

**COMPLIANCE CHALLENGES IN THE
YATES MEMO ERA**

HCCA'S 21ST ANNUAL COMPLIANCE
INSTITUTE, March 27, 2017

Gina Simms, Esq.
George Breen, Esq.
Tarra DeShields, AUSA – District of Maryland

SESSION OVERVIEW

The Yates Memo and its Legal Implications in Corporate Investigations.

Enforcement Trends – The Impact on You.

Practical Tips to Manage Risks.

2

**Background on
the Players: Federal and State**

- Federal Entities/Individuals:
 - U.S. Department of Justice (USAOs)
 - U.S. Department of HHS, Office of Inspector General
 - Law Enforcement: FBI, HHS-OIG, IRS-CI, OPM-OIG, and other federal government agencies' OIGs
 - CMS: Recovery Audit Contractors (RACs) and ZPICs (Zone Program Integrity Contractors (ZPICs))
 - U.S. Department of Justice- Compliance Counsel
- State Entities:
 - Medicaid Fraud Control Unit (MFCUs)

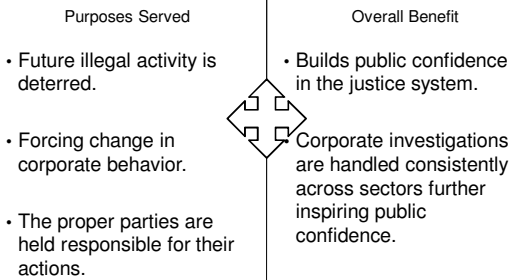
3

THE YATES MEMO – WHAT IS IT?

- First issued on September 9, 2015.
- Referred to informally as the Yates Memo because it is a policy pronouncement made by the then-Deputy Attorney General Sally Quillian Yates.
- Constitutes new guidelines for Department of Justice attorneys' handling corporate investigations and prosecutions.
- Traditionally, a corporation's cooperation with the federal government's investigation may be factored into how to resolve the case. U.S. Attorney's Manual, § 9-28.700.
- Corporations act through individuals and so investigating the conduct of individuals is the logical means of learning the facts and extent of corporate misconduct and individual misdeeds.
- The Yates Memo sets forth the Department's commitment to seeking individual accountability for corporate wrongdoing.

4

WHY THE INTEREST IN INDIVIDUAL ACCOUNTABILITY?



5

YATES MEMO GUIDANCE

The Six Key Points to Understand

- Eligibility for cooperation credit means that corporations must provide the DOJ all relevant facts about individuals involved in corporate misconduct;
- Focus on individuals from start of criminal and civil investigation;
- Criminal and Civil DOJ attorneys will be in routine communication with each other;
- No corporate resolution should provide protection from criminal or civil liability for any individuals;
- Corporate cases should not be resolved without a clear plan to resolve related individual cases; and
- Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based upon factors beyond the ability to pay money to the Government.

6

PRACTICAL IMPACT OF THE YATES MEMO -- WHAT'S CHANGED?

- The most important changes are:
 - Corporations will no longer receive partial credit for their cooperation in investigations;
 - Corporations must provide "all relevant facts relating to individual culpability" to be eligible for cooperation credit;
 - DOJ attorneys will no longer agree to any settlement or corporate resolution that dismisses charges or provides immunity for individual C-suite officers or employees; and
 - Civil attorneys will likely pursue civil remedies against individual wrongdoers even if the person lacks the ability to pay a civil monetary judgment. *See also* 6/9/16, Memorandum of Acting Associate Attorney General Bill Baer, "Cooperation in Civil Investigations."

KEY CHANGE -- COOPERATION CLAUSES

Where They Appear –

- Criminal plea agreements;
- Civil settlement agreements;
- Deferred prosecution agreements; and
- Non-prosecution agreements.

What They Require –

- Fully cooperate with investigations relating to the settlement allegations, including investigations into individuals and entities not released from liability in the settlement;
- Make former directors, officers, and employees available for interviews and testimony; and
- Produce non-privileged documents concerning the conduct covered in the settlement.

YATES MEMO IMPACT

The Acclarent Case – An Example of How Yates Operates:

- Acclarent was a California maker of devices used in sinus surgeries.
- Device FDA approved for use as a spacer used with saline to maintain sinus openings post-surgery.
- Acclarent engaged in off-label promotion of device for an unapproved use.
- Corporate investigation resulted in the CEO and Vice President of Sales being criminally charged and convicted of 10 counts of introducing misbranded and adulterated medical devices into interstate commerce and also securities fraud upon proof that the off-label promotion was intended to increase the company's sales to heighten its attractiveness to potential buyers. The company was bought by Johnson & Johnson.
- Acclarent paid a civil False Claims Act settlement to the United States in the sum of \$18 million dollars.

False Claims Act—31 U.S.C. §3729 et. seq.

Prohibits

- Filing, or *causing* to be filed ...
- "False or fraudulent" claims

•Knowing

- Requires actual knowledge of falsity, or deliberate ignorance or reckless disregard of truth or falsity.

•Intent

- "Intent to defraud" not required
- Filing claims with "reckless disregard" of their truth or falsity is sufficient

10

False Claims Act—31 U.S.C. § 3729 et. seq.

- Liability
 - 3X Damages
 - Was \$5,500 to \$11,000 *per claim*; As of 8/1/16, \$10,781.40-\$21,562.80 per claim)
 - *Potential exclusion consequences*
- Can include false statements in support of a claim.
- Materiality of claim is an issue
- Anti-kickback Statute as a predicate for FCA liability
- 60 days to return "known" overpayment- Reverse False Claims Act liability

11

False Claims Act—31 U.S.C. §§ 3729 et. seq.

- Whistleblower Provisions
 - Non-Retaliation Policy
 - Relief from Retaliatory Actions:
 - Reinstatement
 - Two times the amount of back pay
 - Interest on back pay
 - Compensation for any special damages

12

Civil False Claims Act Cases

- Corporations and Individuals Can Be Liable
- Examples of Fraudulent Conduct
 - Kickbacks/Inducements
 - Medically Unnecessary Services
 - Billing for Services not Rendered
 - Upcoding

13

Recent False Claims Act Cases

- United States ex. rel. Oughatiyan v. IPC The Hospitalists, Inc. et. al- \$60 million settlement (Feb. 2017)(“upcoding”) – IPC encouraged physicians to bill Medicare, FEHB, Medicaid for a higher level of service than provided
- United States ex. rel. Marc D. Baker v. Walgreens- \$50 million settlement (Jan. 2017) (inducements/kickbacks)- FCA and AKS violations-gov’t beneficiaries received discounts/monetary incentives under “prescription savings club” to induce them to patronize Walgreens pharmacies.
- United States ex. rel. Daniel v. Vibra Healthcare, LLC- \$32.7 million settlement (Sept. 2016) (medically unnecessary services)- patients admitted to long-term care hospitals and in-patient rehab who did not need hospital-level care.
- United States ex. rel. Drakeford v. Tuomey Healthcare Systems- \$72.4 million judgment after jury trial (Oct. 2015) (STARK –physician compensation arrangements-referrals by doctors with improper financial arrangements)→ **Ralph J. Cox, III** (Sept. 2016) –**former Tuomey CEO- and Board Member** \$1 million settlement agreement & 4 years’ exclusion from federal programs - ignored “red flags” raised by attorney regarding contracts.

14

Sample of Applicable Federal Criminal Statutes

- Anti-Kickback Statute- 42 U.S.C. § 1320a-7b
- Health Care Fraud- 18 U.S.C. § 1347
- Wire Fraud- 18 U.S.C. § 1343
- False Statements- 18 U.S.C. §1035
- False Claims- 18 U.S.C. §287
- Conspiracy, 18 U.S.C. §371
- Money Laundering- 18 U.S.C. §§ 1956-1957
- Forfeiture Allegations

15

Criminal False Claims and False Statements

Examples of Fraudulent Conduct

- Kickbacks
- Billing for services not rendered
- Up-coding
- Medically unnecessary services
- Obstruction of Justice

Corporations and Individuals Can Be Liable

- U.S. Sentencing Guidelines
 - Fines- Corporations
 - Jail Time or Probation
 - Restitution

16

Recent Criminal Cases

- [United States v. Michael Babich, et. al.](#) (Dec. 2016) (RICO conspiracy, Mail Fraud, Wire Fraud)- former **Insys Therapeutics, Inc.** CEO and executive managers charged with paying bribes and kickbacks to pain management physicians to prescribe drugs to patients who did not have cancer.
- [United States v. Alan Beauchamp et. al.](#) (Nov. 2016) (conspiracy to violate the Anti-Kickback Statute, Travel Act)- Forrest Park Medical Center (FPMC), a physician owned surgical hospital- President, Board Members and other executives charged with bribing physicians for referring Tricare and other patients to FPMC
- [United States v. Tenet Healthcare Corporation](#) (Sept. 2016)(conspiracy to violate the AKS)- Tenet and two of its subsidiaries agreed to pay \$513 million to resolve criminal charges and civil claims related to paying bribes for referrals.
- [United States v. Olympus Corporation of the Americas](#) (March 2016)-\$623.2 million to resolve criminal and civil charges related to scheme to pay kickbacks to doctors and hospitals in exchange for purchasing equipment.
- [United States v. Warner Chilcott](#) (Oct. 2015)(health care fraud)- \$22.9 million fine-related to the submission of false prior authorization requests for osteoporosis drugs. Simultaneous \$91.5 million FCA settlement for AKS violations. Several individuals also charged with criminal conduct

17

OIG Exclusion Authority

Exclusion

- Mandatory exclusion bases include convictions of various crimes related to provision of services under Medicare/Medicaid or healthcare fraud.
- Permissive exclusion bases include:
 - Conviction of certain misdemeanors and other crimes.
 - Administrative determination that individual or entity has committed an act that is subject to civil money penalties or criminal penalties (including anti-kickback statute) under Medicare authorities.

18

OIG Exclusion Authority

- §1128 and 1156 of the Social Security Act.
- Effect of Exclusion:
 - No Federal health care program payment may be made for items or services:
 - Furnished by an excluded individual.
 - Directed or prescribed by an excluded individual, where person furnishing the item or service knew or had reason to know of the exclusion.

19

OIG Exclusion Authority

- Excluded individual also subject to Civil Monetary Penalty of \$10,000 for each violation, plus potential treble damages.
- 20 statutory bases for exclusion.
 - 4 bases for mandatory exclusion.
 - 16 bases for permissive exclusion.

20

OIG Exclusion Authority

OIG Mandatory Exclusion

- § 1128 (a) of the Social Security Act.
- 5 year minimum term.
- Resulting from:
 - Felony convictions relate to health care fraud or controlled substances.
 - Felony or misdemeanor convictions for program related crimes or patient neglect or abuse.

21

OIG Exclusion Authority

OIG Permissive Exclusion

- § 1128(b) of the Social Security Act

Select Bases:

- Engaging in fraud, kickbacks or other prohibited activities.
- Performance of unnecessary or substandard services.
- License revocation/suspension.
- Conviction relating to obstruction of investigation.
- Entities controlled by a sanctioned individual.

22

OIG Exclusion Authority

- § 1128 (b)(15) permits exclusion of the following individuals within a “sanctioned entity” based on the entity’s conviction of certain offenses or exclusion:

- Owners – if they know or should have known of the wrongful conduct leading to the sanction.
- Officers and Managing Employees – based solely on their position with the sanctioned entity, regardless of their knowledge.

23

OIG Exclusion Authority

OIG Guidance for Implementing Permissive Exclusion

The OIG may consider:

- Circumstances of Misconduct.
- Conduct during Government’s Investigation
- Significant Ameliorative efforts
- History of Compliance

24

Expansion of Exclusion Authority January, 2017

- 10 year SOL for Affirmative exclusion actions.
 - §1128(b)(7) (fraud, kickbacks or other illegal activities).
- Exclusion for conviction of offense related to interference with or obstruction of an audit.
- Exclusion for failure to provide payment information when requested by federal healthcare programs.
- Exclusion for false statement, omission or misrepresentation of material fact in applications to enroll as provider or supplier.

25

Civil Monetary Penalties Actions

- Affirmative fraud litigation.
- Standard = knows or should know
 - Actual knowledge
 - Deliberate indifference
 - Reckless disregard
- 6 year S.O.L.
- Generally spin off, or companion to pending FCA case.

26

Exclusion In Action

- Roben Brookham 1/17
 - Convicted, unlicensed dentist
 - \$1 million fine
 - 50 year exclusion
- Labib Riach, M.D. 11/16
 - \$5.25 million FCA settlement
 - 20 year exclusion
- Susan Toy 9/16
 - Billing company owner
 - \$100K CMO
 - 5 year exclusion

27

**Enforcement Trends:
Where Can You Look to Find Them?**

- DOJ and HHS-OIG Settlements, CIAs & Press Releases
- OIG's Yearly Work Plans
- OIG's Semi-Annual and Annual Reports
- HHS-OIG Fraud Alerts

28

HYPOTHETICAL

- Employee Hypothetical:
 - Employee is a sales person at a pharmaceutical company that seeks to become the market leader.
 - Employee is given an expense account for use in conducting business and given directives from upper management on how best to deploy this tool to increase sales. Bonuses are given at year's end for the most sales of the company's product.
 - Employee hosts dinners, reimburses travel, gives cash, medical supplies, equipment and speaker's fees for bogus speaking engagements and case studies to physicians and clinics to induce the use of the company's product.

29

Yates Memo
Impact

HYPOTHETICAL
CONTINUED

The Employee's
Conduct

- Legal and regulatory issues raised by the employee's conduct?
- Inferences to be drawn from the involvement of certain enforcement entities?
- What proactive response could you undertake first?

30

HYPOTHETICAL- COMPANY UNDER CIA

- Company is subject to a Corporate Integrity Agreement ("CIA").
- In connection with obligations imposed by the CIA, Company Senior Vice President was obligated to certify that during the time period of the CIA, Company was in compliance with terms of participation in Medicare and Medicaid and the terms of the CIA.
- You have discovered that during the time period of the CIA, Company provided loans to another health care provider.
- You have also discovered that during the time period of the CIA, the healthcare provider would refer patients to Company.
- You have additionally learned that during this same time, the Company and healthcare provider entered into contractual relationship for provider to provide services to Company.

31

Yates Memo Impact
Hypothetical Continued:
COMPANY UNDER CIA

- Legal and regulatory issues raised by the employee's conduct?
- Inferences to be drawn from the involvement of certain enforcement entities?
- What proactive response could you undertake first?

32

HYPOTHETICAL- BILLING COMPANY

- ABC Billing Company ("ABC") is a national provider of billing services for physicians, hospitals and other health care providers
- Your entity, Honest Quality Care Health System (HQCHS) hired ABC to submit claims to Medicare, Medicaid and FEHB insurers for services performed by emergency room physicians at one of its hospitals, Loving Care Hospital (LCH), which is located in Louisiana
- ABC receives medical records and other information related to the services rendered in the emergency room of LCH.
- You are a compliance officer at HQCHS. You receive an anonymous call from someone who claims to be a former ABC coder. He tells you that he has seen ABC coders submit claims forms to Medicare, Medicaid and FEHB insurers that reflect higher E/M services than LCH's ER doctors performed. He also tells you that he has seen some ABC coding supervisors tells staff to add charges to the E/M claims for minor services that were not performed by ER physicians, but, rather, by LCH nursing staff.
- You are so busy that you do not have time to act on this immediately. You don't even bother to try to get the caller's name or phone number. You do, however, make a note to ask your audit department to look into this further.
- 10 days after the call, you receive subpoenas from HHS-OIG and the MFCU in Louisiana demanding documents related to services provided by your ER physicians for the past 7 years.

33

Yates Memo
Impact
HYPOTHETICAL
(CONTD)
Third Party Vendor-
Billing Company

- Legal and regulatory issues raised by the employee's conduct?
- Inferences to be drawn from the involvement of certain enforcement entities?
- What proactive response could you undertake first?

34

Summary Slide: "Take aways" from Recent Government Enforcement Activity

- Substantial Government Expenditures re: Fraud and Abuse/Coordinated Efforts
 - "Takedowns"- Criminal Cases (HEAT)
- Increase in Qui Tam Actions
 - Aggressive Application of Laws
 - Review as Criminal Actions
- Increase in AKS Investigations
- Administrative Resolutions: Exclusion and CMPs
- Personal Liability Claims
 - Yates Memorandum
- Blurring Between Mistakes/Overpayments v. False Claims

35

Practice Tips: How Do You Respond to Allegations of Wrongdoing?

- Consideration of legal issues:
 - Analyze applicability of civil or criminal statutes/regulations
- What is your first step regarding complaint received?
- Develop an Investigation/Incident Response strategy
 - How quickly must you act? False Claims Act: 60-day overpayment issues?
- Conduct an internal investigation
 1. Document Preservation Hold: consult with experienced legal counsel
 2. Draft an Investigations Plan- Timeline
 - Document/data collection (e-docs, v/m, texts)- who are the relevant custodians?
 - Who will assist you with the investigation?
 - Analyzing data- who are the relevant players to assist you?
 - Interviewing witnesses- "buddy system"
 3. Expert witness/consultants
 4. To whom do you report your findings?

36

Practice Tips: What Should You Be Doing in a “Yates Memo World?”

- Make sure that all managers and leadership are aware of:
 - Yates Memorandum;
 - recent case examples;
 - DOJ’s Compliance Counsel;
 - DOJ’s Criminal Fraud Section’s “Evaluation of Corporate Compliance Program” Document (February 8, 2017);
 - and the U.S. Sentencing Guidelines Manual: §8B2.1
- Root Cause Analysis Required
- “Notice/Knowledge” Assessment
- Remedial Measures

37

Practice Tips: What Should You Be Doing in a “Yates Memo World?”

- How effective is your current compliance program?
 - How robust is your documentation of how well compliance works
 - How promptly do you investigate complaints and do you document CAPs
 - Questionnaire re: what the employees know about your compliance policies
- Risk Assessment:
 - Arrangements with physicians
 - Practices of sales/marketing employees
- Specific Compliance Training
 - AKS, STARK, FCA, Health Care Fraud, Conspiracy, Obstruction of Justice and Witness Tampering
- Social Media Policies

38

Practice Tips: What Should You Be Doing in a “Yates Memo World?”

- Third Party Vendor Relationships
- Auditing
- Independent Entity conducts Compliance Assessments
- Periodic Meetings with Business Leaders/Service Lines

39



