

Compliance Today, Effectiveness Tomorrow: The Necessary Steps to Success

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Today's Agenda

- Enforcement Update
- CIA Trends and Impact on Compliance
- Compliance Today
- How Does Your Organization Look From The Outside?
- Compliance Leading Practices
- Conclusion

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Enforcement Agenda

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Enforcement Agencies

United States Department of Justice (DOJ)

- Commitment to prosecute healthcare fraud
 - Criminal/Civil/Antitrust Divisions
 - Consumer Protection Branch
 - Healthcare fraud coordinators within 94 United States Attorneys' Offices
 - Federal Bureau of Investigation
 - Drug Enforcement Agency
 - Partnerships with private payors
- Distinct funding sources

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Enforcement Agencies, cont'd.

Other Enforcement Agencies

- Local District Attorneys
- Offices of Inspector General
 - Federal and State
- Medicaid Fraud Control Units
 - Centers for Medicare and Medicaid Services
 - Medicaid State agencies
 - Tricare Management Authority
- Federal/State contractors
 - Commercial "Special investigative units"
- Licensing boards
- Whistleblowers

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Enforcement Outlook in 2017

- Federal budget shortfalls
- State and federal enforcement actions increasing
- Medicare insolvent in 15 years
- State budget shortfalls
- Greater attention by U.S. Attorneys, DOJ, and OIG-HHS
- Investment and use of data analytics will continue to drive enforcement
- Increased focus on individual actors

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Recent DOJ Activity

DOJ recovered more than \$4.7 billion in FY 2016

- Up from FY 2015 \$3.8 billion recovery
- ROI for the Health Care Fraud and Abuse Control Program \$6 returned for every \$1 expended

Continues 4-year record of recoveries over \$3 billion

Of \$4.7 billion –

- \$2.5 billion from healthcare industry, including \$330 million from hospitals
- \$2.9 billion (more than half) from cases filed by whistleblowers under FCA

Number of *qui tam* suits exceeded 700

- Up from FY 2015 600
- But way up from 1987's 30
- Whistleblowers received \$519 million

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HHS-OIG's General Policy on Exclusion

Exclusion only apply to misconduct from the past 10 years

Early Reinstatement Process

Aggravating Factor Threshold Elevated

- Amount will have to be at least \$50,000 in several scenarios

Mitigating Factor for Exclusions

- Patient access to care significantly harmed by exclusion

Audit Obstruction Policy

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Increased Focus on Individual Actors – Yates Memo

Sept. 9, 2015 DOJ Guidance -

"One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing."

Six Steps

1. Corporations must provide all relevant facts on responsible individuals to get cooperation credit
2. Investigations should focus on individuals from the inception
3. Criminal and civil attorneys handling should be in routine contact
4. Individuals should not be released from liability when resolving a matter with a corporation absent policy or extraordinary circumstances
5. DOJ attorneys should not resolve matters with a corporation without a plan to resolve individual cases, and should memorialize any declinations as to individuals in such cases
6. Civil attorneys should focus on individuals and evaluate whether to bring suit against an individual based on considerations beyond ability to pay

See <http://www.wirk.com/docs/IndividualAccountabilityforCorporateWrongdoing.pdf>

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Parallel Proceedings

Simultaneous Civil/Criminal/Administrative investigation of same defendant(s)

- Usually jointly handled
- Can be federal and state/local or multi-district

Not every case is appropriate

- Examples of common parallel matters
 - Procurement and gov't program fraud
 - Health care fraud
 - Asset forfeiture and FLU actions
 - Environmental crimes
 - Diversion/internet pharmacies
 - SEC and antitrust investigations

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Health Care Fraud Statute

Federal criminal statute for public AND private health care fraud, 18 U.S.C. § 1347

Knowingly and willfully execute/attempt a scheme or artifice to:

- Defraud health care benefit program; or
- Obtain by false or fraudulent pretenses property under custody/control of program in connection with delivery or payment for items or services

10-year imprisonment, restitution, and fine

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Federal Anti-Kickback Statute

Criminal statute, 42 U.S.C. § 1320a-7b(b)

- Remuneration is anything of value
- One Purpose Test

Recommend or arrange for items/services under federal programs

- Includes non-clinicians
- State analogs may limit kickbacks in cash/private plans

Greater compliance with safe harbor generally means less risk

- Advisory Opinions address industry concerns

Forms basis for civil liability

Must be commercially reasonable

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Stark Law

Prohibits self-referrals for federal business, 42 U.S.C. § 1395nn

- Must involve physician referral
- Designated health services
- Medicare and Medicaid only
- Ownership interest or compensation arrangement
- Generally must be commercially reasonable and fair market value
- State law may limit non-Medicare business agreements

Strict liability

- Must fully satisfy statutory or regulatory exception

Remedy is payment disallowance

- Exclusion and CMP liability
- May be violation of FCA

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Civil Monetary Penalties

HHS-OIG Administrative Remedy

42 U.S.C. § 1320a-7a(a)

- Permissive exclusion and money damages for specific violations like payment or receipt of illegal kickbacks

Mirrors FCA but not governed by civil rules of procedure or evidence

- Limited discovery
- Hearsay admissible

OIG usually releases this authority in exchange for compliance obligations

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False Claims Act (FCA)

Generally a false/fraudulent claim/statement made or caused to be made for payment to the United States, 31 U.S.C. § 3729(a)

- Includes conspiracy and "reverse" false claims provisions

Claim must be submitted "knowingly"

- Actual knowledge
- Deliberate ignorance
- Reckless disregard
- No specific intent to defraud required

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FCA, cont'd.

Six-year statute of limitations

- Three years from date material facts are known or reasonably should be known by responsible official
- Not more than 10 years after the violation
- Increased penalties for violations which occurred after Nov. 2, 2015
 - Minimum per claims penalties: \$10,781 from \$5,500
 - Maximum per claim penalties: \$21,563 from \$11,000
 - Effective for penalties assessed after August 1, 2016, if the violation of law occurred after November 2, 2015
 - Excessive fine under U.S. Constitution?
- Attorney's fees and costs
- Damages not required

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FCA Qui tam Provisions

Qui tam actions brought by private individuals ("relators" a.k.a. whistleblowers) on behalf of the Government

Procedure

- Relator must file a complaint, under seal, in a U.S. district court that has jurisdiction over the case
- Relator must also serve written disclosures on DOJ describing "substantially all material evidence and information the person possesses"
- DOJ has 60 days to investigate and decide whether to intervene, but extensions are liberally granted. 31 U.S.C. § 3730(b)(2).
Trend is to limit extensions

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Qui tam Provisions, cont'd.

After the Government fully investigates, it can:

- Intervene in the case, assuming primary responsibility for the litigation
- Decline to intervene, which allows the relator to carry on without the Government
- Move to dismiss the case (even if the relator objects)
- Seek to settle the case

Bars to qui tam suits include:

- Public disclosure (anyone could have filed this suit)
- First-to-file rule (someone already filed)
- Previous Government action (U.S. is already involved)

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Escobar: Key Supreme Court Case

Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989 (2016)

- Allowed implied certification BUT relied on whether material to payment
- Unanimous decision
- Implied certification can be a basis for liability under certain circumstances
- Courts continue to parse *Escobar* regarding materiality requirement

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CIA Trends and Effect on Compliance Programs

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Notable Requirements - 2015 CIA

- Extensive management certifications
- Focus arrangement database and process, policies, etc.
- Risk assessment and internal review process regarding arrangements and focus arrangements.
- Independent Review Organization (IRO).
 - Arrangements systems review – systems, processes, policies and procedures relating to the initiation, review, approval and tracking of arrangements.
 - Arrangements transaction review – 50 – to determine whether they complied with the focus arrangement procedures and requirements.

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Who must certify?

President/Chief Executive Officer
 General Counsel
 Director, Internal Audit
 Regional Chief Executive Officers
 Chief Operating Officers
 Chief Financial Officers
 Human Resource Directors
 Vice President, Strategic Planning
 Senior Vice President, Communications and Marketing
 President, Health Foundation
 Vice President, Government and Community Relations
 Senior Vice President, Chief Human Resource Officer
 Senior Vice President, Chief Financial Officer
 Senior Vice President, Chief Operations Officer
 Vice President, Physician Services
 Senior Vice President, Chief Information Officer
 Vice President, Community Health Services
 Chief Medical Officer
 Vice President, Designated Institutional Office
 Vice President, Corporate Compliance/Chief Compliance and Privacy Officer
 Children's Diagnostic and Treatment Center Administrator
 Practice Administrator
 Accountable Care Organization Administrator

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Certification Statement

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and xxxxx policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of xxxxx is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

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2014 CIA

- Appointment of service area compliance officers
- Service area compliance committees
- Must submit to OIG all documentation reviewed and actions taken related to oversight of compliance program
- Board resolution of compliance with CIA and, if cannot achieve, reasons why
- Certifications:
 - Executive leadership (9).
 - Operations leadership (15).
 - CFO; with annual report submission.
- Inpatient admission medical necessity
- Risk assessment and internal review process

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Risk Assessment and Internal Review Process Under CIAs

Within 90 days after the Effective Date, xxxx shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements....

The risk assessment and internal review process should include: (1) a process for identifying and prioritizing risks, (2) developing remediation plans in response to those risks, including internal auditing and monitoring of the identified risk areas, and (3) tracking results to assess the effectiveness of the remediation plans.

The risk assessment and internal review process should require compliance, legal and department leaders, at least annually, to evaluate and identify risks associated with Arrangements and develop and implement specific plans to address and mitigate the identified risks..... Term of the CIA

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LEGAL INDEPENDENT REVIEW ORGANIZATION CIA (July 14)

- Assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations, directives, and other guidance documents related to these statutes.
- Expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review...
- Respond to all OIG inquiries in a prompt, objective, and factual manner...
- Not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the Legal IRO's engagement...
- 50 Focus Arrangements that were entered into or renewed by IHS during the Reporting Period with: (1) physicians or other health care professionals; or (2) entities owned or controlled, in whole or in part, by physicians or other health care professionals. The Legal IRO shall select its sample of Focus Arrangements for review in consultation with OIG.
- The Legal IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and xxx shall furnish such documentation and materials to the Legal IRO, prior to the Legal IRO initiating its review of the Focus Arrangements...

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Focus Arrangements (not really new)

You need to identify which of your contracts are focus arrangements. CIAs define "focus arrangements" as:

- Between entity and actual source of healthcare business or referrals to medical center and involves, directly or indirectly, the offer, payment or provision of anything of value;
- Between entity and any physician who makes a referral to medical center for designated health services; or
- Between entity and any physician (or a physician's immediate family member) or medical practice that involves, directly or indirectly, the offer, payment or provision of anything of value in anticipation of that physician becoming an actual source of healthcare business or referrals (e.g., for purposes of recruitment).

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June 2015 – OIG Fraud Alert Focuses on Physician Compensation Arrangements

- Targeted at physicians and directs that all compensation arrangements need to be FMV and reflect payment for bona fide services that have been provided
- If any purpose of the arrangement is to compensate a physician for past or future referrals, the potential exists AKS violation
- Could result in possible criminal, civil or administrative sanctions, including exclusion and potential draconian FCA penalties

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Who is Covered by CIA....

Be Proactive in Determining

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Effective Compliance - Today

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What Should Your Compliance Program Look Like?

Factors to consider

- Size of the organization
 - Large organizations
 - Small organizations
- Recurrence of similar misconduct
- What are you competitors doing
- What is the government doing
- Applicable governmental regulations and industry practice

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Three Lines of Defense

"The Third Line"
Independent Compliance Oversight and Internal Audit will provide independent oversight and monitoring.



"The Second Line"
Compliance will provide compliance management, framework and policies.



"The First Line"
Management is accountable for identification of risks, internal controls, and compliance activities and monitoring in order to be compliant with laws and regulations.



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What is an Effective Compliance Program?

Effective compliance programs should mitigate/eliminate regulatory/criminal risks, **foster a culture of integrity** and provide organizations with the ability to defend against allegations of fraud or abuse.

Incorporated into the OIG's various Compliance Program Guidance Documents and promulgated in the Federal Sentencing Guidelines; the Seven Elements represent the basic tenets of an effective compliance program.

1. Oversight:
 - Compliance Office & Committee
 - Oversight-boards
2. Written Standards:
 - Code of Conduct
 - Policies & Procedures
 - Event/Function specific guidance documents
3. Training:
 - Adequate training on company specific compliance policies and expectations
 - Should include all relevant employees and 3rd party agents working on behalf of the organization

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Effective Compliance Program, cont'd.

- 4. Communication:
 - Anonymous Compliance Hotline
 - Access to supervisors and compliance personnel
 - Positive compliance tone from leadership
- 5. Risk Based Auditing & Monitoring:
 - Risk Assessment
 - Internal and 3rd party auditors
 - Business-based monitoring
- 6. Disciplinary Guidelines and Enforcement of Company Standards:
 - Clear, specific and transparent disciplinary policies
 - Consistency with consequences
 - Intentional/material vs. negligent violations
- 7. Responding to Detected Problems & Corrective Action
 - Investigations process
 - Identification of Root Cause
 - Development and corrective action/mitigation plan

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Board Governance – Leading Practices

- Does board receive tailored education to what is occurring (internally and externally)?
- Does board understand various types of risk?
- Compliance officer can communicate with the board whenever he or she wants without hesitation?
 - Does CCO have routinely scheduled executive sessions with board?
 - Does CCO report to board?
- Does the board have any role in CCO's performance evaluation?
- Is there a formal compliance committee of the board?
- Are board members involved in the compliance program oversight?
- What is the compliance knowledge level of board?
 - Engage experts to assist in program functioning/validation of "effectiveness" of compliance program.
 - Is external assistance available when necessary?
- Does board receive updates from the organization?

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Executive Leadership – Leading Practices

- Does leadership understand the seven elements of compliance?
- Does the CCO report to the CEO?
- How frequently does the CCO meet with the CEO?
 - Are the meetings formally scheduled?
 - Are agendas prepared?
 - Are notes taken?
 - Are minutes taken?
 - How often are these meetings canceled/rescheduled?
- Can employees give examples of leadership's commitment to compliance?
- Does CCO have an understanding of employees' perceptions of executive leadership's commitment to compliance?

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Leading Practices, cont'd.

- Does leadership participate in operational compliance committee/matters?
- Does leadership provide outreach to employees regarding compliance
- Does leadership evaluate/consider suggestions regarding:
 - Risks
 - Value
 - Strategic Vision
 - Growth
- Does leadership kickoff annual compliance risk assessment process?
- Does leadership introduce the hotline at least annual?
- Does leadership offer frequent/comprehensive compliance training?
- Does leadership compensation include compliance metrics?

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How Does Your Organization Look From The Outside?

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How Does Your Organization Look From The Outside?

Consider the following:

- What are your most utilized codes?
- Who are your highest paid providers?
- Who utilizes the highest and lowest E&M codes?
- Who is responsible for denials?
- Are you performing claims reviews?
- Are you being reimbursed for non-medically necessary services?
- Are you trending findings? Are you refunding money?
- Who receives reimbursement from potential referral sources?
- Which physicians are receiving the most \$ from industry?
- Do you do business with PODs?
- Do you assess FMV when acquiring physicians?
- Do you have a documented, strategic, compliant approach to physician compensation and acquisitions?
- Have you compared physician contract amounts to accounts payable?

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How Does Your Organization Look, cont'd.

Ultimately...

- Do you know what your organization's compliance risk profile looks like?
- Do employees know their compliance responsibilities?
- Are they held accountable for them regardless of title?
- Are your compliance efforts satisfactory?
 - Could you attest that they are?
 - Could your board?
 - Could your executive leadership team?
 - Could operational management?
- Has the compliance program ever been assessed?

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Compliance Leading Practices

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Compliance Leading Practices

- Ensure that systems are in place to track, monitor and report time and effort
- Track nonmonetary compensation
- Conflicts of interest disclosures
- Keep documentation of negotiations
- Proactively manage complaints or concerns and ensure corrective action
- Track remuneration to and from all parties
- Track services and activity logs
- Monitor use of leased space or equipment
- Regularly audit logs and reports to substantiate payments

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Leading Practices, cont'd.

Identify potential sources of obligations to repay

- Claims submissions
- Enrollment forms
- Contracts
- Certifications

Keep up with evolving legal standards

Receivables monitoring, auditing, disclosure

Listen and investigate when an employee, contractor, agent, or anyone tells you that there is a "problem" at the company

- Remediate promptly
- Consider self-disclosure, repayment strategies, and obligations

Leading Practices, cont'd.

Keep up with current enforcement trends!

The following entities are being scrutinized:

- Labs/Toxicology Labs
- Specialty Pharmacies
- Workers Comp/DOL
- Pain Management

Beware:

- Alleged Federal Carve Outs
- Uneducated sales reps willing to push the envelop for huge commissions
- Physicians' relationships with questionable entities
- Guilt by association

Compliance is Critical

If an organization is found guilty of a violation of state or federal laws, the government may offer a reduction in penalties if an effective compliance program is in place.

Concluding Thoughts

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- Thirty years of diversified healthcare management, operations and compliance experience.
- Former SVP, chief of ethics and compliance officer at UMDNJ.
 - Credited with re-engineering the compliance program of the nation's largest free-standing public health sciences university.
 - Successfully led the compliance program to adhere to CIA with DHHS/OIG that occurred following a Deferred Prosecution Agreement.
- Chief compliance and privacy officer at Deborah Heart and Lung Center.
 - Three-year CIA, first settlement of Voluntary Disclosure Protocol.
 - Compliance program recognized by HCCA as a "Best Practice."
- Certified in HCCA and the Medical Group Management Association.
- Author of The Compliance Officer's Handbook.



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- Sean McKenna focuses his practice on healthcare enforcement and regulatory issues, representing individuals and providers under civil or administrative investigation by the Department of Justice, Offices of Inspector General, and Attorneys' General Medicaid Fraud Control Units, as well as in criminal investigations and matters involving the United States and State Attorneys General.
 - Former ten-year Assistant United States Attorney
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 - False Claims Act/*Qui tam*
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- Ken is a licensed attorney with approximately 20 years of regulatory, compliance experience. Ken assists clients with compliance program assessments, risk assessments, investigations, coding compliance engagements, Independent Review Organization (IRO) engagements and Pre-IRO engagements.
- Ken has performed approximately 55 comprehensive compliance program assessments. He has assisted public hospitals, academic medical centers, integrated health systems, community hospitals, pediatric hospitals, medical device companies, payors, dialysis providers, physician practices and post-acute care providers.
- Ken leads a team of coding compliance professionals to perform coding compliance assessments to satisfy compliance program monitoring activities, to assist compliance programs with internal investigations and to assist counsel with attorney client privileged investigations.

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