

Using Published Guidance to Achieve Compliance Program Effectiveness

Judy Ringholz
Founder and Principal
Sage Compliance Advisors, LLC
Fort Lauderdale, FL

Edward (Ted) Case
Partner
Harter, Secrest & Emery, LLP
Rochester, NY

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Objectives

- The Importance of Compliance Effectiveness and the Guidance Used to Measure It
- What It Means to be “Effective”
- When and How to Evaluate Effectiveness
- How to Maximize the Value of a Compliance Effectiveness Review



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LEVEL SETTING

The Evolution of Compliance Programs
From Elements to Effectiveness



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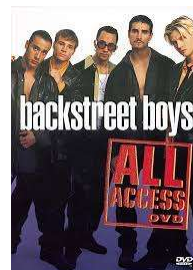
Level Setting: The Origin of Health Care Compliance Programs

- 1998: OIG Issues “Voluntary” Compliance Guidance for Hospitals.
- 1998-2000: OIG adds guidance for Home Health, Lab, 3rd Party-Billing, DME, Hospice, Managed Care, SNF, Physicians.
- Providers dutifully followed the guidance and developed programs in response. Many went no further.
- Popular View: Having a program in place that addressed the 7 elements (on paper or otherwise) was considered “compliant”.
- Is that still true? Is it still OK?



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Reminder: This Was Also Popular in 1998



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Was it Ever True?

- True or False: The OIG's initial focus was on the 7 Elements. Effectiveness became important later.
- False: Effectiveness has always been the core OIG objective:

The OIG . . . Will consider the existence of an **effective** compliance program that pre-dated any Government investigation when addressing the appropriateness of administrative penalties

- Mentions "effective compliance program" 13 times!

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The Increasing Importance of Compliance Effectiveness Assessments



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United States Federal Sentencing Guidelines

- Provides for sentence reduction “ if the organization had in place an **effective** compliance and ethics program.”
- Directs decisionmakers to consider whether the organization took reasonable steps to “**evaluate periodically**, the **effectiveness** of the organization’s compliance and ethics program”
(FSG §§ 8B2.1.)



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DOJ Justice Manual

- Directs prosecutors to consider the following when deciding whether to bring charges or negotiate plea agreements:
 - Adequacy and **effectiveness** of corporation's compliance program at time of offense and time of charging
 - Corporation's remedial efforts to implement an adequate and **effective** corporate compliance program or to improve an existing one.

(JM 9-28.300)



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Compliance Assessment Resources



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OIG: Supplemental Compliance Guidance for Hospitals (2005)

- Discusses effectiveness in the context of each of the seven compliance program elements.
- Introduces the concept of regular review of health care compliance program effectiveness
- Includes questions organizations can explore in assessing if the program is effective
- Emphasizes the need to look at both outcomes (indicators) and structure (design)

Available at: <https://oig.hhs.gov/compliance/compliance-guidance/>



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DOJ Criminal Division: Evaluation of Corporate Compliance Programs

- First issued February 2017, last revised March 2023
- Purpose: To help US Attorneys make “informed decisions as to whether and to what extent, the corporation’s compliance program was effective. . . .”
- Applies to all industries – not just healthcare

Available at <https://www.justice.gov/criminal-fraud/page/file/937501/download>



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DOJ Criminal Division
Evaluation of Corporate Compliance Programs

- Q. 1: Is the program well designed?
 - Risk Assessment
 - Policies and Procedures
 - Training and Communication
 - Reporting and Investigation
 - Third Party Oversight

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DOJ Criminal Division
Evaluation of Corporate Compliance Programs

- Q. 2 Is the program being applied earnestly and in good faith? Is it resourced and empowered?
 - Commitment by Senior Management and Middle Management
 - Compliance Program Autonomy
 - Compliance Program Resources
 - Compensation Structure, Consequence Management

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DOJ Criminal Division Evaluation of Corporate Compliance Programs

- Q. 3 Does the program work?
 - Continuous Improvement, Periodic Testing and Review
 - Investigation of Misconduct and Response
 - Analysis of Underlying Misconduct

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Other Resources

- HCCA-OIG Measuring Compliance Program Effectiveness: A Resource Guide
 - Developed through HCCA-OIG Roundtable with industry participation
 - Organized around the seven elements
 - Provides granular detail on how organizations can evaluate compliance program effectiveness (401 ideas! 😊😓)
 - Not intended to be used as a checklist to review a compliance program

Available at:

<https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf>

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Other Resources

- Corporate Integrity Agreements – particularly your segment of the health care industry
- OIG Compliance Guidance documents – particularly the risk assessment sections
- Special OIG Fraud Alerts
 - 2022 Telemedicine
 - 2020 Speakers Bureau

All available at: <https://oig.hhs.gov/compliance/>

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What It Means To Be Effective

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Q.1. Effective at What? -- System Issues



■ An Effective Compliance Program Uses a Multi-Level Approach Including

- Training and Education, Policies and Procedures and Internal Controls to **Prevent** Problems
- Auditing, Monitoring and Open Communications to **Detect** Problems and
- Investigations, Self Disclosures and Disciplinary Measures to **Resolve** Them

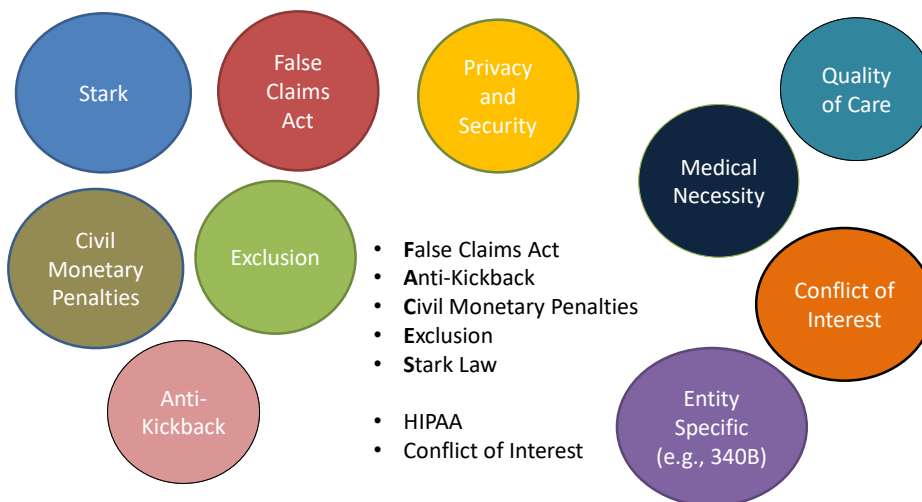
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Q.2. Effective at What? -- Scope Issues



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Advice for Dealing With Scope Issues

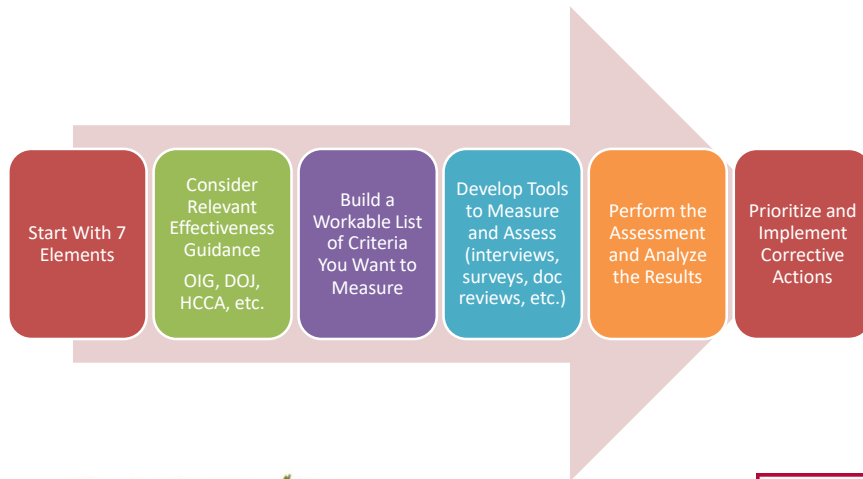
- *DO* make sure your plan clearly defines what is in scope for your compliance program and office.
- *DO* speak up immediately if you don't have the resources or skill set to address in-scope items.
- *DO* initiate the conversation about how compliance with new regulatory requirements will be achieved (e.g., No Surprises Act).

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Effectiveness Assessment Process



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Effectiveness Considerations -- Training

- Timely Completion Rates (dashboard)
- Comprehension of Training (testing)
- Appropriateness of Training
 - Job Specific vs. General
 - Staff vs. Board Training
 - Tailored and Revised for Organizational Risks
- Feedback Regarding Training (surveys)

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Effectiveness Considerations – Communication and Investigation

- Hot line use & awareness (benchmarks and surveys)
- Rate of internal vs. external reporting (anecdotal)
- Comfort with reporting issues (surveys)
- Issues investigated, resolved and documented (log)
- Corrective actions (root cause, follow up, sanctions)
- Retaliation is strictly prohibited/promptly and sternly addressed

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Effectiveness Considerations Auditing and Monitoring

- Thoughtful, rigorous regular risk assessments?
- Effective preventative monitoring programs?
- Adequate and appropriate auditing resources?
- Audits prioritize most significant risks (not stale)?
- Prompt and responsive corrective actions?
- Periodic follow up?

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Effectiveness Considerations – Compliance Officer, Committee and Program

- CCO Reporting Structure (Board, CEO)
- CCO Autonomy and Authority
 - Executive Session
 - Authority to Hire Counsel
 - Rank/Title, Access, Resources (vs. other leaders)
- Compliance Resources and Funding
- Compliance Committee Composition and Engagement

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Effectiveness Considerations – Leadership and Culture

- Has Board and Senior Leadership “clearly articulated the company’s ethical standards, conveyed and disseminated them in clear and unambiguous terms?”
 - Demonstrated leadership in compliance
 - Set expectations for middle management
 - Impeded or supported compliance function
- Does the Board have access to compliance expertise?
- Is compliance an element of performance reviews?
- Does compensation structure incentivize compliance and disincentivize non-compliance (impact on bonus)?

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Compliance Effectiveness Reviews

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When to Consider An External Evaluation

- New Compliance or Organizational Leadership
- Changes in Structure (merger, reorganization, etc.)
- New Healthcare Services (DME, 340B, etc.)
- Increase in Internal or External Compliance Issues
- Periodically, as Part of Commitment to Continuous Improvement

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Benefits of External Evaluation, and Limits

- Objective and independent
- Promotes stakeholder candor re: compliance program and leadership, organizational culture
- Affords opportunity for benchmarking vs industry and government guidance, best practices and similar organizations
- Focused on program structure; NOT an evaluation of whether the organization is "in compliance"

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Designing an Effective External Review

- Design inputs: Board, Sr. Leadership, CCO, etc.
 - What do we *really* want to learn and from who?
- Methodology:
 - Interviews and surveys
 - Document reviews (policies, training, logs, audits reports. . .)
 - Benchmarking, etc.
- Structure of Report (Begin with the End in Mind)
- Confidentiality, Non-Retaliation and Non-Intimidation
- Deliverables (Draft vs. Final Report)
- The Role of Attorney Client Privilege

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Overcoming Reluctance and Resistance

- Almost all organizations annually hire external CPA's to audit their financial statements and assess their financial controls
- For many organizations, the risks associated with an ineffective compliance program under the Stark or Anti-Kickback laws or the Civil False Claims Act are as great, if not greater, than those addressed annually by a financial audit

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Maximizing the Value of a Compliance Effectiveness Review

Follow Up Strategies

- Stakeholder communication (Board, Sr. Leadership, CCO, Compliance Committee)
- Prioritize recommendations, develop goals and timelines
- Monitor progress against goals
- Modify plan as necessary
- Report regularly to Board, Leadership, Compliance Committee. Consider dashboard level reporting

Maximizing Value

- Scope of Program Findings (e.g., Research)
- Compliance Workforce Findings (FTEs, Skills)
- Data and Tracking Tool Recommendations
- Compliance Culture Findings
(Reporting and Retaliation)

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Questions?

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