law enforcement or other agencies

Practical Decision Points to Consider

- Scope of review
- Frequency and number of reviews to be conducted
- Criteria for review (e.g., divisions, departments, entire organization)
- Potential use of sampling methodology
- Process for conducting reviews
- Who will conduct review
  - Legal/Compliance
  - Outside Counsel
  - Combination
- Use of results of review
  - Topics of discussion
  - Suggest or require process improvements/remediation
  - Reporting
  - Change in business operations
  - Other

Katten’s Perspective on Compliance

- National health care practice representing health systems, hospitals, large physician groups, ancillary service providers, health plans and life science companies
- Our perspective on compliance program effectiveness is informed by our experience:
  - Representing clients in internal investigations, government investigations and qui tam suits
  - Negotiating and navigating settlement agreements, corporate integrity agreements and deferred prosecution agreements
  - Counseling clients through self-reporting options
  - Developing and updating compliance plans and policies
  - Participating in compliance education programs
  - Conducting compliance program effectiveness reviews
Questions?