

**HCCA 3rd Annual Healthcare Enforcement
Compliance Institute**

October 29, 2017

**ARE WE INEFFECTIVE AT ASSESSING
COMPLIANCE PROGRAM EFFECTIVENESS OR
ARE INDUSTRY AND GOVERNMENT USING
DIFFERENT STANDARDS?**

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Goals of Session

- **Review** recent developments demonstrating the convergence of Compliance and Enforcement
- **Discuss** expansion of entities evaluating organizational compliance program effectiveness and related consequences
- **Highlight** significant escalation in expectations for compliance program infrastructure, operations, risk mitigation efforts and the risks of falling short
- **Explore** potential strategies to proactively fortify critical compliance infrastructure and related processes needed to maintain organizational compliance program and related processes

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Industry Developments Impacting Compliance Program Effectiveness

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LANDSCAPE CONTINUES TO INTENSIFY

- Several recent enforcement and other developments have impacted the compliance landscape, including:
 - **Enforcement agencies widening the compliance lens**
 - Compliance 1.0 vs. Compliance 2.0
 - Regulatory defense vs. Proactive operational machine
 - Significantly enhanced expectations for *enterprise wide compliance* programs and support at all levels
 - Board
 - Leadership
 - Management

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LANDSCAPE CONTINUES TO INTENSIFY (CONT'D)

- **Enforcement agencies articulating importance of compliance profile and compliance story**
 - Reflected in recent guidance
 - Ex: U.S. DOJ, Criminal Division, *Evaluation of Corporate Compliance Programs* (February 2017)
 - Similar themes articulated in *A Resource Guide to the U.S. Foreign Corrupt Practice Act (FCPA Guide)* (2012) and in the *Anti-Corruption Ethics and Compliance Handbook for Business (OECD Handbook)*(2013)
 - Reflected in staffing
 - Ex: DOJ hiring of special compliance counsel
 - Reflected in prosecutions and settlements
 - Ex: Pursuit of individuals without regard to depth of pocket

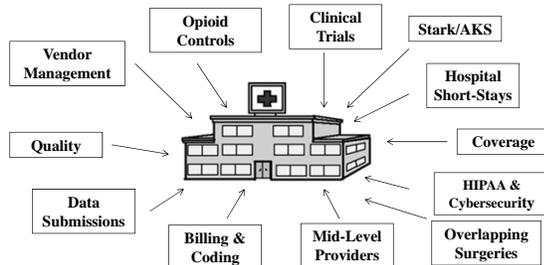
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• Landscape Continues to Intensify

- Several recent enforcement and regulatory developments have impacted the healthcare industry, including:
 - Increased FCA penalties
 - Aggressive Relator Strategies
 - DOJ Compliance Counsel
 - Focus on Individual Accountability
 - Enhanced OIG compliance program expectations

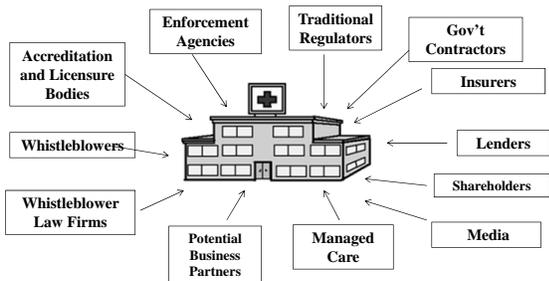
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Enforcement Areas Are Fluid



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Expanding Universe of Evaluators



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Intersection of FCA and Compliance Program Effectiveness

“The absence of a high-functioning compliance program may be used to establish [FCA] intent.”

Thomas Beimers (Former Senior Counsel with HHS OIG)

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Aggressive Relator Strategies

- Whistleblower cases continue to increase
- Defense counsel must be prepared to defend litigation, not merely investigation
- Even if government declines to intervene, relator’s counsel continues case
- Private equity funding

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FCA Penalties - The Stakes Are High

- Increased False Claims Act (FCA) financial penalties for non-compliance
 - In 2017, the *minimum* per claim penalty increased to \$10,957, and the *maximum* increased to \$21,916
- Example of damages with new FCA penalties:

Defense Contractor 12 claims/year		Healthcare Provider 2,000 claims/year	
Triple Damages	\$300,000	Triple Damages	\$300,000
Penalty (20,000 x 15)	\$282,992	Penalty (20,000 x 1,000)	\$43,832,000
Total Recovery	\$582,992	Total Recovery	\$44,132,000

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DOJ Compliance Counsel

- During the summer of 2015, DOJ revealed that it was hiring compliance counsel to assist DOJ prosecutors in assessing the effectiveness of companies' corporate compliance programs.
 - DOJ historically has relied on OIG for this assessment.
 - Underscores:
 - Increased importance of the effectiveness of corporate compliance programs
 - DOJ's intent to be more active

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DOJ Compliance Counsel

- **Original Design:**
 - DOJ Compliance Counsel was expected to help prosecutors "differentiate the companies that get it and are trying to implement a good compliance program from the people who have a near-paper program"
- **Practical Consequences:**
 - Created a new "step" in significant investigations
 - In healthcare, providers having to demonstrate compliance program effectiveness with DOJ prior to presentation to OIG
- **Recent Announcements:**
 - Hui Chen (initial DOJ Compliance Counsel) is leaving the position
 - DOJ is actively seeking applicants for Hui Chen's replacement

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DOJ Compliance Counsel: Job Description

Job Description:

As an Attorney Advisor (Compliance Counsel), the incumbent will:

- Assist the Fraud Section in assessing corporate compliance standards and compliance efforts, including developing general criteria for the evaluation of any compliance program;
- Assist in evaluating whether an organization's compliance program is effective and reasonable;
- Work with compliance professionals to better understand the realities of compliance in the multitude of industries in which the corporate actors that appear before the Fraud section function;
- Work with monitors appointed in Fraud Section cases to assist in establishing and assessing an organization's ongoing remediation efforts; and
- Perform consultant services to attorneys in connection with, or in anticipation of, the Fraud Section's litigation involving corporate compliance matters.

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Yates Memorandum

- On September 9, 2015, former Deputy Attorney General, Sally Quillian Yates, issued a memorandum (the Yates Memo) regarding individual accountability for corporate wrongdoing.
 - Provides guidance for both civil and criminal investigations.
- Emphasizes the need to hold individuals who perpetrated corporate wrongdoing accountable, “particularly in the aftermath of the financial crisis.”
- Although Sally Yates is no longer with DOJ, the Yates memo continues to be DOJ policy.

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Recent Examples of Individual Liability

- Recent examples of the individual accountability:
 - Former CEO of Tuomey Healthcare settled alleged Stark violations for **\$1 million**
 - Former CFO of Pacific Hospital entered a **plea agreement** with DOJ for his involvement in a fraud scheme
 - Cardiologist and his practice paid **\$2 million** and released claims to an additional **\$5.3 million** in suspended Medicare funds to settle allegations of fraud and kickbacks to patients

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Recent Examples of Individual Liability

Law360, New York (August 10, 2016, 1:53 PM ET) -- The former chief financial officer of an Alabama nonprofit health clinic for the poor and homeless will serve 17 years in prison and forfeit nearly \$2 million for her role in an \$11 million fraud against two clinics and the federal government, the U.S. Department of Justice announced Tuesday.

Ex-Clinic CFO Gets 17 Years After Taking \$11M From Grants

Justice News
Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE
Monday, September 19, 2016

North American Health Care Inc. to Pay \$28.4 Million to Settle Claims for Medically Unnecessary Rehabilitation Therapy Services

Chairman of the Board and Senior Vice President of Reimbursement Analysis to Pay an Additional \$1.5 Million

In total of the Justice Department's Chief Counsel: "Health care providers will be held accountable if they bill for unnecessary services or treatments."

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Significance of 60-Day Overpayment Rule

- One of the most significant regulatory developments in the last 20 months
 - Medicare Parts A and B overpayment rule
- The 60-day law is the darling of the enforcement and whistleblower community
- Expect to see significant enforcement activity in this corridor

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OIG's Focus on 60-Day Rule

- **Language from OIG Compliance Review:**
 - Audited provider should “exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day rule, and identify returned overpayments as having been made in accordance with this recommendation.”

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OIG's Focus on 60-Day Rule

- **Language from New CIAs:**
 - *Repayment of Identified Overpayments.* [Provider] shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) (the “CMS overpayment rule”). If [Provider] determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, [Provider] shall repay that amount at the mean point estimate as calculated by the IRO. [Provider] shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.”

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Focus on Self-Disclosures

- Daniel Levinson – HHS, Inspector General, Remarks at HCCA Annual Compliance Institute (March 2017):

“The self-disclosure protocols has always been a very important part of demonstrating that we’re really on top of our compliance work and that when a firm sees a problem it doesn’t wait in the hopes that it can just be avoided, but it comes forward and makes whole the taxpayer and insures that the firm is able to move forward ethically and legally.”

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Focus on Corporate Governance in Settlements

- On January 17, 2017, a Tennessee federal Judge approved a \$60 million settlement agreement between CHSI and certain directors and executives with the class of CHSI stockholders
- The settlement also requires that CHSI “adopt meaningful corporate governance reforms,” including:
 - The appointment of two new mutually acceptable independent directors to the Board
 - The establishment of a healthcare law compliance coordinator, subject to the approval of OIG
 - The compliance coordinator will work with the Chief Compliance Officer to coordinate and oversee implementation of the Company’s compliance programs, with particular emphasis on Medicare and Medicaid compliance programs

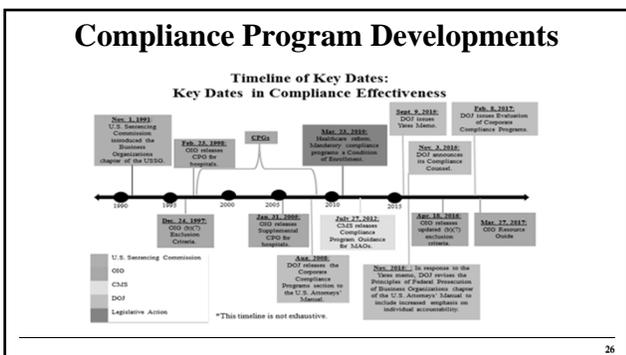
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UPHS Settlement

- The University of Pennsylvania Health System (UPHS) settled false claims allegations that UPHS billed Medicare for home health services that were not reasonable or necessary
- Pursuant to the settlement agreement, UPHS agreed to pay approximately \$75,000 and also agreed to ongoing compliance monitoring by the United States Attorneys’ Office (USAO) through 2019
- As part of the ongoing monitoring, UPHS will be required to conduct semi-annual audits of home health claims and report the results to the USAO
- USPHS is required to annually submit certified compliance reports to the USAO
 - These reports must contain attestations by the USPHS billing compliance officer and the chief counsel. UPHS must also notify the USAO of any home health overpayments that are refunded

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Overview of Compliance Program Expectations and Trends



- ### Traditional Seven Elements of a Compliance Program
1. Designating a Compliance Officer and Compliance Committee
 2. Implementing written policies, procedures and standards of conduct
 3. Conducting effective training and education
 4. Developing effective lines of communication
 5. Conducting internal auditing and monitoring
 6. Enforcing standards through well-publicized disciplinary guidelines
 7. Responding promptly to detected offenses and undertaking corrective actions
- “8th Element” - Risk Assessments**

Compliance Program Expectations Articulated in CIAs

- **Corporate Integrity Agreements**
 - Agreement with HHS-OIG in connection with civil healthcare fraud settlement
 - Requires entity or individual to implement (or continue) certain integrity obligations for a period of years

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Importance of CIA Trends to Non-CIA Obligated Providers

- OIG uses CIAs to communicate prudent approaches to compliance program design and compliance-related initiatives
- Emerging trends in CIAs reflect OIG’s escalating compliance expectations for entities participating in federal healthcare programs
- Why monitor and address emerging compliance trends?
 - Fortify compliance infrastructure
 - A company’s proactive efforts to monitor and address such emerging compliance trends often benefits the company when reviewed by Government enforcement agencies

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Remarks at HCCA Compliance Institute

Daniel Levinson – HHS, Inspector General, Remarks at HCCA Annual Compliance Institute (March 2017):

“Today is very much prevention day and we’re talking about corporate integrity agreements and because of the recent developments with CIAs and the way that we’re now able to focus attention in a much more laser-like way, I think the evolution of CIAs from a broader tool to understand whether a system is operating reasonably well, to being able to focus on particular areas of vulnerability is a real step forward when it comes to CIAs . . .”

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Emerging CIA Trends

- Enhanced Board oversight
- Management’s responsibility for compliance
- Active risk assessment and mitigation
- Risk-based claims testing
- Compliance Expert

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Expectation: Effective Compliance Programs

- **“You get no bonus points for having a compliance program”**
 - HHS Inspector General Daniel R. Levinson, remarks at the Health Care Compliance Association’s Annual Compliance Institute (Apr. 18, 2016)
- The expectation has shifted from incentivizing the adoption of compliance programs to incentivizing the operation of effective compliance programs
- OIG, DOJ, CMS, and other third parties are evaluating the effectiveness of compliance programs

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OIG Permissive Exclusion Authority

- On April 18, 2016, OIG issued a revised policy statement containing the new criteria that OIG intends to use in implementing its permissive exclusion authority under 42 U.S.C.A. § 1320a-7(b)(7) (Revised Policy).



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OIG Permissive Exclusion Authority

• **Compliance Program**

- The existence of a compliance program that incorporates the seven elements of an effective compliance program does not affect the risk assessment
- The absence of a compliance program that incorporates the seven elements of an effective compliance program indicates higher risk
- If the entity has devoted significantly more resources to the compliance function, this indicates lower risk

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Assessing and Measuring Compliance Program Effectiveness

1. FEBRUARY 2017: DOJ ISSUANCE

DOJ Compliance Effectiveness Guidance

- Issued in February 2017 without the typical fanfare that often accompanies DOJ issuances
- The purpose of the document is to provide “sample questions that the Fraud Section has frequently found relevant in evaluating a corporate compliance program”
- Applies to all industries – *not just healthcare*
- Underscores that DOJ is actively evaluating compliance program effectiveness during investigations

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DOJ Compliance Guidance Exercise

- Observations:
 - **Approach assumes *investigative posture*:**
 - Includes infrastructural questions
 - Includes questions specific to issue under investigation
 - **Interesting reactions to document**
 - Compliance community
 - Legal community
 - C-Suite

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DOJ Compliance Guidance Exercise

- **Practical Use**
 - Roadmap to approach DOJ will take in the contexts of investigations
 - Provides insight as to what DOJ considers critical
- **Valuable tool**
 - Consider your most recent internal investigation...
 - How would you respond to the following questions from the DOJ *Evaluation of Corporate Compliance Guidance Document*:

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DOJ Questions – How would you respond?

• Root Cause Analysis

- What is the company’s root cause analysis of the misconduct at issue?
- What systematic issues were identified?
- Who in the company was involved in making the analysis?

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DOJ Questions – How would you respond?

• Remediation

- What specific changes has the company made to reduce the risk that the same or similar issues will not occur in the future?
- What specific remediation has addressed the issues identified in the root cause and missed opportunity analysis?

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DOJ Questions – How would you respond?

• Oversight

- What compliance expertise has been available on the board of directors?
- Have the board of directors and/or internal auditors held executive or private sessions with the compliance and control functions?
- What types of information have the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred?

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DOJ Questions – How would you respond?

• Stature

- How has the compliance function compared with other strategic functions in the company in terms of stature, compensation levels, rank/title, reporting line, resources, and access to key decision-makers?
- What has been the turnover rate for compliance and relevant control function personnel?
- What role has compliance played in the company's strategic and operational decisions?

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DOJ Questions – How would you respond?

• Funding and Resources

- How have decisions been made about the allocation of personnel and resources for the compliance and relevant control functions in light of the company's risk profile?
- Have there been times when requests for resources by the compliance and relevant control functions have been denied? If so, how have those decisions been made?

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DOJ Questions – How would you respond?

• Communications about Misconduct

- What has senior management done to let employees know the company's position on the misconduct that occurred?
- What communications have there been generally when an employee is terminated for failure to comply with the company's policies, procedures, and controls (*e.g.*, anonymized descriptions of the type of misconduct that leads to discipline)?

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2. MARCH 2017: OIG ISSUANCE

OIG Resource Guide

- March 2017 HCCA/OIG *Measuring Compliance Program Effectiveness: A Resource Guide*
 - Developed following a roundtable including industry and government representatives in January 2017
 - Designed to help organizations with potential approaches to benchmarking and tracking compliance program development
 - The Resource Guide lists individual program metrics, noting that **“the purpose of this list 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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OIG Resource Guide

- The Resource Guide emphasizes that this list is **not** a “checklist” that should be “applied wholesale to assess a compliance program”
- The Resource Guide is structured to provide tools regarding both “what to measure” and “how to measure”

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OIG Resource Guide

- **What to Measure:**
 - Compliance culture and support and involvement from the board and senior leadership
- **Examples of How to Measure:**
 - Board interviews
 - Qualifications of compliance officer (Certification in Healthcare Compliance, etc.)
 - Ability of compliance officer to:
 - Engage outside legal counsel
 - Initiate a working group
 - Implement a bill hold

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Remarks at HCCA Compliance Institute

Daniel Levinson – HHS, Inspector General, Remarks at HCCA Annual Compliance Institute (March 2017):

“But I talk about Compliance 2.0. I want to focus on the *human factors* that have really developed over the last few years as more and more people have thought about what it means to have a corporation, a company and enterprise really devoted to being able to maximize the resources at its disposal . . . We need to have an idea what the tone at the top is. OIG focuses on that - *what’s the tone at the top* when we’re looking at CIAs and trying to understand what the *internal culture* of the enterprise is. And sure enough, everybody seems to agree with it. So it’s an extremely important part of how we’re thinking about *culture* and that’s the *human component*. . .”

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OIG Resource Guide

- **What to Measure:**
 - Ability to self-evaluate and assess risk
- **Examples of How to Measure:**
 - Examine risk assessment process to determine:
 - Who participates?
 - How are topics prioritized?
 - How are mitigation steps determined?
 - How does the risk assessment aid in the work plan creation process?

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OIG Resource Guide

- **What to Measure:**
 - Self-policing and self-disclosure
- **Examples of How to Measure:**
 - Written guidelines for self-disclosures?
 - Consider conducting “devil’s advocate” mock presentations to probe potential regulator’s view of internal investigative and remediation efforts
 - 60-Day Rule tracking documentations
 - Review of a sample of investigative files

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OIG Resource Guide

- **What to Measure:**
 - Screenings
- **Examples of How to Measure:**
 - How broad are screening searches constructed (e.g., do the search parameters include maiden names and aliases)?
 - Policies and procedures for potential “hits” on screening lists
 - Identification of high risk positions (such as clinicians working with children or mental health patients and individuals handling cash)

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OIG Resource Guide

- **What to Measure:**
 - Third-party relationships
- **Examples of How to Measure:**
 - Auditing vendors and other third parties to ensure evidence of compliance training and orientation to code of conduct and applicable compliance policies and procedures
 - Certifications from vendors and other third parties to ensure such parties have complied with screening expectations
 - Consideration of consequences for vendors who fail to comply with compliance program expectations

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OIG Resource Guide

- **What to Measure:**
 - Individual Accountability
- **Examples of How to Measure:**
 - Evaluation of discipline imposed for misconduct, including compliance officer's input into disciplinary action decisions
 - Distribution of high-level results of disciplinary action to other employees to illustrate consequences of misconduct
 - Disciplinary action against individuals who failed to report issues (not just perpetrators)
 - Whether investigative plan includes communication approach for interviews of current and prior employees

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Key Takeaways

Key Takeaways

- Culture is critical to overall compliance success
- Compliance Program expectations continue to intensify, with increased scrutiny from multiple government agencies
 - DOJ
 - OIG
 - Other government entities
- The government continues to be focused on individual accountability

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Key Takeaways

- While investment in compliance has been important for numerous reasons, it is now also critical for providers to demonstrate in the context of government investigations and inquiries
 - These developments should be vetted by leadership and management and action should be pursued as a result
 - Governing bodies should be well aware of these developments as well

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Key Takeaways

- Consider the breadth of your compliance program
 - DOJ and OIG emphasize the importance of oversight of third-party vendors
- Private equity companies are becoming more interested in a potential target's compliance profile
 - More exacting due diligence strategies
 - Lending may be declined if compliance profile suggests high risk target

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Q&A
