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*Responding to Investigations:
How to Ensure Effective Compliance
When Facing Scrutiny*

June 2, 2017
HCCA Philadelphia Regional Conference

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Overview

- > Enforcement Agencies and Landscape
- > Statutes
- > Government Procedure
- > Internal Investigations
- > Responding to Government Action
- > New Enforcement Agenda?
- > Conclusion

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Enforcement Agencies

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U.S. 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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Other Enforcement Players

- > Local District Attorneys
- > Offices of Inspector Generals
 - 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 Landscape

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Government Activity

- > Big budget for enforcement
 - \$672 million for Health Care Fraud and Abuse Program
 - ROI at least \$5 to \$1
- > DOJ Recovery in 2016
 - Total \$4.7 billion (up from \$3.8 billion in 2015).
 - \$2.5 billion paid from healthcare industry
 - \$2.9 billion from whistleblower cases
 - Whistleblowers received a record \$519 million.



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Notable 2016 Settlements

- > Wyeth and Pfizer, Inc.: \$784.6 million
 - Allegation that Wyeth underpaid drug rebates to Medicaid for drugs used to treat acid reflux
 - Largest health care settlement of 2016
- > Olympus Corp. of the Americas: \$646 million
 - Allegation that Olympus paid kickbacks to doctors and hospitals in exchange for the purchase of endoscopes and other medical and surgical devices



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Notable Settlements, continued

- > Novartis Pharmaceuticals Corp.: \$410 million
 - Allegation that Novartis paid kickbacks to specialty pharmacies to promote distribution of certain drugs
 - Novartis agreed to expand an existing CIA to include its specialty pharmacy relationships and extend agreement by five years
- > Millennium Health: \$260 million
 - Allegation that Millennium:
 - Billed Medicare, Medicaid, and other federal programs for excessive and unnecessary urine drug and genetic testing; and
 - Gave free items to physicians to obtain lab tests in violation of the Anti-Kickback Statute (AKS) and the Stark Law



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OIG-HHS Activity

- > Creation of Health Care Fraud Prevention and Enforcement Action Team
 - New laws and tools for government to combat fraud, waste, and, abuse
- > In June 2015 announced formation of new affirmative litigation team to focus exclusively on pursuing civil monetary penalties and exclusions
 - Doubles number of litigators to bring cases
 - Team will review FCA cases as sources of potential enforcement actions



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Measuring Compliance Program Effectiveness: A Resource Guide

- > Known as the *Compliance Guide*
Product of a January 2017 roundtable between OIG and HCCA professionals
- > Provides health care organizations with an "idea bank" for measuring the elements of their compliance programs
- > The Compliance Guide is *not* a checklist—organizations should select measures that are practical to their effectiveness reviews in any given year



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The Compliance Guide: Seven Elements

- > Standards, Policies, and Procedures
- > Compliance Program Administration
- > Screening and Evaluation of Employees
- > Communication, Education, and Compliance Training
- > Monitoring, Auditing, and Internal Reporting Systems
- > Discipline for Noncompliance
- > Investigations and Remedial Measures



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DOJ's Yates Memorandum



- > Yates Memo (9/9/2015): *"Individual Accountability for Corporate Wrongdoing"*
- > Emphasizes DOJ's commitment to combat fraud "by individuals."
- > Recommends:
 - Not to give cooperation credit unless company provides facts re: individuals
 - To focus investigations on individuals "from the inception"
 - Not to release "culpable individuals" from liability absent "extraordinary circumstances"
 - Not to settle with company without "clear plan to resolve related individual cases"

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A New Era?



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Future Investigations Outlook

- > State and federal enforcement actions rising
 - Increased *Qui tams* in 2016
- > Medicare insolvent in 15 years
- > State budget shortfalls
- > Federal and commercial rules remain complex
- > Demonstrating effective compliance is crucial
- > Increasing attempts to ensure individuals accountable



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ACA and Enforcement

- > Patient Protection and Affordable Care Act
 - Enacted March 23, 2010
- > Amendments to Anti-Kickback statute
 - Rejects stringent definition of knowledge
 - Violations result in falsity under the False Claims Act (FCA)
 - FCA violations can occur even if claim was submitted by an “innocent” third-party
- > Clarification of sentencing guidelines
 - Presumption intended loss is value of claim, not actual payment



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Changing Political Makeup and the Potential Effect on False Claims and Anti-Kickback

- > A new administration could ease *Yates* policy and other agencies could follow lessening individual liability
- > Change in Supreme Court
 - Could weaken interpretation of *Escobar* and what is “material” to a false claim
 - 100 vacancies for federal judges

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Changing Political Makeup, continued

- > Congress recently passed repeal and replace of ACA, but outcome on FCA remains uncertain
 - Public Disclosure Bar
 - Removed express reference to jurisdictional nature of public disclosure bar
 - Gave government the ability to object to dismissal due to the public disclosure bar
 - Narrowed categories of what constitutes as “public” disclosure
 - Repeal could expand the protections of this defense
 - Provided relator with a lower standard to qualify as an “original source”

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Changing Political Makeup, continued



- > Outcome on FCA remains uncertain
 - 60-Day Rule: A person who has received an overpayment must report and return such overpayment within 60 days after overpayment was identified
 - Repeal could cause confusion over timing and what qualifies as “overpayment”
 - Provided violation of Anti-Kickback constitutes a false claim
 - Repeal could weaken government’s implied certification argument

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Overview of Healthcare Statutes



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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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The 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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FCA

- > A false claim or statement for payment to the United States 31 U.S.C. § 3729(a)
 - Conspiracy
 - "Reverse" false claims is the knowing retention of a known overpayment
- > Claim must be submitted "knowingly"
 - Actual knowledge
 - Deliberate ignorance
 - Reckless disregard
 - No specific intent to defraud required
- > Other state/federal law violations may be bases for liability



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FCA, continued

- > Six-year statute of limitations
 - Three years from date material facts are known or reasonably should be known by responsible official
 - DOJ is the official, not agent
 - Not more than 10 years after the violation
- > Remedies
 - Damages not required
 - If found liable, mandatory **treble** damages and penalties
 - Attorneys' fees and costs
- > Increased penalties for violations after Nov. 2, 2015
 - Minimum per claims penalties: \$10,781 from \$5,500
 - Maximum per claim penalties: \$21,563 from \$11,000



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Statutory Considerations

- > Civil (31 U.S.C. § 3729)
 - Either USAG or a relator (whistleblower) may bring FCA cases
 - *Qui tam* provisions filed under seal
 - DOJ has 60 days to intervene
 - Awards relator 15-30% recovery + attorneys fees
 - 6 year SOL and 3 year tolling provision
 - 29 states and D.C. have adopted a statute equivalent to FCA
 - Remedies: Mandatory treble damages and civil monetary penalties between \$10,781 and \$21, 563 per false claim
- > Criminal



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FCA *Qui tam* Provisions

- > Relator files case on behalf of government
 - Under seal for at least 60 days as DOJ reviews and usually longer
 - May pursue without DOJ involvement
 - Protected from retaliation under section 3730(h)
- > Plead with particularity under Rule 9(b)
- > Relator entitled to share of proceeds
 - 15 – 25% if government joins
 - 25 – 30% if government declines
- > Procedural defenses
 - Public disclosure bar
 - First-to-file rule



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Dodd-Frank

- > Dodd-Frank Wall Street Reform and Consumer Protection Act enacted on July 21, 2010
- > Established “bounty” for reports by whistleblowers could receive 10-30% of the monetary sanctions over \$1,000,000 collected
 - > Has to be based on the original information provided by the whistleblower
 - > See 15 U.S.C. § 78u-6(b)(1),
- > A whistleblower is “any individual who provides, or 2 or more individuals acting jointly who provide, information relating to a violation of the securities laws to the Commission [SEC], in a manner established, by rule or regulation, by the Commission [SEC]”
 - > See Section 15 U.S.C. § 78u-6(a)(6)



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Types of FCA Cases

- Fraudulent Billing
- Anti-Kickback Statute Violations & Stark schemes – physician salaries, discounted office space, etc.
- Pricing fraud - “Best Price” AWP fraud, best value, 340(b) diversion
- “Off-Label” marketing
- Switching schemes
- Hospice – ineligibility
- Nursing home worthless services
- Nursing home inflation of RUG scores/medically unnecessary
- Unnecessary lab testing – especially urine testing for opioids
- Manufacturing standards
- Other medical necessity claims
 - Ambulance
 - DME rentals
 - Home health



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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 Law

- > 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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Government Procedure

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Risk Areas

- > False/fraudulent claims
 - Billing for items or services not rendered
 - Upcoding and product substitution
 - Misrepresenting nature of items or services
 - Seeking reimbursement for unallowable costs
- > Retention of overpayments
 - Refusal to return erroneous payments
- > Improper financial relationships/referrals
 - Sham compliance with safe harbor or exception
 - Excessive payments
- > Insufficient documentation of work performed

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Sources of Investigative Cases

- > Partnering by enforcement agencies
- > Data mining
- > Initiatives, working groups, and task forces
- > Competitor complaints
- > Patient/family complaints
- > Self-disclosures
- > Whistleblowers
- > Social media
- > Traditional media

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Internal Investigation Triggers

- > Hotline calls
- > Reports to management or compliance
- > Vendor communications
- > Departing employees
- > Industry rumors
- > News articles
- > Subpoenas or other government requests
- > Government interviews of employees or related parties
- > Private litigation

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Government Investigations

- > Parallel proceedings are simultaneous civil/criminal /administrative investigation of same defendants
 - Usually jointly handled
 - Can be federal and state/local or multi-district
- > Examples
 - Procurement fraud
 - Financial frauds
 - Healthcare fraud
 - Asset forfeiture actions
 - Drug diversion
 - SEC and antitrust investigation

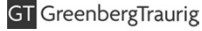

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U.S. v. Jacques Roy: Dallas Doctor Guilty of Nation's Biggest Home Health Care Fraud Scheme

- > Roy certified around 11,000 Medicare patients as part of a nearly \$400 million home health care scam
 - Alleged "swapping" to certify so he could see homebound patients
 - Largest medical necessity case in Texas
- > Roy recruited some patients – including some of Dallas' homeless to submit fraudulent health care claims
- > In April 2016, Roy convicted of:
 - 8 counts health care fraud
 - 2 counts for making false statements to law enforcement
 - 1 count obstruction of justice
 - 1 count conspiracy to commit healthcare fraud



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Investigations, continued

- > Surveillance
- > Consensual monitoring
- > Qui tams
- > Data analytics
- > Interviews
- > Search warrants
- > CIDs
- > Subpoenas
 - Grand jury
 - Inspector General
 - AID (HIPAA)
- > Requests for information

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Investigations, continued

- > Obtain information
 - Claims/contracts/payments
 - Interview
- > Issue warrant, subpoena, or request
 - Internal/external correspondence/e-mails
 - Policies/practices
 - Specific claims/patient files
- > Review information gathered
 - What is knowledge/intent?
- > Determine how to proceed
 - Civil/criminal/administrative or parallel

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What to Do When facing an Investigation

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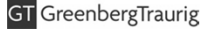

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Preliminary Assessment

- > Have an initial discussion of the issues with the point of contact and other relevant individuals
- > Goals should be to get information on the background and context of the issue, the identity of individuals with relevant information, and the business concerns of the client
- > Recognize that the information received likely is incomplete and inaccurate
- > Scope should be dynamic dependent upon findings, needs to be consistently reassessed

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Corrective Action

- >Critical step
- >Disciplinary actions
- >Training
- >Policy revisions
- >Corrective communications
- >Culture adjustments
- >Monitoring and implementation
- >*Evidence of the Above?*



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Leading Practices 101

- > Tracking all reports/assessments
- > Documenting investigation plan
- > Preservation of information
- > Protections to ensure confidentiality
- > Conducting investigation
- > Determining scope of disclosure
- > Reporting of conclusions/findings to appropriate parties
- > Corrective actions for responsible persons/departments
- > Discipline of bad actors
- > Non-retaliation reinforcement
- > Taking remedial measures (repayment or disclosure)



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Repayment and Disclosure

- > FIRST fix any problems
- > Federal law requires repayment of known overpayments within 60 days
 - CMS issued final rule at 77 Fed. Reg. 9179 (Feb. 16, 2016)
- > Disclosure to DOJ
 - Possible non-prosecution of business entity
 - See USAM § 9-28.000, *et seq.*
 - Limited civil FCA multiplier
 - See False Claims Act § 3729
- > HHS-OIG Self-Disclosure Protocol
 - Lower damages/no integrity obligations
- > CMS Voluntary Self-Referral Disclosure Protocol
 - Do not disclose both to CMS and OIG
 - Use OIG protocol if implicates other laws

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Resources for Enforcement Information

- > Advisory opinions
- > Published cases
- > OIG Compliance program guidance publications
- > State and federal work plans/audits/evaluations
- > Settlement/integrity agreements
- > Press releases
- > GAO reports
- > Comments/preambles to safe harbors/exceptions

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Outcomes and Remedies



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Possible Outcomes of an Investigation

- > Suspension of payments
- > Termination from gov't programs
- > Civil recoveries from responsible parties
- > Criminal convictions and restitution
- > Exclusion/debarment/revocation
- > Licensing board action
- > Compliance or integrity obligations
- > *Cost of responding*
- > *Loss of business/goodwill/morale*



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Criminal Resolution of Investigations

- > Indictment/information and conviction:
 - Public allegations and trial
 - All questionable past statements/actions raised
 - Billed, not paid, amount drives loss
 - Special enhancements for fraud
 - "Relevant conduct" increases sentence/fine
 - Automatic exclusion/debarment
 - Collateral estoppel under FCA
 - State and private liability

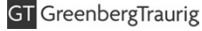

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Civil or Administrative Resolution

- > Civil action and fraud judgment:
 - Mandatory trebling/penalties
 - Most evidence admissible
 - To avoid self-incrimination = increase risk/liability
 - State and private liability
 - Agencies usually seek permissive exclusion/debarment
- > Administrative proceedings and adverse finding
 - Multiple programs/agencies
 - Rules of evidence not applicable
 - Negative impact on civil/criminal case



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Outcome - *U.S. v. Jacques Roy*



- > Sentencing
 - Roy lost medical license and faces more than 80 years in prison
 - Each conspiracy and fraud count has statutory penalty of 10 years in federal prison and \$250,000 fine
 - Obstruction of justice and each false statement have a maximum penalty of five years in federal prison and \$250,000 fine
- > Raising suspicion
 - OIG said Roy came to the agency's attention following a data analysis targeting suspicious billing.
 - Most physicians to refer fewer than 100 patients for home health services but Roy had "by far" submitted the most Medicare claims in the nation for home health services
 - This type of data analytics is routinely used to find outliers
 - Large majority of "innocent" home health agencies were suspended due to association with Roy.
 - Most out of business now

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Concluding Thoughts



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Takeaways

- > Implement an effective compliance program
- > Assess status - target, witness or subject
- > Get ahead of government's investigation
- > What is scope of representation
 - Does anyone need separate counsel (Yates Memo)
 - Has anyone talked to the Government
 - Invoke insurance coverage
- > Evaluate ALL liability - criminal, civil, admin, state, licensure, and private
- > Strategy has implications for parallel case

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Remember Compliance Matters

- > 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

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