Viewing Investigations from a Different Angle: Law, Compliance, and Crisis Management in Your Internal Investigation Process

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The New World of Tell-all Investigations

• Compliance/counsel role in reporting, investigations, remediation
• The relationship with prosecutors
• The relationship with employees, stakeholders and media
• Social media, whistleblowers, document dumps
• Reputation and trust
Case Example #1-Hacienda

- Hacienda Health -female in-patient in persistent vegetative state for 14 years gives birth in facility on December 29, 2018. “One of the patients just had a baby, and we had no idea she was pregnant,” the nurse said.
- Story first appears in Phoenix 3TV/CBS 5 January 4.
- On January 4, Hacienda HealthCare spokeswoman Nancy Salmon said, "Hacienda Healthcare has been in business in the valley for over 50 years, and has an outstanding reputation providing high quality specialized care for our patients. (Ms. Salmon’s husband, was a Hacienda lobbyist until 2011, Member of Congress 2013-17)"

Mandatory Duty to Report Abuse (applies to individuals, not entities)

- Arizona Statutes 46-454. Duty to report abuse, neglect and exploitation of vulnerable adults; duty to make medical records available; violation; classification
- All of the above reports shall be made immediately in person or by telephone and shall be followed by a written report mailed or delivered within forty-eight hours or on the next working day if the forty-eight hours expire on a weekend or holiday
Romley January 14 Press Conference Video

Rick Romley Hacienda Press Conference-1/14/19

- Statement and questions
- "when you begin to do these internal reviews, you find out things that maybe you did not know. And I was not going to be one that basically buried it."
- My “own personal belief”
- Will you release report?
- “It was discussed ‘how we restore confidence’
- If you come across wrongdoing, will you disclose it to law enforcement?”
- “It is my intention . . “
- It’s a new day . . .
- “truthfully,”
- I began to meet some of the leadership, and “they assured me”
Two Previous Arizona Republic Hacienda Investigations (reported 1/24/19)

• Documented years of staff complaints of sexual harassment (first reported in 2006) by former longtime CEO Bill Timmons and allegations of financial fraud, leading the state to launch a criminal investigation over allegations it billed the state more than $4 million in bogus charges.

• Board Chair Pomeroy said the board ordered Timmons to get counseling, attend training sessions and docked his pay. But financial records show the board continued awarding Timmons raises and bonuses. By 2015, Timmons was making $609,000 annually.

Hacienda Story on Phoenix 3TV/CBS 5 - 2/5/2019

• In a letter to Attorney General Mark Brnovich, Arizona Governor Ducey said he wanted him to prosecute Hacienda HealthCare and its governing body "for their actions or lack thereof" in connection with the rape, the staff's failure to notice the pregnancy and "any other actions" that violate the Adult Protective Services Act.
Arizona Republic 2/19/19

• Hacienda Board members who oversee the Phoenix care facility where an incapacitated patient was raped have a long record of self-dealing and nepotism.
• Hacienda HealthCare board members and their relatives benefited financially from their positions.
• Some board members do business directly with Hacienda, and some board members have business dealings with each other. Some of their children were hired at Hacienda.
• Hacienda’s board chairman brokered health insurance for roughly 800 Hacienda employees through his private company for decades, reaping lucrative commissions (4-7%) on the contracts.

How Not to Do An Investigation- 2/26/2019- Attorney Romley Quits

• "When I started this assignment, I made it very clear if I was not able to conduct my work with complete objectivity and if any issue came up that caused me any concerns, I would terminate my contract," Romley said.
• Cites “termination of engagement” clause in retention agreement
• Romley said his issues were with Hacienda’s board of directors but declined to elaborate. He also could not share details from the partially completed review because it involved records that belonged to Hacienda. It was unclear if anyone would resume the investigation he started.
• Romley said he believes several employees who quit would come back if there was an entirely new board.
• "If they really cared about the patients and the organization, they would consider resigning," Romley said.
How Not to Do An Investigation-15
Resignations-March 4 TV interview

• Dr. Kevin Berger never thought his dedication to the Hacienda HealthCare board of directors for six years, would turn out like it has. “How would you describe all of this that’s happened?” asked CBS reporter Briana Whitney. “Catastrophic. Unimaginable,” Dr. Berger said.
• Berger is now one of 15 major resignations involved with Hacienda, but one of only two board members who has stepped down.
• Inside sources told us Dr. Berger was well-respected by senior leadership at Hacienda, and that issues lie with other board members.
• “A lot of these resignations, the emails, have cited problems with the board of directors as the reason why they left.”
• Berger said the only way to even attempt to restore trust, is by every board member stepping down and completely starting over.

LEGAL ETHICS

• Identifying the client
• Determining the scope, objectives, and limits of the engagement-engagement letter
• Determining what information is confidential, and how to protect it
• Providing notice to employees and third parties of counsel role
• Reporting results-to whom, format
• Withdrawal
COMPLIANCE ETHICS-HCCA CODE

• **R1.4** If, in the course of their work, HCCPs become aware of any decision by their employing organization which, if implemented, would constitute misconduct, adversely affect the health of patients, residents, or clients, or defraud the system, the professional shall: (a) refuse to consent to the decision; (b) escalate to the highest governing authority, as appropriate; (c) if serious issues remain unresolved after exercising “a” and “b”, consider resignation; and (d) report the decision to public officials when required by law.

Hacienda Compliance Director

• Reported as compliance officer on IRS 990-2016; LinkedIn profile describes this person as “Director of Medical Support Services” since 2012.
• Corporate Compliance Plan clicked link 3/18
• “Not Found”
• “Apologies, but the page you requested could not be found.”
Hacienda, Inc.'s Charitable Mission

• “is to enrich the lives of individuals with special needs in a home-like atmosphere, to acknowledge each individual and each family as unique with distinct needs. To improve the standards in our community by providing the highest quality of care.”

What Should Hacienda have done?

• Crisis Management
• Communication
• Oversight
• Legal
• Compliance
Who Else Has An Interest?

- Patients and families
- State health care agency-what happens
- AG-receivership? Who will take it?
- Staff members
- CMS

Case Example #2 –Dr. Richard Paulus

- Stents to prevent clots in cardiac arteries
- Cardiologist interpreting cardiac angiograms to determine need-
- Standard: if angiogram shows 70% or more blockage, patient can be stented for that artery without further testing
- If 50-70%, further testing
- If <50%, no stent
Risks of Cardiac Stents

- Bleeding
- Clots
- Post-procedural use of blood thinners (Plavix)
- Reaction to drugs in stents
- Unnecessary hospitalizations
- Bloomberg reports cardiac stents were linked to deaths in 773 incident reports submitted to the Food and Drug Administration in 2012, up 71 percent from the same measure in 2008

Dr. Paulus

- First physician in the nation in total angiograms per year
- Hospital does 28% more stents than any other in state (2011)(city not even in top ten)
- Dr. Paulus annual salary from hospital-$2.5 million
- Salary based upon per procedure comp package
- Audits by Medicare(2008), by Anthem(2010), and by the state medical board (2012) found that actual stenosis was often less than the reported 70% reported by Dr. Paulus
Dr. Paulus and His Hospital

- 2011-federal investigation of hospital and Dr. Paulus begins
- What should the hospital do?
- What does the Department of Justice expect?

Dr. Paulus - The science

- 2007 randomized controlled trial in The New England Journal of Medicine. The main outcomes of interest were heart attacks and death. Researchers gathered almost 2,300 patients with significant coronary artery disease and proof of reduced blood flow to the heart. They assigned them randomly to a stent with medical therapy or to medical therapy alone. The stents didn't make a difference beyond medical treatment in preventing heart attacks or death.
- 2012, meta-analysis in JAMA Internal Medicine came to same conclusion.
- 2013 lawsuits alleged that doctors at Paulus' hospital misrepresented the severity of 500 patients' heart conditions to justify procedures such as installing stents in order to get payments from federal healthcare programs.
- 2018 double blind study-no difference in outcomes when stents placed
US Deputy AG Rod Rosenstein on Compliance (Feb. 21, 2019 at UPenn)

• “the Department of Justice should reward companies that try in good faith to deter crime – those that voluntarily implement meaningful compliance programs. When crimes occur, good corporate citizens investigate it, report it to the authorities, cooperate in investigations, and implement appropriate remedies.”

“Good Corporate Citizens”

• Investigate ourselves?
• Report on the company and senior officials?
• Cooperate against officials and our financial interests?
• Remediate?
• “Rewards”-declination of prosecution, deferred prosecution agreements, reduced civil penalties
DOJ defines “Cooperation:”
The Yates Memo-2015 and the 2018 Rosenstein revision

- Yates: For a corporation to be eligible for cooperation credit, corporation must provide to DOJ “all relevant facts” “about individuals involved in corporate misconduct.” “if the corporation does not disclose such facts, it will not be entitled to receive any credit for cooperation.” Rosenstein: this policy that the company identify every employee “impeded investigations and wasted resources.”

- Yates: Prosecutors are directed to pursue senior individuals criminally and civilly even after criminal resolution for corporation. Rosenstein: “absent extraordinary circumstances, a corporate resolution should not protect individuals from criminal liability.”

- Yates: No civil releases for individuals as part of corporate civil settlement. Rosenstein: never mind.

“ROSENSTEIN REVISION”

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<thead>
<tr>
<th>Criminal Enforcement</th>
<th>Yates Memo Requirement</th>
<th>Rosenstein Revisions</th>
</tr>
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<tbody>
<tr>
<td>Eligibility for Cooperation Credit in Criminal Case</td>
<td>Must provide all relevant facts about all individuals involved in corporate misconduct</td>
<td>Must identify every senior individual who was substantially involved in or responsible for the criminal conduct</td>
</tr>
<tr>
<td>Consequences for Company if Individuals Refuse to Cooperate</td>
<td>No Cooperation Credit Available</td>
<td>Full Cooperation Credit available provided company makes good faith efforts to cooperate fully</td>
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### “ROSENSTEIN REVISION”

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<tr>
<td>Eligibility for <em>Any</em> Cooperation Credit in Civil Case</td>
<td>Must provide all relevant facts about all individuals involved in corporate misconduct</td>
<td>Must identify all wrongdoing by senior officers, including members of senior management or the board of directors</td>
</tr>
<tr>
<td>Eligibility for <em>Partial</em> Cooperation Credit in Civil Case</td>
<td>Not Available</td>
<td>Must honestly and meaningfully assist the government’s investigation – credit offered at discretion of DOJ civil attorney with supervisory review</td>
</tr>
<tr>
<td>Eligibility for <em>Maximum</em> cooperation credit in Civil Case</td>
<td>Must provide all relevant facts about all individuals involved in corporate misconduct</td>
<td>Must identify every individual who was substantially involved in or responsible for the misconduct (same as standard for cooperation credit in criminal case)</td>
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### Decision Points in Healthcare Investigations

- Investigation-compliance, or under privilege and work product
- Who is represented? Who has common counsel?
- What records to make of investigation (written report?)
- Full(!) Cooperation
- Employee Discipline/resolution
- Evidence of compliance, remediation
Decision Points for Healthcare Investigations

- Senior management, compliance and board roles, crisis and risk planning, preparation; building resiliency into your company and compliance program
- Who manages communications-incoming and outgoing
- Messages for employees, patients, donors, referring physicians
- Living up to your commitments- Code of Conduct, whistleblowers, donors, patients

#3 The Managed Care Investigation

- Health Care Partners allegations- Independent Physicians Association submitted “inflated” diagnoses to obtain higher reimbursement
- Searched records for support for diagnoses not reported by treating physicians
- Hired outside vendor- vendor only reported diagnoses which increased reimbursement; plan employees reported diagnoses to Medicare Advantage
- Hypothetical: contract signed by CMO, who received bonus for increasing revenues per MA member
Rosenstein-Full Corporate Credit for Cooperation—“Lack of Cooperation of Particular Individual(s)"

– Corporate Miranda disclosures in internal investigations” (Rule 1.13 of the attorney Rules of Professional Conduct)
– Identify Scope of Representation: Explain who the attorney represents.
  • “I am a lawyer for MCO. I represent only the MCO and do not represent you personally. If you would like legal advice, you should consult your own attorney.”
- Explain Purpose of Interview: Lawyer must explain to the employee that the purpose of the communications with the employee is to gather facts in order to provide legal advice for the corporation.

Corporate Response to Rosenstein Investigation

• Question 1: How should compliance officer or counsel advise its employees of the risk/likelihood that company must “identify all individuals substantially involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the Department all relevant facts relating to that misconduct.” (training programs, employee manual, specific investigation)
• Question 2: Does Rosenstein require reporting on individuals at a contractor “involved in or responsible” for the conduct? If yes, how should corporation obtain information about individuals at the contractor “involved in or responsible” for the conduct? (compliance programs, contract clauses, specific investigation)
• Question 3: How should the corporation or counsel advise employees of its decision regarding cooperation in a specific investigation? Of the facts that it discloses to the Government? Of facts implicating specific individuals?
Corporate Response to Rosenstein Investigation

• Question 4: You were the Chief Compliance Officer at the times the diagnosis data was submitted to Medicare Advantage.
  • You were part of the review chain for the vendor contract, and you reviewed the reporting document submitted to MA.
  • You obtained a required certification from the Chief Medical Officer that all data submitted by the Plan to MA was “true, accurate, and complete.”
  • Do any of these facts bar your participation in the investigation?

Corporate Response to Rosenstein Investigation

• “What the government seeks and needs to advance its legitimate (indeed, essential) law enforcement mission is not waiver of (attorney-client or attorney work product) protections, but rather the facts known to the corporation about the putative criminal misconduct under review.”
  • Justice Manual 9-28.710
Yates and Rosenstein DOJ Process-9-28.710

• “while a corporation remains free to convey non-factual or "core" attorney-client communications or work product—if and only if the corporation voluntarily chooses to do so—prosecutors should not ask for such waivers and are directed not to do so.”


• the company may be eligible for cooperation credit regardless of whether it chooses to waive privilege or work product protection in the process, if it provides all relevant facts about the individuals who were involved in the misconduct.
Yates/Rosenberg  DOJ Process-9-28.710

• Many corporations choose to collect information about potential misconduct through lawyers, a process that may confer attorney-client privilege or attorney work product protection on at least some of the information collected. Other corporations may choose a method of fact-gathering that does not have that effect—for example, having employee or other witness statements collected after interviews by non-attorney personnel. Whichever process the corporation selects, the government’s key measure of cooperation must remain the same as it does for an individual: has the party timely disclosed the relevant facts about the putative misconduct

Corporate Response to Yates/Rosenberg Investigation

• Question 5: How can counsel for the corporation provide all relevant facts about the individuals who were involved in the misconduct if it obtained the relevant facts as the result of attorney-client communications within the corporation or the attorney work product of investigation?

- To receive cooperation credit for providing factual information, the corporation need not produce, and prosecutors may not request, protected notes or memoranda generated by the interviews conducted by counsel for the corporation. To earn such credit, however, the corporation does need to produce, and prosecutors may request, relevant factual information—including relevant factual information acquired through those interviews.

Corporate Response to Yates/Rosenstein Investigation

- Question 6: VP of Finance states that diagnosis data submitted to managed care entities and Medicare was probably not accurate—the consulting firm told him they only looked for chart information that would result in an upcode, and was paid on a contingency basis for successful upcodes. What is the “factual” information in this admission? How should the MCO provide this information?
Yates/Rosenstein Investigations
DOJ Manual- 9-28.730
Joint Defense Agreement with Vendor

• “the corporation may wish to avoid putting itself in the position of being disabled, by virtue of a particular joint defense or similar agreement, from providing some relevant facts to the government and thereby limiting its ability to seek such cooperation credit. “

Yates and Rosenstein-Corporate Response and Remediation-9-28.1000

• “Among the factors prosecutors should consider and weigh (in deciding whether to prosecute the corporation) are whether the corporation appropriately disciplined wrongdoers, once those employees are identified by the corporation as culpable for the misconduct.
• “Effective internal discipline can be a powerful deterrent against improper behavior by a corporation's employees. Prosecutors should be satisfied that the corporation's focus is on the integrity and credibility of its remedial and disciplinary measures rather than on the protection of the wrongdoers.
• “(a) corporation's quick recognition of the flaws in the (compliance) program and its efforts to improve the program are also factors to consider as to the appropriate disposition of a case.
**Corporate Response to Yates/Rosenstein Investigation**

- **Question 7:** How should the corporation appropriately discipline wrongdoers during the course of the investigation? Can the corporation consider employee cooperation in deciding on appropriate discipline? Can the corporation resolve disciplinary charges by settlement?

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<th>Question 8: What has happened in Yates Prosecutions?</th>
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<td>• Acclarent, Inc. medical device company $18 million False Claims Act civil settlement.</td>
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<tr>
<td>• CEO William Facteau, VP Sales Patrick Fabian acquitted of felony charges, convicted of misdemeanors relating to unlawful distribution of medical devices. (2016)</td>
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Question 8: What has happened in Yates Prosecutions?

- Warner Chilcott-specialty drug manufacturer-guilty plea, $22 million criminal fine and $102 million settlement for kickbacks to physicians
- Carl Reichel, president, acquitted of single count of conspiracy
- District managers entered guilty pleas
- Physician charged with accepting kickbacks ($23,500 in meals and speaker fees) (case pending)

What has happened in Rosenstein Prosecutions?

- Insys-$150 million civil settlement in principle-August 2018-off-label marketing of sublingual fentanyl based opioid
- Criminal indictments of individuals:
  - Michael L. Babich, the former CEO and President of the company
  - Alec Burlakoff, former Vice President of Sales
  - Richard M. Simon, former National Director of Sales;
  - Former Vice President of Managed Markets, Michael J. Gurry
“ROSENSTEIN REVISION”

• Some Yates Memorandum materials are shown as the November 2015 updates which are still effective; Rosenstein revisions are the November 2018 updates
• Current (as of December 2018) Justice Manual materials attached as Exhibit 1.

Thank You for Your Attention

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