HCCA ATLANTA REGIONAL CONFERENCE

COMPLIANCE 2.0:
RECENT DOJ AND OIG COMPLIANCE
EFFECTIVENESS MEASURES

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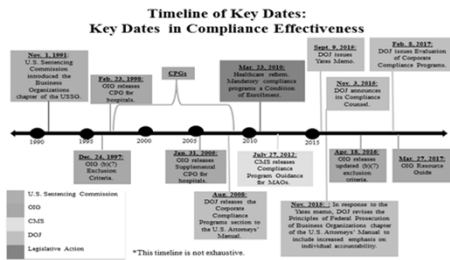Patrick.Braley@btcpa.net

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Goals of Session

- **Discuss Compliance 2.0** and renewed focus on compliance program effectiveness
    - traditional stakeholders
    - new players on the scene
- **Consider** recent DOJ and OIG issuances reflecting current perspectives and enhanced expectations
- **Explore** potential strategies to utilize recent DOJ and OIG effectiveness in your compliance program
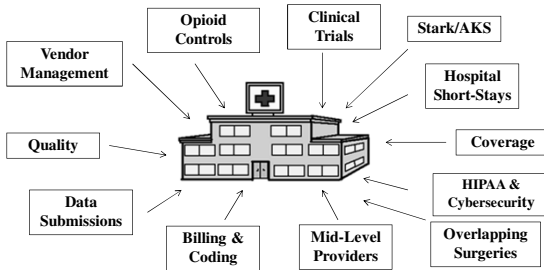
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INDUSTRY REALITIES

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Compliance Program Developments

Timeline of Key Dates:
Key Dates in Compliance Effectiveness

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Enforcement Areas Are Fluid

Vendor Management	Opioid Controls	Clinical Trials
		Stark/AKS
		Hospital Short-Stays
Quality		Coverage
Data Submissions		HIPAA & Cybersecurity
	Billing & Coding	Mid-Level Providers
		Overlapping Surgeries

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Enforcement and Compliance Are Converging

- In **Compliance 2.0**, the enforcement community is widening the compliance lens:
  — Issues under investigation must be put into context
  — Compliance program efforts demonstrate an organization's profile
- DOJ and OIG are issuing guidance documents to:
  — Guide prosecutors, agents and others on key issues to evaluate when assessing compliance program effectives
  — Guide industry on how DOJ will approach the evaluation of compliance program effectiveness

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Compliance 2.0

Compliance 2.0 - What is Old is New Again

Repeating themes in recent DOJ and OIG materials on evaluating effectiveness of Compliance Programs
- Technology – Change with the times
  — Leverage technology to isolate, compare, and monitor risks
  — Identify metrics to monitor issues of concern
  — Establish a dashboard to monitor the metrics
  — Create electronic edits to prevent issues from occurring/recurring
- Culture – Timeless words from Daniel Levinson
  — [Culture drives value and leadership drives culture]
- Compliance should be outcomes driven
  — Output versus outcomes

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What is Culture?

- 85% of CFOs surveyed in a 2015 survey in CFO Magazine said that if culture is not driven by the right values, the organization is "in great danger of making ethical [and legal] mistakes, [and] committing crimes.

  - Trust
  - Coordination
  - Communication
  - Accountability
  - Diversity
  - Collaboration
  - Quality
  - Passion
  - Integrity
  - Vision

Daniel Levinson, Keynote Address, 2017 Compliance Institute

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Compliance 2.0 - Output Versus Outcome

Output	Outcome
— Data	— Behavior Change
— Observations	— Meaningful Results
— Plans	— Quantified Performance
— Activities	— Impact of Activities
— Methods	— Indicator of Effectiveness
— Approaches	— Subjective in some cases (e.g. ROI for Compliance Programs)
— Patterns	
— Tangible	
— *Does not describe risk, value, or impact*	— *Quantification of performance over time*

"Outputs vs Outcomes and Why it Matters", Measurement Resources, Sheri Chaney Jones, Feb. 2, 2014

Measuring Outcomes = Measuring Success

- Describe the desired outcomes
  - Patients are admitted to the appropriate level of care
- Identify the desired quantitative measurement
  - <5% financial error rate on short stay inpatient admissions
- Confirm the desired outcome is reasonable based upon outputs (activities)
  - Data reveals admissions do not meet two-midnight rule; so education is provided, policies are enforced, etc.
- Implement measurements
  - Trend over time
- Demonstrate value
  - Communicate results

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The DOJ's Eleven Evaluation Sample Topics

- Analysis and Remediation of Underlying Conduct
  - Root cause analysis
- Senior and Middle Management
  - Tone at the top and middle
- Autonomy and Resources
  - Independent, well funded, high ranking, and autonomous
- Policies and Procedures
  - Interdisciplinary development and approval, well-communicated to relevant employees and applicable vendors, up-to-date, designed to cover risk areas or communicate expected behavior, enforce accountability, define relevant controls

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The DOJ's Eleven Evaluation Sample Topics

- Risk Assessment
  - Method to identify and prioritize risks, use of technology, benchmarks, flexibility
- Training and Communication
  - Targeted to risks and relevant persons, monitored, availability, clearly communicated with feedback mechanism
- Confidential Reporting and Investigations
  - Thoroughly assessed, objectively and competently investigated, appropriately documented, remediated, and mitigated
- Incentives and Disciplinary Actions
  - Accountability – including managers supervising individuals or functions where misconduct occurred, consistent discipline without regard to organizational rank, appropriate incentives

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The DOJ's Eleven Evaluation Sample Topics

- Continuous Improvement, Periodic Testing, and Review
  - Internal controls, frequency of control assessment, training on controls, involvement of relevant stakeholders, reports to management, third-party assessment
- Third Party Management
  - Evaluate risk vendors pose, assess need for vendor, integrate into compliance program, monitor controls (audit), validate contracts and payments, document actions against vendors
- Mergers and Acquisitions
  - Thorough compliance due diligence, integrate into compliance culture, remediate known or identified compliance issues

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Risk Assessment

- Risk Assessment
  — Process used to identify, assess, and address potential risks
  — Metrics/benchmarks evaluated (financial data, past performance, public data, etc.)
  — Method employed to prioritize risks - use of technology and opinions of subject matter experts
  — Flexibility of program to account for previously unknown, recently identified risks, or a new acquisition/service line

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CHS Compliance Audit
Program Framework

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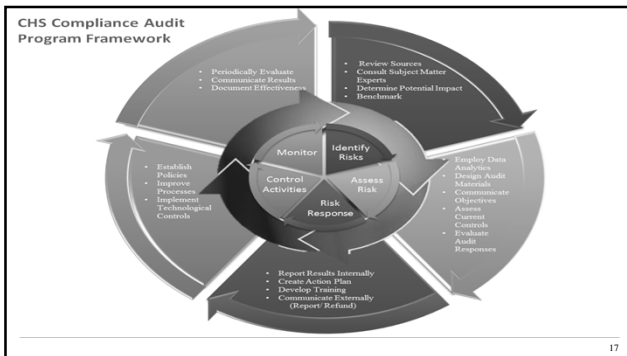
OIG Resource Guide

- 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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OIG's Focus Areas as Seen in CIAs

- Stark Law / Anti-Kickback Statute
  - Physician arrangements
  - Leases
  - Nursing Facilities → Hospitals
  - Medical device sales
  - EMR software sales price incentives
  - Pharmaceutical subsidies for patients

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OIG's Focus Areas as Seen in CIAs (cont.)

- Medical Record Coding & Medical Necessity
    - Health systems
    - Ambulatory billing services
    - Home Health services
    - Hospice services

- Managed Care – Program Reporting
    - Provider Networks
    - Risk Adjustment Data

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Recent CIA Requirement Changes

- Compliance Experts

- Management Certifications

- Claims Review modifications

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Common CIA Comment Letter Inquiries

- Compliance Officer's report and handouts to the Board of Directors
- Background of Compliance Committee and BOD members
- Steps taken to implement compliance program improvement recommendations
- Actions taken to ensure employees receive compliance training
- Copies of disclosure logs, including corrective action plans
- Evidence of claims correction, where applicable

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Demonstrating Effective Compliance

- Tone at the Top
    - Leadership commitment and involvement
    - Visually present and known Compliance Officer
    - Management certifications

- Written Policies and Procedures

- Training Plans and Modules

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Demonstrating Effective Compliance (cont.)

- Compliance and Ethics-Focused Risk Assessment

- Compliance Audit Procedures and Results
    - Monitoring, tracking, evaluating measurable attributes

- Disclosure Logs, Investigative Results, and Resolutions

- Engaged Board of Directors

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Q and A