Compliance Audits and Reviews: A Step-by-Step Guide

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What benefits exist in implementing a robust and active 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

The Perfect Compliance Plan

The 7 Pillars of an Effective Compliance Plan

- The OIG provides seven basic elements of an effective compliance program that pertain to all industries (many of which have been incorporated into the 12-steps):

    1. Implementing written policies, procedures and standards of conduct;
    2. Designating a compliance officer and compliance committee;
    3. Conducting effective training and education;
    4. Developing effective lines of communication;
    5. Enforcing standards through well-publicized disciplinary guidelines;
    6. Conducting internal monitoring and auditing; and
    7. Responding promptly to detected offenses and developing corrective action.

- The OIG also provide industry-specific guidance (e.g., Nursing Facilities, Research, Hospitals, Pharmaceutical Manufacturers, Ambulance Suppliers, Individual and Small Group Physician Practices)

Step 1 – Know Your Scope

- What statutes, regulations, policies and organizational activities are relevant?

- Understand the scope of the areas of compliance that are critical to your specific industry

- Understand the "non-negotiables"

- Proper management of expectations at all levels

- Top-down approach (versus bottom-up)

Step 2 – Understand the Challenges in Establishing an Effective Compliance Program
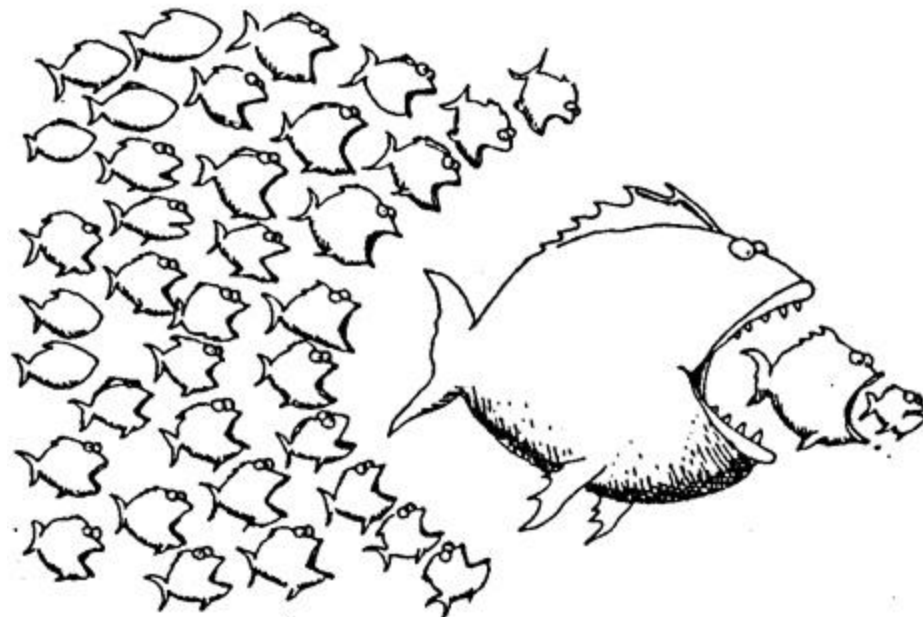
Typical Challenges to Consider

- Limited resources (legal, financial, manpower)

- Ineffective and infrequent compliance education

- Embedding compliance within the business culture

- Getting the business leaders to "own" compliance

- Tone at the middle/manager buy-in (soft spot)

- Inadequate commitment to auditing/internal reviews

- Lack of clear communications channels

Step 3 – Know where the Pitfalls are.

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 arises

- Failure to involve the business in compliance policy development, implementation and education

Ongoing Legal Changes

- CMS and Stark Compliance (Strict Liability)

- OIG and Fraud/Abuse (Intent Based)

- Coding Compliance (High Risk Areas)

- Reimbursement and Billing (High Bar)

- Ramp-up in reinforcement for HIPAA breaches

- Ongoing, periodic changes are the norm in our industry (Ongoing Education in Key)

Board and Management Responsibilities

- The Board and senior management have responsibility to oversee compliance programs and can be held accountable for violations when there is substandard oversight or there is a culture of noncompliance within the business. *United States v. Park*, 421 U.S. 658, 672-74 (1975) (a board member or senior management may be held liable for violations for failing to act if he was in a position of authority to do so).

- The OIG is focused on holding Responsible Corporate Officials accountable for health care fraud (e.g., exclusion of a chairman of a large nursing home for his responsibility in alleged substandard care of residents)

- Must exercise reasonable oversight with respect to implementation and effectiveness of compliance program.

- May delegate oversight of compliance program, but remains accountable for reviewing its status.

- Training and education on compliance program required.

- Should have a means to prove active engagement in the oversight of the program.

Step 4 – Compliance Review Roadmap
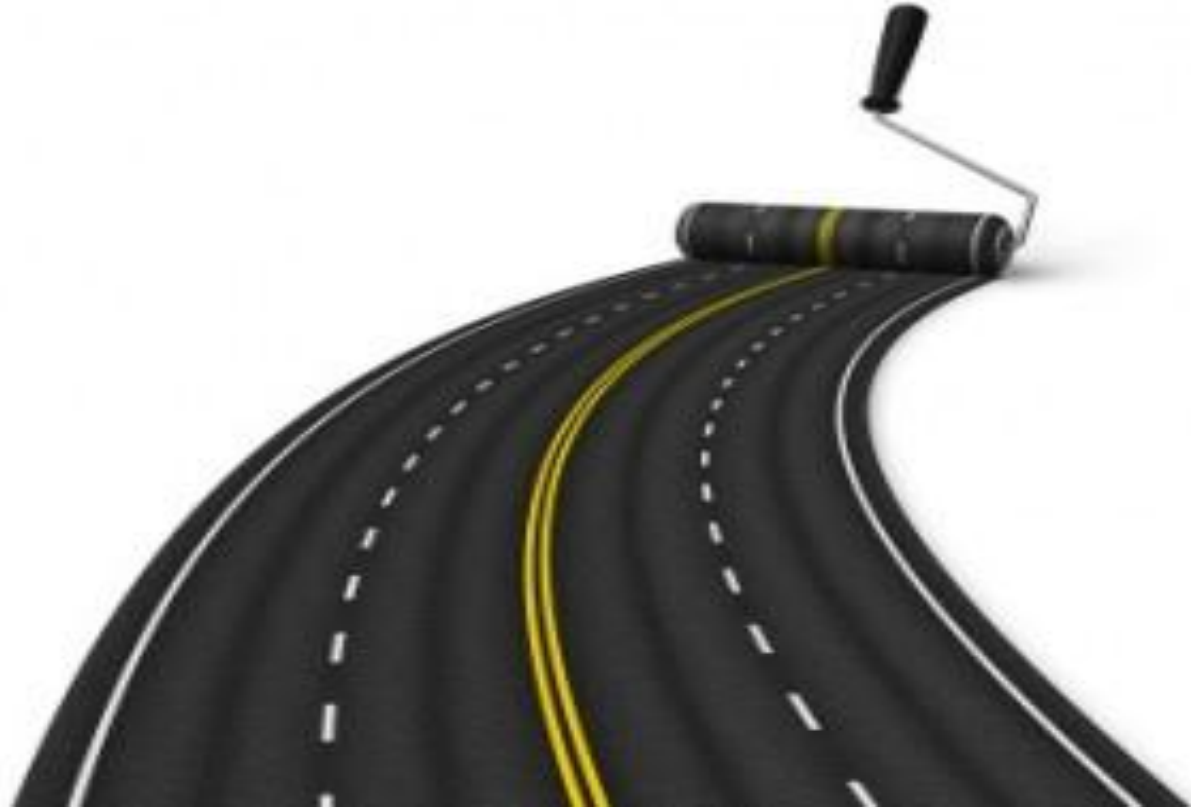
Typical Process for Compliance Review

- Step 1 – *The "Kickoff"* – Initial teleconference/meeting to define project scope, objectives and content/timing of deliverables

- Step 2 – *Disseminate Duties and Deadlines* – Issue work plan and information request

- Step 3 – *Review Underlying Compliance Framework* – Review compliance plan, policies and other documents provided in response to information request

- Step 4 – *The "CSI" Part* – Conduct focus group interviews of key client Compliance and Legal representatives and leadership

- Step 5 – "*Pen to Paper"* – Deliver draft report identifying gaps from regulatory/ best practice standards and recommendations to fill gaps

- Step 6 – *The Download* – Vet preliminary report with Compliance and Legal.

- Step 7 – *The Clean-Up* – Revise report and draft executive summary

- Step 8 – *The Pitch* – Present findings and recommendations to Board or Audit Committee

"Deeper Dive" – 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

"Deeper Dive" – 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 First Tier, Downstream and Related Entities (*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

"Deeper Dive" – Gap Review

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

Where are the Usual <u>Knowledge</u> Gaps?

- State and Federal False Claims

- Billing, Coding and Documentation

- Anti-Kickback Statute Safe Harbors

- Stark Law

- Licensing and Medicare/Medicaid Requirements

- Tax Exemption Considerations

- "Know Your Business"

Where are the Usual <u>Process</u> Gaps?

- Compliance program infrastructure

- Channels for communicating compliance issues and seeking guidance

- Compliance education

- Auditing/monitoring function

- Billing/coding function coding

- Licensing requirements

Gap Analysis "Tips"

- 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

What happens next?

Step 5 – The Playbook – How to Implement Changes
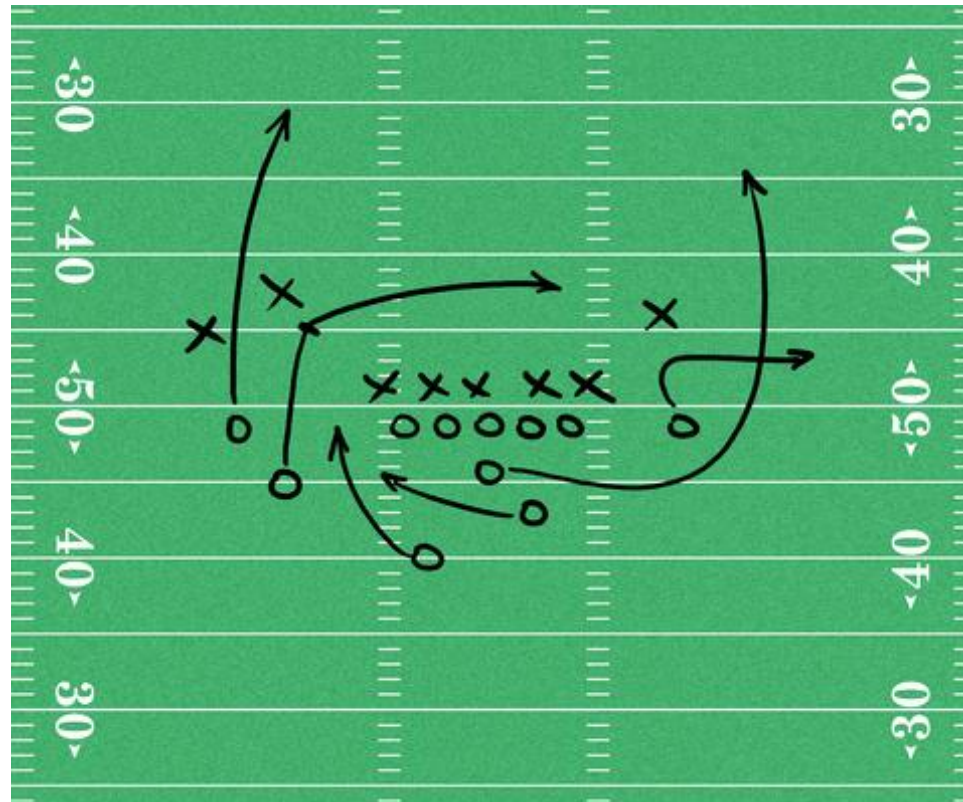
Key Recommendations

- Establish revamped communication protocols and policies (for e.g., if there are significant billing and coding issues, implement clear processes for addressing ambiguities as to particular codes)

- Upgrade policies, tools and educational programs on weakness areas (e.g., if physician transactions are problematic, target educational on such areas)

- Require business ownership of all policies (e.g., require business leaders to take part in presenting policies and educational efforts, consider more interactive solutions)

- Develop internal controls to guard against violation of scope of practice and scope of authority parameters (e.g., consider where the "gaps" are and figure out how best to address – directly and indirectly)

- Sometimes outside resources are necessary (e.g., utilize contract tracking mechanisms)

Additional Key Recommendations

- Institute a "rapid response protocol" to address Government inquiries (even if not immediately, become a "prepper" for such events)

- Formalize a process to make compliance a part of the annual review process (e.g., incorporate compliance in the employee review process as well as part of 360 review)

- Create more effective channels of communication to assure awareness of compliance policy changes, legal developments and potential compliance issues (e.g., intranet, web-based tools, etc.)

- Implement an ongoing "compliance management" plan and investigation protocols to address risk areas

- Shift from retrospective to concurrent auditing in known risk areas

Oversight/ Appropriate Compliance Infrastructure Recommendations

- Enhance Compliance Committee charters, agendas and minutes

- Updates to CEO/Executive Team on program status and issues

- Periodic Board updates, agendas and minutes

- Ability for Compliance Officer to make in-person reports to CEO, Executive Team, GC Office and/or Board

- Separate counsel from compliance – OIG comment - "*Does the compliance officer have independent authority to retain legal counsel?*"

  - This question suggests that in-house counsel may not be well suited to serve the advising needs of the organization's compliance officer, and that having the option to seek outside counsel on compliance issues may better preserve the officer's independence.

- Org charts to demonstrate clear, established reporting structure

Training and Education Recommendations

- Institute an 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 (how can you make sure that it "stuck?)
- 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, third party review, cross-department review)
- Compliance training as a documented element of performance reviews (see earlier comment)

Communication Recommendations

- Multiple, well-publicized communication channels available to employees, Board and FDRs – for example:
  - Anonymous reporting option available and easy to access
  - 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 (not just process but who is responsible)
- Policy or statement of non-retaliation (and comply with it)
- Documented hotline testing
- Email blasts, newsletters and other forms of information exchange on compliance issues and developments
- Compliance officer feedback to management on compliance risk areas

Auditing and Monitoring Recommendations

- Risk assessments (targeted and specific with reporting obligation)

- Annual work plans and progress tracking (SWOT – "Strength, Weakness, Opportunities, Threats" analysis)

- Development data analysis/process to identify fraud, waste and abuse

- Keep track of auditing and monitoring activities, frequency, systems used

- Continue to streamline and improve process to audit and monitor FDRs (e.g., monthly review of sanctions and exclusions (FDRs)

- Document coordination with other areas – as applicable (Legal Office, Risk Management, Internal Audit, Compliance, Business owners, Special Investigation Unit, etc.)

Enforcement Recommendations

- Develop policies and procedures with clear, specific disciplinary standards

- Timely and consistent enforcement applied (don't make "exceptions")

- Provide examples of non-compliant conduct

- Retention of records of non-compliance

- Intelligent tracking (so it can be trended or reported, as needed, e.g., to physician national data bank)

- Management team accountability for foreseeable compliance failures of subordinates (e.g., develop viable "Plan B's" and the "What If" scenarios)

Step 6 – What if the "What If's" Actually Happen?

"Rapid Response" Recommendations

- Develop investigation protocols (e.g., what to do when the government comes knocking?) – education should focus on what everyone's jobs are and what they should and should not do

- Implement a policy for document holds and records retention

- If there have been internal investigations:

  - Assure that steps have been logged and well documented

  - Retain documentation of interviews and documents reviewed

  - Segregate privileged materials (as applicable)

- Identify and document root cause of issues

"Rapid Response" Recommendations

- Implement corrective action plans designed to correct and prevent future occurrences

- Assess corrective action plan effectiveness/lack of repeat issues

- Revisit policy revisions and education to prevent recurrence of non-compliant behavior

- Consider whether to report to government authorities when required or deemed appropriate (decision should be handled in a coordinated effort with legal)

- Referrals to law enforcement or other agencies (coordinated with legal)

Step 7 – Practical Considerations and Application

Takeaways – Practical Considerations and Application

- 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
  - Tangible steps
  - Change in business operations
  - Other

Is there a "best practices" in compliance?

Katten's Experience

- National health care practice with "pulse" on areas of risk (in the course of representing health systems, hospitals, large physician groups, ancillary service providers, health plans and life science companies around the country, we have come across a number of compliance issues)

- You don't want your company to be the first (first heart surgery vs. 1000th)

  - 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?

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