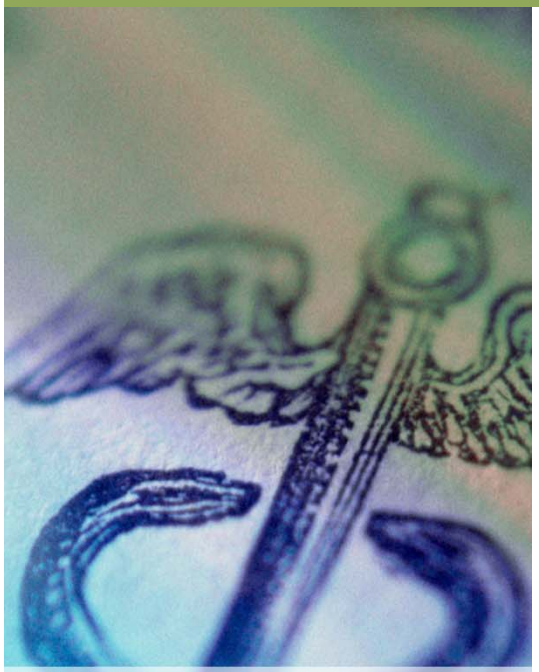

Managing Institutional Risk: Fraud-Proofing Your Organization

Healthcare Law & Compliance Institute

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Top 5 Fraud and Abuse Risks Facing Health Systems

- Non-compliant physician relationships
- Non-compliant vendor relationships
- Falsified or inadequate documentation
- Billing/coding errors
- Failures of care – “worthless services”

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Results of Enforcement Action

- $4.3B recovered under Health Care Fraud and Abuse Control Program in 2013.
  - $19.2B recovered over last five years
  - Since 1997, $25.9B returned to the Medicare Trust Fund
- In FY13, DOJ opened 1,013 new criminal and 1,083 new civil health care fraud investigations.
  - 718 defendants convicted of health care fraud related crimes
- $1.5 B in Health Care Fraud and Abuse Control Program funding in 2013.
- ROI (2011-2012): $8.10 per dollar expended

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Top 5 Steps Health Systems Can Take To Minimize Fraud & Abuse Risk

- Policies on physician contracting, non-monetary compensation and vendor relations ***with robust internal controls***
- Targeted auditing focused on specific billing, coding and documentation risks
- Multiple well-publicized reporting channels
- Robust investigations and corrective action plans
- Quality compliance audit

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Non-Compliant Physician Relationships: Recent Headlines

- A New Jersey hospital paid $12.5M to settle allegations that it created fraudulent advisory board to induce cardiology referrals.
- A health system paid $14.1M to settle FCA allegations that it improperly paid referring physicians above FMV rates for teaching services and charged physicians less than FMV for supplies.
- A Florida hospital paid $7M to settle charges that physician compensation arrangements exceeded FMV and included inappropriate productivity bonuses.
- A health system paid $25.5M to settle allegations that it paid bonuses to employed physicians that took into account referrals and had non-compliant lease arrangements.
- An AMC paid $2.8M to settle FCA claims that it paid salaries/benefits of PAs and NPs whose services were billed by a physician group.
- A dialysis company paid $400M to settle charges that its JV arrangements with physicians conveyed unlawful kickbacks.

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Avoiding Physician Relationship Pitfalls

Common Pitfall	Risk Minimization Strategies

No signed, written contract	• Audit A/P detail to ensure all physician payments are supported by fully executed contract
	• Adopt contract approval policy requiring legal approval of arrangements outside pre-approved parameters
	• Educate all employees in a position to deal with physicians on policy
	• Implement contract tracking system with automated flags ***and update/monitor regularly***
	• Institute safeguards to ensure no keys given out and no payments made without fully executed contract
	  o Build internal controls into A/P function to ensure that payments match fully executed contract
	  o Centralize leasing function under direction of strong, well-educated manager

Not FMV/commercially reasonable	• Adopt compensation plan and compensation review process for employed physicians • Engage reputable valuation experts when appropriate and review valuations with critical eye • Consider "group practice" subsidiary structure • Consider Board, Committee or designated executive approval of high risk arrangements (*e.g.*, with "disqualifying persons" or involving compensation in excess of financial thresholds) in accordance with IRS rebuttable presumption process
No need for services	• Document rationale for services from non-employed physicians • Consider requiring responsible executive certification

Provision of non-monetary compensation in excess of Stark law cap	• Adopt Non-Monetary Compensation Policy with pre-approval and tracking mechanisms
	  o Consider outright prohibitions on most problematic types of non-monetary compensation (*e.g.*, entertainment)
	  o Address controversial areas like golf, attendance at charity events and CME
	• Adopt letter agreement approach for meals provided in connection with committee and other unpaid physician services

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Non-Compliant Vendor Relationships: Recent Headlines

- Spine surgeon paid $2.9M for accepting inducements under sham IP agreements with device company.
- Sanofi paid $109M to resolve AKS claims associated with giving physicians free injectables to induce product purchases.
- Amgen paid $24.9M to settle charges that it gave kickbacks to switch providers from competitor drugs via rebates tied to market share/volume outside AKS discount safe harbor.
- Victory Pharma paid $11.4M to resolve liability arising from physician inducements: tickets to sporting events, concerts and plays; spa, golf and ski outings and expensive dinners.
- June 2014 OIG Special Fraud Alert on compensation paid by lab companies warns of abuses inherent in specimen collection and registry fees.

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Avoiding Vendor Relationship Pitfalls

Common Pitfall	Risk Minimization Strategies
Capital equipment and non-disposables provided without charge to induce implant/supply purchases	• Have legal review all significant vendor contracts and those that include provision of “no charge” items • Provide role-based training to supply chain
“Discounts” that don’t quality for discount safe harbor	• Develop approved vendor discount parameters • Require legal review of contracts that provide discounts outside predefined parameters
Charitable contributions and grants provided as inducements	• Adopt charitable contributions policy with criteria for vendor contributions • Erect wall between fundraising and vendor relations functions • Solicit vendors only as part of general fundraising campaigns • Execs and vendor decision makers should NEVER solicit vendor donations
Gifts, meals and entertainment	• Adopt vendor relations policy providing clear parameters to agents and employees regarding vendor gifts, meals and entertainment • Educate all executives, managers and physicians with “need to know” • Provide vendors with vendor guidelines and require signed acknowledgement • Consider reporting/tracking system for vendor remuneration (keeping “Sunshine” Act in mind)
Above FMV compensation from vendors	• Cover payments from vendors in vendor relations policy • Establish review and approval process • Consider requiring physicians to report and receive approval for relationships with “Industry” in light of Sunshine Act considerations

Billing/Coding Pitfalls: Recent Headlines

- Numerous hospitals and health systems have entered into multimillion dollar settlements for:
  - Allegedly performing medically unnecessary stent and cardiac catherization procedures.
  - Admitting patients for procedures that could have been performed on an outpatient or observation basis.
- A sleep diagnostics company paid $15.3M to resolve allegations that it violated the FCP because tests were performed by individuals who lacked appropriate credentials.
- A health network paid $35M to settle charges that it provided inpatient rehabilitation services that did not meet coverage criteria.
- A nationwide hospitalist firm paid $14M to settle charges that it upcoded E&M services.
- OIG report indicates Medicare overpaid HHAs $2.2B between January 2011 and December 2012 due to violations of F2F requirements; several HHAs have entered into multimillion dollar settlements.
- OIG work plan targets specific coding discrepancies (e.g., mechanical ventilation, outpatient dental services, outpatient E/M claims and kwashiorkor, bone marrow/ stem cell transplants and cardiac catherizations with endomyocardial biopsies).

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Avoiding Billing/Coding Pitfalls

Common Pitfall	Risk Minimization Strategies
Site of service issues	• Develop guidelines/protocols for inpatient v. outpatient procedures • Audit site of service, not just coding
Staff lack necessary credentials	• Perform at least annual credentials audits of clinical staff • Develop credentials database for staff, flagging expirations and CME requirements • Billing audits should focus on who performs services, not just coding
Upcoding	• Audit trends and level of service distributions • Develop investigation triggers for adverse audit results • Track and analyze denials
Staff not familiar with reimbursement criteria	• Consider specialization for billing/coding staff • Require annual, specialized education • Develop and regularly update billing instructions based on service-specific payor guidance
Lack of F2F documentation	• Institute internal controls so no services are billed without F2F executed by physician • Maintain physician signature logs to validate physician signatures • Educate staff, emphasizing serious consequences of end runs around F2F requirements
Falsified signatures	• Audit signatures, not just documentation • Educate staff on signature requirements • Institute internal controls to prevent password abuse
Lack of documented medical necessity	• Develop workflow checkpoints to ensure orders are in place prior to service delivery • Audit medical necessity documentation

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Whistleblower Findings*

- Only one in six reporters reported externally.
  - Of those, 84% tried to report internally first.
- Only 2% reported solely outside the company, and only 3% of reports were made externally first.
- Only 5% of individuals would be motivated by a monetary award.
- Reporting rates are impacted by:
  - Awareness and recognition of misconduct.
  - Whether or not employees feel that they can make a difference by reporting.
  - Whether employees feel financially secure and safe from retaliation.
  - Available support from management and coworkers and support systems outside of work.

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* Ethics Resource Center, *Inside of the Mind of a Whistleblower*

Avoiding Reporting Pitfalls

Common Pitfall	Risk Minimization Strategies
Insufficient information re: reporting channels	• Establish multiple reporting channels, including ***but not limited to*** hotline • Post hotline and other reporting channels in break rooms and on intranet site. • Publicize in compliance training and periodic newsletters
Lack of supervisor follow up on employee reports of suspected non-compliance	• Institute "manager responsibility for compliance" policy with clear directive on how to report employee compliance concerns • Make clear that failure to follow up results in significant sanctions.
Ineffectual hotline intake	• Test hotline through "dummy" calls • Develop approved script for intake to ensure all relevant information is solicited • Audit effectiveness
Employees fear of retaliation	• Adopt and enforce clear non-retaliation policy • Include broad definition of retaliation that transcends termination and demotion • Protect cooperation in investigations and corrective actions, not just reporting • Have upper level management/executive reinforce non-retaliation message • Discipline violators
Failure to capture all relevant information reported	• Log all relevant information regarding reports of suspected non-compliance on compliance tracking system (e.g., reporter (if known), persons involved, persons with information, location, time frame and nature of violation) • If reporter is anonymous, institute mechanism for anonymous follow up • Consider "reason codes" to facilitate data analytics/ identification of systemic issues and trends

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Avoiding Investigation Pitfalls

Common Pitfall	Risk Minimization
Failure to appreciate seriousness of issue and need for legal involvement at front end of investigation	• Adopt investigations policy with report triage process • Require analysis of risk level and benefits of privileged investigation during triage process • Compliance should consult with Legal during triage process when appropriate • Adopt guidelines for privileged investigations
"Buzz Factor" undermines investigation integrity	• Emphasize need for confidentiality when scheduling interviews and issuing document requests; re-emphasize during interviews • Review privilege at the outset and conclusion of interviews, if applicable • No ambiguous voicemails or emails • Adopt policy against undermining integrity of investigations/subject violators to discipline
Lack of robust investigation documentation in a centralized repository	• Invest in robust compliance investigation tracking system • Hardwire in linkages to relevant documents/interview summaries • Provide templates that prompt investigators to document each interview/ investigation step and basis for findings/ program tracking system to preclude close out absent essential inputs

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Avoiding Investigation Pitfalls

Common Pitfall	Risk Minimization Strategies
Investigation delays due to: • Difficulty scheduling interviews/cancellations • Delays in document request responses • Heavy workload for investigators	• Include cooperation with investigations in employee code of conduct and/or compliance policies • Make compliance (including cooperation with investigation) an element of performance reviews • Establish escalation procedures with timeframes if employees fail to respond or make themselves available for interviews • Ensure adequate resources to conduct timely investigations • Use auto-reminders/calendar ticklers to check in on investigation status • Require periodic status reports
Variability in effectiveness/ thoroughness of investigations among investigators	• Define investigation responsibilities in investigations policy • Establish quality control (QC) process o Competency testing o Spot checks o Centralized review before closeout o Periodic shadowing of investigators • Require periodic training/education
Failure to address root cause of violations and take steps	• Require root cause analysis prior to investigation close out when reports are substantiated (ideally via mandatory entry in tracking system) • Require corrective action plans that include steps to prevent recurrence (e.g. education, policy changes, system updates)
Failure to ensure that corrective action plans are implemented	• Corrective action plans should identify the responsible party for each action step and target completion dates • Ensure that the business “own” the plan • Track and document implementation • Rationale for delays should be documented • Use auto-reminders and require status reports to monitor to completion

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Quality Compliance Audits

Overview

- Health care reform developments have shifted provider reimbursement for services rendered from payment based on the volume of services provided to payment based on value and compliance with quality metrics and outcomes.
  - ACO quality metrics
  - Medicare Value Purchasing Standards
  - P4P standards
  - Readmissions with 30 days of discharge
  - HACs

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Quality Compliance Audits (cont'd)

- Never events
- Physician Quality Reporting System
- ACE State Medicaid programs
- Joint Commission accreditation standards
- NCQA
- Medicare recently announced that by 2018 it wants 50% of all Medicare payments to physicians based on outcomes and 90% of all payments based on outcomes.

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Quality Compliance Audits (cont'd)

Quality Enforcement Efforts

- False Claims Act
  - The OIG has identified that its principal enforcement tools include allegations of violations of the False Claims Act, use of corporate integrity agreements, including the use of external quality of care monitors, as well as civil fines and, in extreme circumstances, exclusion from the Medicare program
  - Actions have been brought under no care, substandard or worthless services theory by private litigants and the government, sometimes in whistleblower actions.

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Quality Compliance Audits (cont'd)

- United States ex rel. Mikes v. Strauss, 274 F.3d 687 (2nd Cir. 2001) – Did entity make a knowing request of federal reimbursement for a procedure of no medical value?
- U.S. v. Villaspring Health Care Center, Inc., 2011 WL 6337455 (E.D. Ky. Dec. 19, 2011)
- U.S. v. Associates in Eye Care, P.S.C., (Civil No. 13-27-GFVT) (E.D. Ky. Feb. 4, 2014)
- OIG $38 million settlement with Extendicare Health Services for materially substandard skilled nursing services – 10/10/14
- But see U.S. v. Momence Nursing Center, Inc. 764 F.3d 699 (7th Cir. 2014) – "performance of the services [must be] so deficient that for all practical purposes it is equivalent to no services at all".

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Quality Compliance Audits (cont'd)

Quality Enforcement Efforts

- The OIG has made the following statement:

  "To hold responsible individuals accountable and to protect additional beneficiaries from harm, the OIG excludes from participation in federal health care programs individuals and entities whose conduct results in poor care. In enforcement actions against corporate entities, . . . OIG places particular emphasis on high level officials, such as owners and chief executive officers. . . ."

- Grand Jury indicted a Michigan hospital based on its failure to properly investigate medically unnecessary pain management procedures performed by a physician on the medical staff.
- A California hospital paid $59.5 million to settle a civil False Claims Act allegation that the hospital inadequately performed credentialing and peer review of cardiologists on its staff who perform medically unnecessary invasive cardiac procedures.

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Quality Compliance Audits (cont'd)

Quality Enforcement Efforts

- In a settlement with Tenet Health Care Corporation and pursuant to a Corporate Integrity Agreement, a hospital board was required to:
  - Review and oversee the performance of the compliance staff.
  - Annually review the effectiveness of the compliance program.
  - Engage an independent compliance consultant to assist the board and review an oversight of tenant's compliance activities.
  - Submit a resolution summarizing its compliance efforts with the CIA and federal health care program requirements, particularly those relating to delivery of quality care.
- A Pennsylvania hospital recently entered into a $200,000 civil False Claims Act settlement to resolve substandard care allegations related to the improper use of restraints.

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Quality Compliance Audits (cont'd)

Quality Enforcement Efforts

- Rogers v. Azmat (2010)
  - DOJ intervened in a False Claims Act lawsuit alleging that Satilla Regional Medical Center and Dr. Najam Azmat submitted claims for medical substandard and unnecessary services to Medicare and Medicaid . The complaint alleges, among other things, that the defendants submitted claims for medical procedures performed by Dr. Azmat in Satilla's Heart Center that the physician was neither qualified nr properly credentialed to perform. As a result, at least one patient died and others were seriously injured.

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Quality Compliance Audits (cont'd)

Corporate Responsibility in Health Care Quality

- The OIG and AHLA collaborated on a publication titled "Resource for Health Care Boards of Directors on Corporate Responsibility and Health Care Quality"
- Was published "for the specific purpose of identifying the role and responsibility of corporate boards and management with respect to its fiduciary obligations to meet its charitable mission and legal responsibilities to provide health care quality services"
- The OIG cites to key questions reflective of standards against which hospital boards will be measured

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Quality Compliance Audits (cont'd)

Corporate Responsibility in Health Care Quality

- What are the goals of the organization's quality improvement program?
- What metrics and benchmarks are used to measure progress towards each of the performance goals? How is each goal specifically linked to management accountability?
- How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?
- How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?

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Quality Compliance Audits (cont'd)

Corporate Responsibility in Health Care Quality

- Does the board have a formal orientation and continuing education process that helps members appreciate external quality of patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?
- What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement effort?

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Quality Compliance Audits (cont'd)

Corporate Responsibility in Health Care Quality

- Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?
- Do to the organization's competency assessment and training, credentialing and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
- How are these "adverse patient events" and other medical errors identified, analyzed, reported and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?

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Quality Compliance Audits (cont'd)

- Increased enforcement
  - OIG Work Plan
    - Reliability of hospital-reported quality measures data
    - Hospital admissions with conditions coded as "present-on-admission" and accuracy of "present on admissions" indicators
    - Review of Medicaid payments for HACs and never events
    - Acute-care inpatient transfers to inpatient hospice care
    - Safety and quality of surgeries and procedures in surgicenters and hospital outpatient departments

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Quality Compliance Audits (cont'd)

- Quality of care and safety of residents and quality of post-acute care for nursing homes
- Hospital reporting of adverse events
- Hospital same-day readmissions
- Hospitalizations and re-hospitalization of nursing home residents
- Review effectiveness of PSO programs

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Quality Compliance Audits (cont'd)

- January, 2012 OIG Report: "Hospital Incident Reporting Systems Do Not Capture Most Patient Harm"
  - All hospitals have incident reporting systems to capture events and are heavily relied on to identify problems
  - These systems provide incomplete information about how events occur
  - Of the events experienced by Medicare beneficiaries, hospital incident reporting systems only captured an estimated 14% due to events that staff did not perceive as reportable or were simply not reported
  - Accrediting bodies only review incident reports and outcomes but not the methods used to track errors and adverse events

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Quality Compliance Audits (cont'd)

- Other Risks
  - Reduced or lost reimbursement.
  - Removal from ACO and managed care plans.
  - Placement on accreditation watch or worse.
  - Enhanced liability exposure under respondeat superior, apparent agency and corporate negligence theories.
  - Removed from Medicare/Medicaid program.
  - Adverse impact on licensure.

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Quality Compliance Audit – What is it?

- Purpose of the audit is to determine compliance with applicable quality standards and regulatory requirements.
  - Medicare Conditions of Participation
  - Accreditation standards
  - HCQIA/state immunity statutes
  - Incorporation of quality metrics and standards (ACO, VBP, etc.) into privileging/credentialing/peer review procedures, bylaws, rules and regulations
  - OIG board responsibility standards
  - Mandatory reports for never events, HACs and state mandated reports

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Quality Compliance Audits (cont'd)

- QAPI program
- Applicable state laws
- Compliance with state and federal (PSOs) peer review statutes in order to maximize confidentiality and privilege protections
- Hospital's strategic and quality improvement plan
- Does hospital provide periodic quality/utilization reports to its physicians?
- Is quality information effectively shared throughout the ACO/CIN?

- Audit report identifies compliance gaps and along with recommendations for remedial measures and best practices.

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