2021 GOVERNANCE SUPPORT FORUM

MISSION CRITICAL: BOARDS' ROLE IN PROTECTING THEIR ORGANIZATION

Prepared for

GOVERNANCE INSTITUTE | SEPTEMBER 18-19, 2021 THE INTERCONTINENTAL SAN DIEGO, CA

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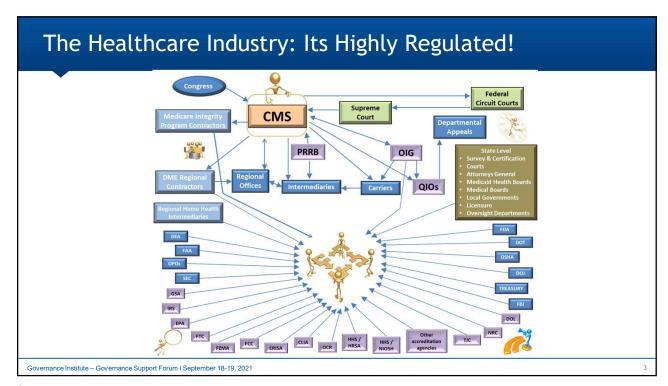


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So, Today's Agenda:

- The History of Heightened Government Enforcement
- Growing Emphasis on Individual Liability in any job position
- Board's Role in Compliance and protecting the Organization
 - Awareness of DOJ enforcement
 - Awareness of HHS-OIG enforcement
 - Awareness of CMS enforcement
 - Use to steer your organization's compliance





CLIA Clinical Laboratory Improvement Amendments CMS Centers for Medicare & Medicaid Services DEA Drug Enforcement Administration DME Durable Medical Equipment DOJ Department of Justice DOL Department of Labor DOT Department of Transportation EPA Environmental Protection Agency ERISA Employment Retirement Income Security Act FAA Federal Aviation Administration FBI Federal Bureau of Investigation FCC Federal Communications Commission FDA Food & Drug Administration FEMA Federal Trade Commission FTC Federal Trade Commission CMS General Service Administration HHS Health & Human Services HRSA Health Resources & Services Administration Internal Revenue Service NIOSH National Institute for Occupational Safety & Health NRC Nuclear Regulatory Commission OCR Office for Civil Rights OIG Office of Inspector General OPO Organ Procurement Organization(s) OSHA Occupational Safety & Health Administration PRRB Provider Reimbursement Review Board QIO Quality Improvement Organizations SEC Securities & Exchange Commission The Joint Commission The Joint Commission	ACRONY AHEAI	YMS
	CMS Centers for Medicare & Medicaid Services DEA Drug Enforcement Administration DME Durable Medical Equipment DOJ Department of Justice DOL Department of Labor DOT Department of Transportation EPA Environmental Protection Agency ERISA Employment Retirement Income Security Act FAA Federal Aviation Administration FBI Federal Bureau of Investigation FCC Federal Communications Commission FDA Food & Drug Administration FEMA Federal Emergency Management Agency	HHS Health & Human Services HRSA Health Resources & Services Administration IRS Internal Revenue Service NIOSH National Institute for Occupational Safety & Health NRC Nuclear Regulatory Commission OCR Office for Civil Rights OIG Office of Inspector General OPO Organ Procurement Organization(s) OSHA Occupational Safety & Health Administration PRRB Provider Reimbursement Review Board QIO Quality Improvement Organizations SEC Securities & Exchange Commission

Large Annual Healthcare Spend

- <u>In 2019</u> U.S. healthcare spending grew 4.6%, reaching \$3.8 trillion or \$11,582 per person, and was 17.7% of US Gross Domestic Product.
- According to CMS, annual healthcare spending for 2028 is projected to exceed \$6.2 trillion, and account for 19.7% of the GDP
- For 2019-28, health spending is projected to grow at an average rate of 5.4% per year
- Federal, state and local government share of health expenditures to increase to 47% by 2028 (Source: CMS office of the Actuary, March 24, 2020)

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The Complexity Of Regulation

- If the 2020 U.S. regulatory costs of \$1.9 trillion were a country, it would be the world's 8th largest economy behind Italy and ahead of Brazil. (Source: Commerce Dept., Bureau of Economic Analysis)
- Federal Register:
 - 2016 had 95,894 pages (highest in history)
 - 2017 had 61,308 pages (36% drop)
 - 2020 had 86,356 (2nd highest in history)



• At the end of 2020, there were 3,852 proposed rules in the Federal Register pipeline.

Source: Competitive Enterprise Institute, "Ten Thousand Commandments, an annual snapshot of the federal regulatory state, 2021."

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Heightened Enforcement: DOJ and HHS-OIG

Aggressive Government Enforcement Continues in Healthcare:

- Vigorous enforcement of healthcare fraud and abuse laws remains a top priority of HHS-OIG and the DOJ
- For FY 2020, DOJ and OIG jointly reported:
 - 990 criminal cases filed
 - 1,860 new civil actions; and
 - 2,148 exclusion actions
- Enforcement is not slowing down. The Federal Government investigative recoveries totaled \$1.8 Billion for FY2020.



(CMS



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CMS: Heightened Enforcement Actions

- Medicare and Medicaid Contractor Audits
 - Zone Program Integrity Contractors (ZPICs)
 - · Generally looking for purposeful fraud
 - Ability to initiate fraud investigations/refer matters to OIG
 - Risk of extrapolated overpayment, may withhold payment or place on pre-payment review
 - **Recovery Audit Contractors (RACs)**

IS WATCHING!!

- Typically random audits
- Complicated Appeals Process
- RAC paid a % of recovery
- Other auditors include: Program Safeguard Contractors (PSCs), Medicaid Integrity Contractors (MICs), and Unified Program Integrity Contractors (UPICs).

Penalties Can Be Assessed For UNINTENTIONAL Violations

- Companies have recently been fined or forced to reimburse Medicare and Medicaid millions of dollars for things like:
 - Failing to encrypt and properly secure devices with PHI on them (laptops, tablets, USB drives, smart phones);
 - Failing to use the most up-to-date forms;
 - Failing to properly document actions/evaluations of patients and medical necessity;
 - Simply failing to sign and date documents, contracts and agreements in a timely manner.

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Recent Government Action

Texas: February 2017

- Children's Medical Center of Dallas fined \$3.2 million over patient privacy breaches dating back to 2007
- Voluntary reported potential disclosures in 2010 of a Blackberry lost at DFW airport allowed unencrypted, non-password access to 3,800 patients' information.
- Security analysis performed in 2007 had reported this gap to management, as did a separate report in 2008. No action taken.

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Whistleblowers: A Major Source Of Enforcement Information

The Rise of the Whistleblower

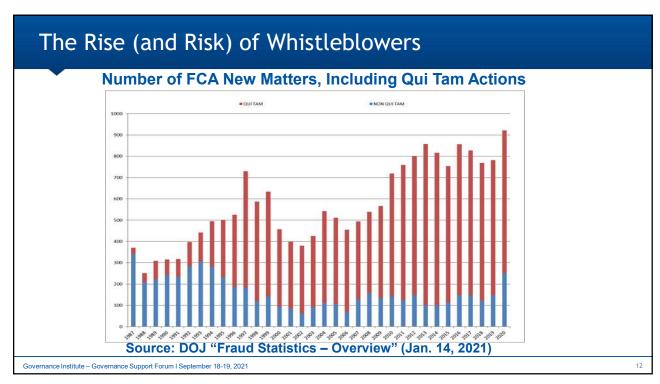




"Remember the good old days when it was a suggestion box?"

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Why Are There More Whistleblowers Than Ever?

- Expansion of whistleblower protections under federal law
- Case law expanding protected activity and making retaliation claims more difficult to defend
- Government increasingly relying on whistleblowers as source for new cases
- False Claims Act creates a "bounty" for whistleblowers to recover a percentage of recovery - up to 30% of recovery
 - For 2020, DOJ reported that there were <u>672 Qui Tam suits</u> filed an average of 13 per week.







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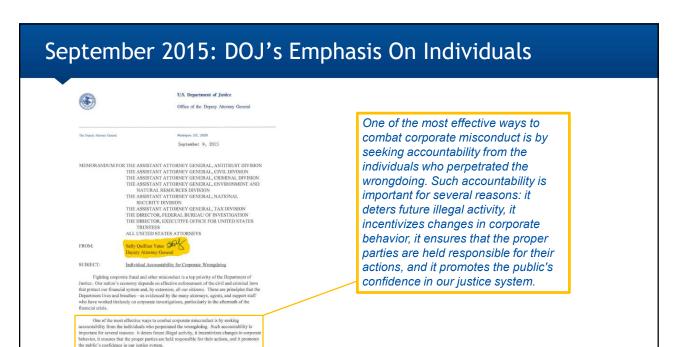
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Recent Government Action - Started by a Whistleblower

Texas: December 2017

- Dallas Based EmCare, Inc:
- pays \$29.8 million to resolve False Claim Act Allegations
- 2008-2012, EmCare received payment from HMA (now defunct) to increase Medicare admissions at HMA hospitals by recommending admissions for patients who should have been billed as out patient or observation services. EmCare got bonus and contract renewed
- Whistleblowers (the former ER staffing company) received \$6.2 million of recovery

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Yates Memo Guidance: 6 Key Points For Fed Prosecutors

- 1. Conditions eligibly for cooperation credit on disclosure of what corporation knows about individual misconduct.
- 2. Focus on individual conduct from inception.
- 3. Communication between civil and criminal prosecutors.
- 4. Resolution with corporation will not provide liability relief for individuals.
- 5. Corporate cases should not be resolved before deciding how to resolve related individual cases.
- 6. Individual's ability to pay should not factor in determining whether to pursue civil actions against individuals.

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DOJ: Yates Memo

Significance:

Provides that in order for a corporation to receive "cooperation credit," the corporation has to identify <u>all</u> individuals who had any involvement in the conduct at issue.



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The Federal Sentencing Guidelines for Organizations

- "These guidelines offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program. The prevention and detection of criminal conduct, as facilitated by an effective compliance program, will assist an organization in encouraging ethical conduct and in complying fully with all applicable laws."
 - U.S.S.C., Ch. 8, Sentencing of Organizations, Introductory Commentary (November 1, 2018).

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Personal Accountability

- Board Members and Officers of Health Care Organizations are responsible for:
 - Knowing and adhering to laws and regulations that affect the Organization.
 - Supervising the Compliance Program and policies and procedures.
 - Devoting sufficient resources to compliance.
 - Taking appropriate action when compliance problems are identified in the Organization.



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November 2018 - DOJ: Justice Manual Revision

- Modifies Yates Memorandum
- Deputy Attorney General Rod Rosenstein revised policy for more lenient path for corporations to receive credit.
- <u>Criminal Cases</u>: Corporation <u>must</u> identify every individual substantially involved/responsible for misconduct, in order to receive maximum cooperation credit.
- <u>Civil Cases</u>: DOJ attorneys have discretion to reward cooperation, so in civil matters (FCA cases) corporations need "only" identify individuals (e.g., senior management and board of directors) who were "substantially involved".

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Implication of DOJ's November 2018 Revision:

- 1. Yates policy on individual liability remains.
- 2. Critical the Board demonstrate throughout the entity its support for the Compliance program and those who administer it (general counsel, chief compliance officer).
- 3. Board should remain aware of tension between senior executives and the board created by continued corporate credit emphasis on senior management . . . and Board Members.

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Yates Memo Takeaways For Compliance:

- For the corporation's workforce (executives/employed physicians) focused legal exposure remains for those who are risk-insensitive and who are inclined to push the edge of the legal/regulatory envelope with their style of work.
- Compliance program needs routine continued education on
 <a>(a) regulatory requirements and (b) consequences for individuals who disregard rules/regulations.

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Individual Prosecution: CEO of Rural Texas Hospital

February 2019

- Palo Pinto General Hospital, Mineral Wells, Texas
- Public Hospital District
- Laboratory Service billed through hospital's NPI number
- 6 allergy/genetic testing invoices sent for non-hospital patients when hospital did not have equipment or performance service.
- Hospital paid back + \$8 Million

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Individual Prosecution: CEO of Rural Texas Hospital

- CEO charged in February 2019
- Sentenced in July 2019
 - 5 years probation
 - \$2.4 Million restitution
 - 250 hours community service
- CEO did not have personal gain from arrangement
- Exclusion



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February 2019: New England Pain Associates (Boston, MA)

- Physician provided pain management services and was the second highest prescriber of oxycodone in Massachusetts (behind only a hospital).
 - Falsely billed Medicare for services that he <u>did not provide</u>.
 - Prescribed pain medications without performing physical exams.
 - <u>Lied</u> in patient records about time spent per patient to maximize billings.
 - Performed unnecessary urine drug tests.
 - Falsified patient records after a Medicare audit.
- Result: 75 months in prison and \$1,852,459 in restitution

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HHS-OIG: Maintaining and Measuring a High-Functioning Compliance Program:

February 1998:

- 1. While historically providers were encouraged to maintain effective compliance programs, there were few resources.
- 2. The OIG published a document commonly called the "Seven Elements of an Effective Compliance Plan."



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1998: The OIG's "Seven Elements"

- 1. Implementing written policies, procedures, and standards of conduct.
- 2. Designating a compliance officer and compliance committee.
- 3. Conducting effective training and education.
- 4. Developing effective communication lines to receive complaints and protect anonymity.
- 5. Conducting internal monitoring and auditing.
- 6. Enforcing standards through well-publicized disciplinary guidelines.
- 7. Responding promptly to detected offenses and undertaking corrective action.

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The OIG's "Seven Elements" (cont.)

- Essentially this guidance establishes a framework for a compliance program that, through the compliance officer, develops policies, receives complaints, monitors and audits conduct, and responds to compliance concerns.
- However, the seven elements do not address or provide guidance on measuring the effectiveness of a compliance program.



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Six Months Later:

August 1998:

• Shortly after publishing the seven elements, the OIG stated that:

"[s]uperficial programs that simply purport to comply with the elements discussed and described in this guidance or programs that are hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could expose [providers'] to greater liability than no program at all."

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So, Now . . . The OIG will:

- Going forward the OIG will focus more on what providers are actually doing to ensure that their compliance programs are functioning effectively and less on how the compliance program is structured.
 - a) View poorly a well written compliance plan that sits on the shelf
 - b) View favorably a well funded, resourced compliance program
 - c) View favorably an independent compliance officer, with direct access to C-suite and Board

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March 2017: HHS-OIG Shift in Focus Continues:

- This shift in focus is also the reasoning behind the release of the publication Measuring Compliance Program Effectiveness: A Resource Guide.*
- Publication was a collaboration between industry association and government agency.

Measuring Compliance Program Effectiveness: A Resource Guide

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 | Washington, DC



*HCCA-OIG Compliance Effectiveness Roundtable March 27, 2017.

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March 2017: OIG/HCCA Compliance Program Effectiveness Guide

- 50+ pages with over 400 ideas on measuring the effectiveness of the Seven Elements of an effective compliance program
- Some key areas:
 - Standards/Policies & Procedures
 - Compliance Program Administration (including Boards)
 - Screening & Evaluation of Staff, Vendors and other agents
 - Communication, Education and Training
 - Monitoring, Auditing and Internal Reporting
 - Principal for Non-Compliance
 - Investigation and Remedial Measures

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March 2017: OIG/HCCA Compliance Program Effectiveness Guide

- The stated purpose of the Guide is:
 - "To give health care organizations as many ideas as possible, be broad enough to help any type of organization, and let the organization choose which ones best suit its needs."



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March 2017: OIG/HCCA Compliance Program Effectiveness Guide

• Guide's comments on Board's Role:

	What to Measure How to Measure	
	Board of Directors:	now to measure
2.1	Active Board of Directors	Review minutes of meetings where Compliance Officer reports in-person to the Audit and Compliance Committee of the Board of Directors on a quarterly basis Conduct inventory of reports given to board and applicable committees.
2.2	Board understanding and oversight of their responsibilities	Review of training and responsibilities as reflected in meeting minutes and other document (training materials, newsletters, etc.). Do minutes reflect board's understanding? Review/audit board education – how often is it conducted? Conduct interviews to assess board understanding.
2.3	Appropriate escalation to oversight body	Review minutes/checklist in compliance officer files
2.4	Commitment from top	Review compliance program resources (budget, staff). Review documentation to ensure staff, board and management are actively involved in the program. Conduct interviews of board, management and staff.
2.5	Process for escalation and accountability	Process review (document review, interviews, etc.). Is there timely reporting and resolution of matters?

March 2017: OIG/HCCA Compliance Program Effectiveness Guide

- Note also, that while there were over 400 ideas, HHS Inspector General David Levinson noted when announcing the Guide, that no organization is expected to adopt all or even a large number of the suggestions, nor is the Guide the same as a "Checklist" or certification program.
- Rather, each organization should select measures based on the specific needs, resources and risks of the organization.

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Meanwhile, Over at the Department of Justice:

February 2017:

About the same time as the HCCA-OIG's "Measuring Compliance Program Effectiveness", the Department of Justice published its guidance in "Evaluation of Corporate Compliance Programs."

• Drafted by DOJ Criminal Division, Fraud Section.

*U.S. Department of Justice, "Evaluation of Corporate Compliance Programs" (available at www.justice.gov/criminal-fraud/page/file/937501/download).

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The Department of Justice:

• This 2017 publication provided an extensive list of more than 100 questions that federal investigators use to inquire across a range of compliance program operating functions and that were found to be useful in evaluating provider fraud, waste, or abuse.



U.S. Department of Justice Criminal Division

Evaluation of Corporate Compliance Programs

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April 2019: DOJ Updates its 2017 Guidance

April 2019 Update:

- Criminal Division updates the February 2017 edition "Evaluation of Corporate Compliance Programs."
- Status:
 - Advises federal prosecutors that corporate compliance **must** be evaluated in specific context of the criminal prosecution; not a rigid formula to assess the effectiveness of the compliance program.



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April 2019: DOJ Update

 DOJ recognizes there are <u>common questions</u> a federal prosecutor should ask in course of making an individual determination, the "Principals of Federal Prosecution of Business Organizations" in the Justice Manual notes <u>three "Fundamental Questions"</u> a prosecutor should ask:

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April 2019: DOJ Update

- 1. <u>Is the Corporation's Compliance Program Well Designed?</u>
 - Risk Assessment
 - Policies/Procedures
 - Training/Communication
 - Confidential Reporting & Investigatory Process
 - Third Party Management
 - Mergers/Acquisitions



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April 2019: DOJ Update

- 2. <u>Is the Corporation's Compliance Program Being Implemented</u> Effectively?
 - Commitment by Senior Management (including the Board)
 - Autonomy & Resources
 - Incentives & Disciplinary Measures



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June 2020: DOJ Update

- DOJ recently updated its "Evaluation of Corporate Compliance Programs." Question 2, Was revised to state:
 - Is the Corporation's Compliance Program adequately Resourced and Empowered to Function Effectively?
- The board of directors and executives should set the tone for the rest of the company (page 10)
- The "governing authority" shall be knowledgeable about the content and operation of the compliance/ethics program and exercise reasonable oversight
- Ask: What compliance expertise has been available to the board?
 - Have the board and external auditors held executive sessions with compliance and control functions?
 - What information has the board executed in oversight role?

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April 2019: DOJ Update

- 3. Does the Corporation's Compliance Program Work In Practice?
 - Continuous Improvement, Periodic Testing and Review
 - Is there actual investigation of Misconduct
 - Analysis and Remediation of Any Underlying Misconduct



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April 2019 and June 2020 DOJ Updates

The Takeaway:

The answers to these three questions are designed to assist federal prosecutors determine to what extent a corporation's compliance program was effective at the time of the offense and at resolution, for determining:

- a) Form of resolution or prosecution
- b) Monetary penalty, if any; and
- c) Compliance obligations for any corporate criminal resolution (e.g.: monitoring or reporting obligations)



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May 2019 - Texas: Seminole Hospital District of Gaines County

EXECUTION COPY

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on hehalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the United States), the State of Texas, acting through the Office of Inspector General (HHSC-OIG) of the Health and Human Services Commission of the State of Texas (HHSC), an agency of the State of Texas (collectively, Texas), and Seminole Hospital District of Gaines County, Texas (the District) through their authorized representatives.

RECITALS

- A. The Seminole Hospital District of Gaines County, Texas was created by the Texas legislature in 1971. As a political subdivision of the State of Texas, the District is charged by statute with providing medical care to the inhabitants of Gaines County, Texas.
- B. On September 21, 2018, the District, through Counsel, delivered a letter to the United States Attorney's Office for the Northern District of Texas, the Texas Health and Human Services Commission, and the Office of Inspector General for the Texas Health and Human Services Commission (the Disclosure). In the Disclosure, the District states that from 2012 through 2017 it improperly paid physicians Dr. Wendell Parkey, Dr. Lance Martin, Dr. Jean-Pierre Letelller, Dr. Timothy Gioyd, and Dr. Gilbert Sayegh (collectively, the District Physicians) more than fair market value for their services.

- Paid 5 physicians more than FMV
- 2012-2018
- Settled valid \$25 million claim for \$7 million repayment
- Did not release claims against other parties (i.e. doctors?)

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May 2019 - Texas: Seminole Hospital District of Gaines County

- <u>District Agrees in settlement to cooperate with ongoing investigation:</u>
 - 1) "The District agrees to cooperate fully and truthfully with the investigation of individuals and entities not released in this Agreement by either the United States or Texas. Upon reasonable notice, the District shall encourage, and agree not to impair, the cooperation of the directors, officers, and employees of the District in the investigation of individuals and entities not released in this Agreement by the United States or Texas, and the District shall further use their best efforts to make available, and encourage, the cooperation of former directors, officers, and employees of the District for interviews and testimony, consistent with the rights and privileges of such individuals. The District further agrees to furnish to the United States and Texas, upon request, complete and unredacted copies of all non-privileged documents. . ."

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Texas: Seminole Hospital District of Gaines County - May 2019 (cont.)

2) This Agreement is intended to be for the benefit of the Parties only. The Parties <u>do not release any claims against any other person or entity</u>, except to the extent otherwise explicitly provided for herein.



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A Final Thought: Do Not Strive To Take Unnecessary Risks Or Be A Market Leader In Creative Compliance

- Due to the technical nature of many of the healthcare laws and regulations (FCA, Stark Law, and Anti-Kickback), it is wise to be conservative in your approach to compliance
 - Even small technical violations can potentially lead to large penalties and fines
 - Consider use of the self-disclosure protocol if violations are detected and to increase your potential to minimize liability exposure especially for minor technical violations

WINNING AT RISK MANAGEMENT

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Questions?



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