
Compliance Programs for Physician Practices

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Session Topics

- Changes in the Regulatory Environment
 - 7 Elements of an Effective Compliance Program
 - DoJ Guidance
 - OIG Guidance and Best Practices
 - Applying the 7 Elements in Physician Practices
 - Common Implementation Issues
 - Implementation Strategies
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Current Environment for Compliance Plans

- Civil False Claims Act (*qui tam* lawsuits)
 - Kickback prosecutions
 - Federal Sentencing Guidelines
 - OIG Compliance Guidance(s)
 - DRA requirements for Medicaid providers
 - NY Medicaid mandatory compliance programs
 - Medicare Advantage requirements
 - PPACA requirements for nursing facilities
 - Request for Comments (9-23-2010)
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Cost of Noncompliance

- Overpayment recoveries
 - Monetary penalties and damages
 - Exclusion from federal programs
 - Criminal prosecution
 - Damage to reputation
 - Cost of investigation /defense
 - Impact on operations and quality
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Benefits of an Effective Compliance Program

- Avoiding noncompliance, violations and “reckless disregard”
 - Improving quality and efficiency
 - Enhancing operational consistency
 - Reducing penalties and fines
 - Reducing whistleblower risk
 - Avoiding Corporate Integrity Agreements (CIAs)
 - Certification of Compliance Agreements (CCAs)
 - Demonstrating good corporate citizenship
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DOJ Compliance Focus

- Department of Justice is seeking to change *corporate conduct* and force the industry to a model of *self-policing*
 - “[A] priority of DOJ is to look to prevention as part of our strategy”
 - “[P]roviders have the responsibility to prevent health care fraud.”
 - Federal Sentencing Guidelines
 - Chapter 8, Sentencing of Organizations
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OIG Compliance Guidance for Physicians

- “[U]nlike other guidances issued by OIG, this guidance for physicians does not suggest that physician practices implement all seven components of a full scale compliance program.”
 - “in recognition of the financial and staffing resource constraints faced by physician practices.”
 - “Each physician practice can undertake reasonable steps to implement compliance measures, depending on the size and resources of that practice.”
- **OIG Compliance Program for Individual and Small Group Physician Practices** (65 Fed. Reg. 59434 (Oct. 5, 2000))

Effective Compliance Program: 7 Elements

1. Compliance Standards and Procedures
2. Oversight Responsibility
3. Due Care in Delegation of Authority
4. Employee Training
5. Monitoring, Auditing and Communication
6. Enforcement and Discipline
7. Response and Prevention
8. **Policy of Non-Intimidation and Non-Retaliation**
 - New York Medicaid OIG requirements

1. Standards and Procedures

- *Federal Sentencing Guidelines*
 - An organization must have established standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct
 - *OIG Guidance and Best Practices*
 - Code of Conduct, policies and procedures adopted by Board of Directors
 - Communicated to employees, contractors and agents
 - Second-tier policies and procedures
 - Integrate compliance and operations
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Typical Code of Conduct Standards

- *Obligation to report potential compliance issues*
 - *Obligations to patients / medical ethics*
 - *Fair treatment of employees*
 - *Patient care, rights and privacy*
 - *Billing practices*
 - *Accuracy and retention of records*
 - *HIPAA Privacy and Security*
 - *Ethical business practices*
 - *Antitrust*
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Typical Code of Conduct Standards

- *Conflicts of interest*
 - *Marketing and advertising*
 - *Business/professional “courtesy”*
 - *Controlled substances / abuse*
 - *Health, safety, environment*
 - *Harassment / workplace violence*
 - *Equal employment opportunity*
 - *Government investigations*
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2. High Level Responsibility/Oversight

- *Federal Sentencing Guidelines*
 - Specific individual(s) within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures.
 - *OIG Guidance and Best Practices*
 - Compliance officer must have authority and ability to initiate change
 - Compliance officer must have unfiltered access to CEO and Board of Directors (governing body)
 - Compliance committees and liaisons
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OIG Guidance for Physician Practices

- Single responsible person is best
 - Can assign responsibilities to multiple people
 - “In lieu of having a designated compliance officer, the physician practice could instead describe in its standards and procedures the compliance functions for which designated employees, known as “compliance contacts,” would be responsible.”
 - Outsourced compliance officer functions
 - “[I]f this role is outsourced, it is beneficial for the compliance officer to have sufficient interaction with the physician practice to be able to effectively understand the inner workings of the practice.”
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Compliance Officer Characteristics

- High integrity and credibility
 - Strong analytical skills
 - Effective communication skills
 - Effective interpersonal skills
 - Good organizational skills
 - Independent (not reporting to General Counsel, CFO, or Controller)
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Compliance Officer Responsibilities

- Overseeing plan implementation
 - Reporting regularly to Board and CEO
 - Revising program when needed
 - Overseeing training of personnel regarding the program and regulatory requirements
 - Coordinating personnel discipline issues
 - Coordinating internal reviews
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3. Careful Delegation of Authority

- *Federal Sentencing Guidelines*
 - The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities.
 - *OIG Guidance and Best Practices*
 - Screening for sanctioned and excluded individuals and entities
 - Background checks (?)
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4. Training of Personnel

- *Federal Sentencing Guidelines*

- The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, *i.e.*, by requiring training programs or by disseminating publications that explain in a practical manner what is required.

- *OIG Guidance and Best Practices*

- All personnel trained on compliance program
 - Additional training related to job functions
 - Training must be documented
 - Line management accountability
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5. Monitoring, Auditing and Communication

- *Federal Sentencing Guidelines*

- The organization must have taken reasonable steps to achieve compliance with its standards
 - by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents
 - by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution
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5. Monitoring

- *OIG Guidance and Best Practices*
 - Monitor on an ongoing basis (day-to-day)
 - Use benchmarks, profiles, variances and trend analyses to identify high-risk issues by functional area
 - Hold line managers accountable for routine monitoring
 - Periodic reviews by Compliance Officer
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5. Auditing

- *OIG Guidance and Best Practices*
 - Adopt formal audit and review plan
 - Target high-risk areas
 - Focus on suspected violations and internal control weaknesses
 - Periodic reviews by sampling claims, documentation, payments and denials
 - Reviewers independent of line managers
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5. Communication

▪ *OIG Guidance and Best Practices*

- All personnel required to report potential issues
 - “conduct that a reasonable person would, in good faith, believe to be erroneous or fraudulent”
 - Anonymous (if possible) / Confidential (e.g., drop box)
 - No fear of retribution (policy and procedure)
 - NY OIG Element No. 8, Non-Intimidation, Non-Retaliation
 - Widely-publicized
 - Reports promptly investigated and documented
 - Posting 1-800-HHS-TIPS number (?)
 - Coordination with billing company compliance officer
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6. Enforcement and Discipline

▪ *Federal Sentencing Guidelines*

- The standards must have been consistently enforced through appropriate disciplinary mechanisms, including appropriate discipline of individuals responsible for the failure to detect an offense.
 - Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; the form of discipline that will be appropriate will be case specific.
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6. Enforcement and Discipline

- *OIG Guidance and Best Practices*

- Administration of policies must be consistent at all personnel levels
 - Compliance policy violations must be treated as seriously as other disciplinary matters
 - Compliance concepts should be part of annual performance evaluation process
 - Publish range of actions for deterrent effect
 - Intentional or reckless noncompliance
 - Failure to detect noncompliance or discipline
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7. Response and Prevention

- *Federal Sentencing Guidelines*

- After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately and to prevent further similar offenses – including any necessary modifications to its compliance program to prevent and detect violations

- *OIG Guidance and Best Practices*

- Establish formal protocols for handling reported issues and suspected violations
 - Appropriate corrective actions must implemented
 - Findings and corrective actions must be documented
 - Prompt reporting/ voluntary disclosure
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Implementation Timing – OIG Guidance

- “The OIG acknowledges that full implementation of all components may not be feasible for all physician practices. Some physician practices may never fully implement all of the components.”
 - “[A]s a first step, physician practices can begin by adopting only those components which, based on a practice’s specific history with billing problems and other compliance issues, are most likely to provide an identifiable benefit.”
 - “Programs hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could cause greater harm or liability to the [entity] than no program at all.” OIG Guidance for Hospitals
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OIG Suggested Implementation Steps

1. Auditing and monitoring
 2. Establish practice standards and procedures
 3. Designation of Compliance Officer/contacts
 4. Conducting appropriate training and education
 5. Responding to detected offenses and developing corrective action initiatives
 6. Developing open lines of communication
 7. Enforcing disciplinary standards through well-publicized guidelines
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Keys to Successful Implementation

- Compliance should be part of the culture
 - Leadership by governing body, physician management
 - Integrate compliance with operating systems
 - Focus on core processes using a risk-based approach to policy development
 - Develop policies and procedures in collaboration with physicians and line personnel
 - Empower all personnel to identify and report compliance issues
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Implementation Strategies

- Establish structure / program documents
 - Risk assessment
 - Consider baseline audit
 - Identify and act on "quick hits"
 - Prioritize based on risk assessment
 - Draft and publicize a reasonable phased implementation plan
 - Share the work with compliance committee, task forces, line managers, physician champions
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Challenging Practical Issues

- Compliance Officer / Function / Structure
 - Compliance committee(s)
 - Functions / Composition
 - Baseline audits
 - Role of legal counsel
 - In-house vs. outside
 - Special expertise
 - Compliance Programs of Other Organizations
 - Hospitals, IPAs, HMOs, provider networks
 - Opportunities and challenges
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Compliance Committee Functions

- Developing standards of conduct
 - Analyzing environment and risks
 - Evaluating policies and procedures
 - Developing internal control systems
 - Reviewing monitoring activity
 - Investigating / corrective actions
 - Overseeing/recommending disciplinary actions
 - Encouraging reporting of problems
 - Monitoring progress of compliance efforts
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Baseline Compliance Reviews (Audits)

- Evaluate “corporate state of mind”
 - “Snapshot” of operations
 - Identify systemic problems
 - Test current internal controls
 - Benchmark for program evaluation
 - Potential elements
 - Financial relationships
 - Policies and procedures
 - Billing records and documentation
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Essential Tensions in Policy Development

- Control vs. Responsiveness
 - Interactive process vs. Implementation progress
 - Billing system design vs. Reliance on audits
 - Buy or build capacity (training, monitoring, auditing, routine refunds)
 - Internal expertise vs. consultants

 - Pay attention now or pay later
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Compliance Policy Areas

- Billing, coding and medical records
 - Adequate and accurate medical records
 - Proper coding (procedure, diagnosis, POS, NCCI)
 - Nonphysician practitioner services (supervision, collaboration, counter-signatures, charge capture)
 - Encounter form and requisition design
 - EHR development (templates, menus, cut/paste, information forward, log in, coding modules)
 - Medical necessity (NCD, LCD, ABN)
 - Quality indicators
 - Hospital patient status determinations/ orders
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Compliance Policy Areas

- Fraud and abuse (anti-kickback/ self-referral)
 - Physician practice acquisitions
 - Hospital-based physician contracts
 - Vender and supplier contracts
 - Provider network affiliations
 - Gainsharing and Physician Incentive Plans
 - Marketing / Patient inducement
 - Stark notice re in-office CT, MRI, PET services
 - Office compensation practices
 - Don't encourage upcoding or other noncompliance
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Compliance Policy Areas

- Managed Care Contracts
 - Enrollment/ disenrollment
 - Marketing activities
 - Representations in negotiations
 - Physician incentive plans
 - Complaints and grievances
 - Diagnostic Services
 - Anti-Markup rule
 - IDTF requirements
 - CLIA certification and proficiency testing
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Compliance Policy Areas

- HIPAA Privacy and Security
 - Provider enrollment / reassignment
 - Sanctioned and excluded parties
 - Business Office
 - Copayments / Discounts / “Courtesy”
 - Credit Balances
 - Remittance Review and Refunds
 - OSHA compliance
 - Harassment and workplace violence
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Medical Necessity Issues

- “OIG recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, a physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary.”
 - OIG Guidance for Physicians
 - “The compliance officer should ensure that a clear, comprehensive summary of the ‘medical necessity’ definitions and rules of the various government and private plans is prepared and disseminated appropriately.”
 - OIG Guidance for Hospitals
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Approaches to Monitoring/Auditing

- Billing by chart abstraction
 - EHR program coding modules
 - Pre-billing reviews
 - Post-billing reviews
 - Post-payment reviews
 - Review of payer denials
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Billing Relationships Affecting Monitoring

- Reassignment / Services Billed by Others
 - Professional services billed by hospitals
 - Purchased interpretations
 - *Locum tenens* billings
 - Billing agents / Managers
 - Services Ordered by Others
 - Billing Companies
 - See OIG Compliance Program Guidance for Third-Party Medical Billing Companies
 - 63 Fed. Reg. 70138 (Dec. 18, 1898)
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Reporting Mechanisms

- Hot-Lines
 - Outsourcing hot-line functions
 - Handling multiple avenues
 - Non-threatening, no retaliation
 - Confidentiality /Anonymity
 - Feedback to callers
 - Documentation (issues/responses)
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Corrective Action

- Do not panic, but act promptly
 - First, do no harm
 - Do not jump to conclusions
 - Exposure
 - Culpability
 - Applicable law and standards
 - Review available information
 - Just the facts (what, who, when, why, how much)
 - Applicable regulations and requirements
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Corrective Action

- Review applicable regulations, interpretations and implications
 - Consider repayment / disclosure
 - Consider disciplinary action
 - Review current policies and procedures
 - Update compliance program
 - Report in accordance with policy
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Obligations to Disclose

- What to report?
 - Overpayments / Errors
 - Incorrect payments do not necessarily indicate wrongdoing, but may require refunds
 - False Claims / Wrongdoing
 - Where to report ?
 - Incorrect payments
 - Evidence of wrongdoing
 - Other events of regulatory noncompliance
 - Criminal conduct
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PPACA: Mandatory “Voluntary” Refunds

- Requires Providers to:
 - (A) **report and return** the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
 - (B) **notify** the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned **in writing of the reason for the overpayment.**
- Deadline for reporting/returning is the later of—
 - (A) the date which is **60 days after** the date on which **the overpayment was identified**

42 U.S.C. §§ 1320a-7k(d), 1320a-7a(a)(10)

Self-Disclosure Protocols

- **OIG Provider Self-Disclosure Protocol**
 - For potential violations of Federal criminal, civil, or administrative laws
 - Not for overpayments that do not suggest violations of law
 - Not for Stark-only situations
 - **Self-Referral Disclosure Protocol (CMS)**
 - OMB CONTROL NUMBER: 0938-1106
 - Onerous requirements, limited track-record
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Final Recommendations

- Do not panic
 - Don't rush, but don't delay
 - Document the plan and intentions
 - Perfection is the enemy of the good
 - Periodically review compliance program operations
 - Learn from identified issues
 - Make compliance responsibility part of doing the job right the first time
 - Never give up
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Questions

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