

COMPLIANCE 2.0

**2019 HCCA COMPLIANCE INSTITUTE
APRIL 7, 2019**

1

Presenters

2

Andi Bosshart, RHIA, CHC
**Senior Vice President, Corporate
Compliance and Privacy Officer**
CHSPSC, LLC
Andi_Bosshart@CHS.net

Felicia E. Heimer
Senior Counsel
Office of Inspector General
U.S. Dept. of Health and Human Services
Felicia.Heimer@oig.hhs.gov

Tizgel High
**Vice President, Associate General
Counsel**
LifePoint Health
Tizgel.High@LPNT.net

Goals of Session

3

- **Review** recent developments demonstrating the regulators are focused on Effectiveness in Compliance Programs
- **Highlight** significant escalation in government's expectations for compliance program infrastructure, operations, risk mitigation efforts, and potential consequences of falling short
- **Explore** various strategies to evaluate critical compliance infrastructure and related processes to determine sufficiency and effectiveness

Compliance 2.0 - Changing Compliance Landscape

4

- **Recent enforcement and other developments have impacted the healthcare industry, 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**

Changing Compliance Landscape

5

- ❑ Increased FCA penalties
- ❑ Aggressive Relator Strategies
- ❑ Focus on Individual Accountability
- ❑ Enhanced OIG and DOJ compliance program expectations as evidenced by:
 - Recent CIAs
 - DOJ's *Evaluation of Corporate Compliance Programs Guidance Document*
 - OIG/HCCA *Measuring Compliance Program Effectiveness Document*

Intersection of Regulatory Enforcement and Compliance Program Effectiveness

6

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

Thomas Beimers (Former Senior Counsel with HHS OIG)

FCA Penalties - The Stakes Are High

7

Increased False Claims Act (FCA) financial penalties for non-compliance

Defense Contractor 12 claims / year		Healthcare Provider 2,000 claims / year	
Triple Damages	\$300,000	Triple Damages	\$300,000
Penalty (21,916 x 12)	\$262,992	Penalty (21,916 x 2,000)	\$43,832,000
Total Recovery	\$562,992	Total Recovery	\$44,132,000

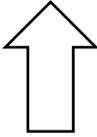
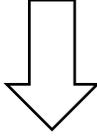
OIG Permissive Exclusion Authority

8

- 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).
- OIG is publishing its fraud risk indicator on its website.



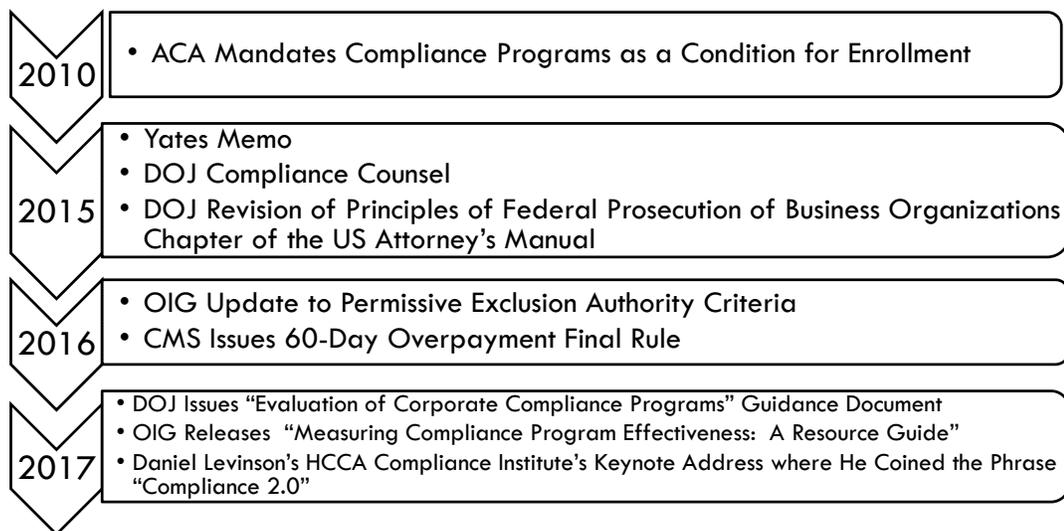
OIG Assessment of Permissive Exclusion

Compliance Program	Impact on Risk Assessment
<p>A compliance program that incorporates the seven elements of an effective compliance program</p> 	<p>Risk assessment not affected</p> 
<p>Absence of a compliance program that incorporates the seven elements of an effective compliance program</p> 	<p>Indicates higher risk</p> 
<p>Entity devoted significantly more resources to the compliance function</p>   	<p>Indicates lower risk</p> 

9

Other Compliance Program Developments

10



11

Compliance 2.0 – Enhancing Compliance Initiatives and Assessing Risk

IG’s Remarks at HCCA Compliance Institute

12

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 . . .”

Qualities of an Effective Compliance Officer

13

- Integrity and a sense of fairness**
- Strength of character and authority**
- Attention for detail while maintaining the ability to see the big picture – “seeing the forest through the trees”**
- Calm demeanor – no hysteria when problems are identified**
- Communication style that may be adaptable to different audiences**
- Engaged in continuous learning**

Emerging CIA Trends Indicate a Focus on Effectiveness and Accountability

14

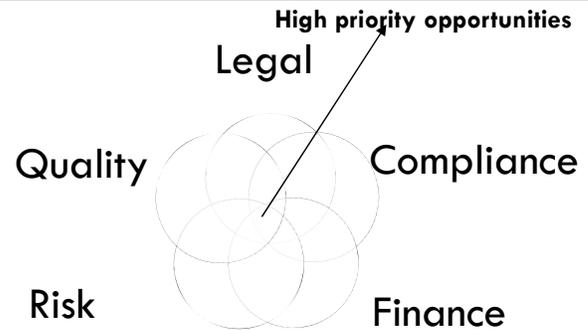
- Use of Independent Monitors**
- Compliance Experts**
- Management Certifications and Increased Stipulated Penalties for False Certifications**
- Heightened IRO Qualifications**
- Risk Assessment and Mitigation**

Risk Assessment in Healthcare

15

□ All of the organization's managers generally have areas where they intersect

- Legal
- Compliance
- Finance
- Risk Management
- Quality



* A collaborative approach to prioritizing organizational risk can help focus the organization's resources in the areas of highest risk. In addition, a collaborative approach will help to drive desired behaviors to avoid compliance issues.

Risk Assessment

16

□ Focus on priority areas where multiple areas of risk intersect.

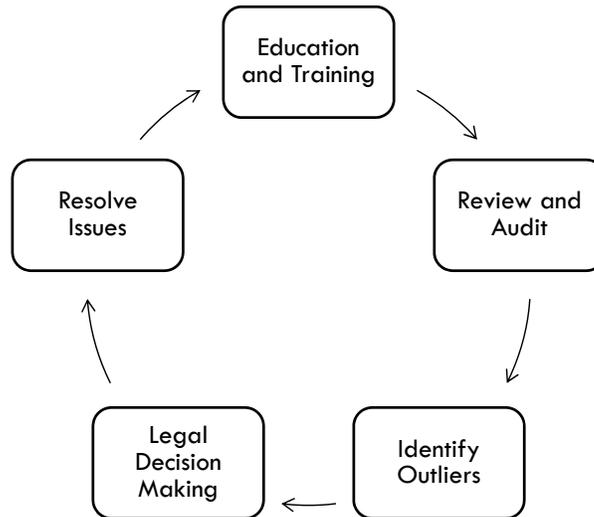
□ Break down of opioid prescribing

- New regulations and guidance pose compliance risk- How do ensure the right people are aware in your organization?
- Standards of care and patient safety are drivers for the new rules and guidance- How to ensure patients have access to high quality care from providers that are up to date on emerging guidance and rules?
- Non-compliance with the new rules/guidance may lead to patient harm and subject your organization to legal risk of enforcement- How do you reduce the risk of harms and financial repayments/penalties?

□ Looking at the spaces of overlap will often lead you to the greatest opportunities for a collaborative and focused effort to develop a compliance plan that can identify and mitigate your highest risk areas.

Legal and Compliance

17



Teamwork

18

- ❑ **Legal and compliance are just two parts of the greater team that is the enterprise. Like any good team:**
 - ❑ **Everyone should play by the same rules and playbook.**
 - ❑ **Each team member should be striving for the same goals. Success has to have the same meaning for each.**
 - ❑ **A supportive environment of respect and collaboration where everyone knows their role and those role are value add to the entire team and to the teammates.**
- ❑ **Establish roles → Continual communication → Everyone moving towards the goal**

Compliance Risk Assessment

19

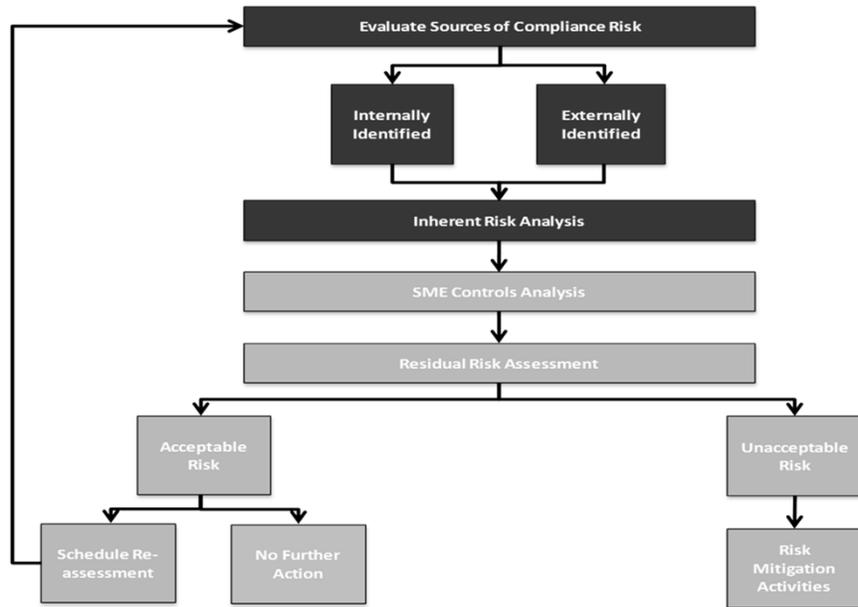
- **A compliance risk assessment (“CRA”) is a process used to identify, assess, and prioritize potential risks**
- **CRA evaluates multiple outputs such as:**
 - **Financial data (to identify potential impact of the topic);**
 - **Past performance (to establish a baseline of known information about the topic); and**
 - **Public data (to ascertain benchmarks)**
 - **Opinions of subject matter experts**
 - **Analysis of existing controls**
 - **Determination of risk tolerance**
- **The CRA includes documentation of the standard operating procedures**

Risk Assessment Definitions

20

- **Compliance Risk – The potential threat posed to the company’s financial, organizational, or reputational standing resulting from a violation of law, regulation, or organization/industry standards of practice**
- **Inherent Risk – Risk posed before internal controls are considered. Inherent risk includes the potential impact of and likelihood of compliance risk**
- **Residual Risk – Remaining compliance risk potential after internal controls such as policies, training, and auditing and monitoring are implemented**

Risk Assessment Process Flow



21

Rating Inherent Risk

Compliance Risk Assessment -Inherent Risk Scoring Guidelines	
Reputation Risk Factor	
HIGH = National Negative Impact - National Media	
MEDIUM = Regional Negative Impact - Regional Media/Specialized	
LOW = Localized Negative Impact - Site Specific Media	
Financial Risk Factor (Revenue Dollars at Risk)	
HIGH = > % 1 Million Dollars	
MEDIUM = < %1 Million and > \$50, 000	
LOW = < \$50,000	
Legal/Regulatory (Civil and Criminal Fines or Penalties and Sanctions)	
HIGH = Federal or State Actions / Investigations	
MEDIUM = Routine Investigation	
LOW = No regulatory or legal actions	
FREQUENCY / LIKELIHOOD	
HIGH = > 1,000 patients / month OR occurs monthly (almost certain)	
MEDIUM = < 1,000 and >500 patients / month or occurs twice annually (Likely)	
LOW = < 500 patients/ month or occurs annually or less frequently (Possible)	
SME	
Please enter the name of the SME as resource / contact for risk item and the designee for completing the Risk Item Control Analysis if applicable.	

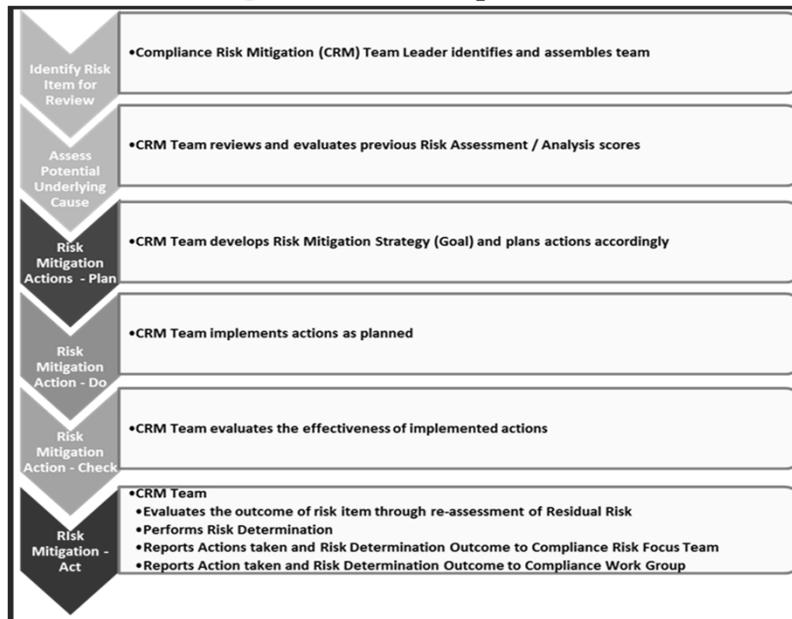
22

CRA – Operational Process



23

Risk Mitigation Operational Flow



24

25

Demonstrating Effectiveness

Output versus Outcomes

26

Output

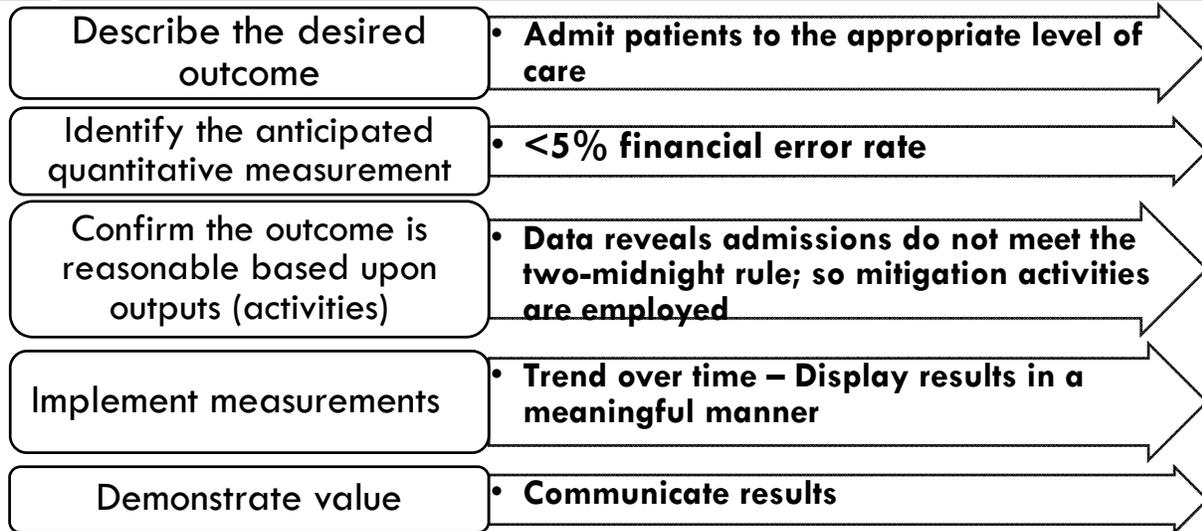
- ❑ Data
- ❑ Plans
- ❑ Activities
- ❑ Methods
- ❑ Approaches
- ❑ Patterns
- ❑ Tangible
- ❑ *Does not describe risk, value, or impact*

Outcomes

- ❑ Behavior Change
- ❑ Meaningful Results
- ❑ Quantified Performance
- ❑ Impact of Activities
- ❑ Indicator of Effectiveness
- ❑ Subjective in some cases (e.g. ROI for Compliance Programs)
- ❑ *Quantification of performance over time*

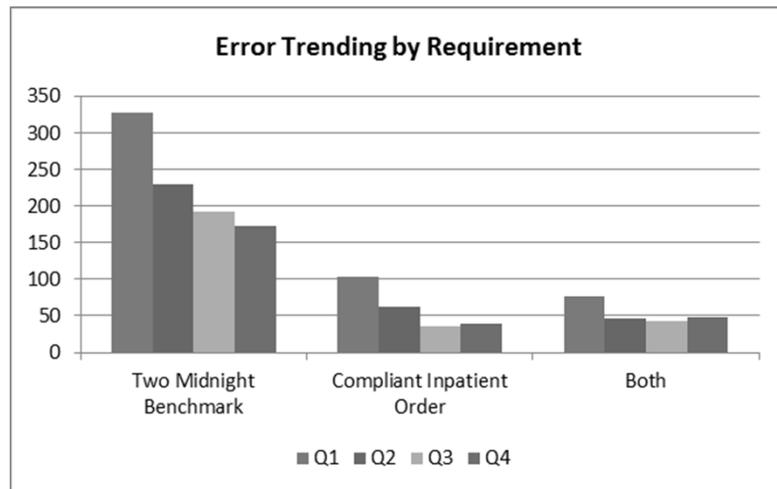
Measuring Outcomes = Measuring Effectiveness

27



Example of an Outcome Graph

28



Focus on Self-Disclosures

29

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

“The self-disclosure protocol 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.”

Resources for Evaluating Compliance Program Effectiveness

30

DOJ’s Evaluation of Corporate Compliance Program

- Issued in February 2017 to provide “sample questions that the Fraud Section has frequently found relevant in evaluating a Corporate Compliance Program”
- Underscores that DOJ is actively evaluating Compliance Program effectiveness during investigations
- Outlines 11 “sample topics and questions”
- Includes questions pertaining to infrastructure of the Compliance Program and other questions issued during an investigation
- Roadmap to the approach DOJ will take in the contexts of its investigations and insight into what DOJ considers critical

OIG/HCCA’s Measuring Compliance Program Effectiveness: A Resource Guide

- Developed following a roundtable including industry and government representatives in January 2017, and published in March 2017 by HCCA and OIG
- Designed to help organizations with potential approaches to move beyond basic compliance program development
- Provides benchmarking and tracking of specific compliance program elements to determine the extent to which they are sufficiently developed and effective
- The Resource Guide emphasizes this publication is not a “checklist” that should be “applied wholesale to assess a compliance program”
- The Guide is structured to provide tools regarding both “what to measure” and “how to measure”

“Best-Practice” Compliance Program

31

- **Model your program after recently executed CIAs**
- **Evaluate composition of compliance committee(s)**
 - **Ensure that committee members understand their role**
- **Allow “sufficient” time for compliance training**
 - **Consider a series of short sessions vs lengthy session**
 - **Track all compliance training that is conducted in-house**
- **Volume of reports of potential compliance issues should correlate to the size of the organization**
 - **Hotline reports might decrease as direct reports increase**

“Best-Practice” Compliance Program

32

- **Monitor results of sanction screening if performed by a third-party vendor**
 - **Understand vendor’s acknowledgement of responsibility**
 - **Memorialize the agreement/indemnification in writing**
- **Effectively manage conflict of interest disclosures**
- **Regular signed attestations by senior leaders**

OIG's Review of CIA Compliance: Common Monitoring and Site Visit Inquiries

33

- **Assess “placement” of compliance within the organizational structure**
- **Validate Compliance Officer’s standing and authority within organization**
- **Evaluate communication between Compliance Officer and Board**
- **Evaluate resources dedicated to compliance program**
- **Compliance Committee Meeting Minutes**
- **Review disclosure log and underlying investigations/reports**
- **History of development/implementation of corrective action plans**

34

Questions