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**Session Goals**

Enable Compliance Professionals to do the following:

- Foster compliance activities by
  - Enabling operators to understand, recognize, and respond to risks of noncompliance.
  - Equipping operators with the knowledge and tools necessary to mitigate and prevent risk of noncompliance.
- Create three-part toolkits
  - Explanation of legal or regulatory requirement or concern;
  - Template for identifying and reporting compliance activity; and
  - Template for addressing compliance matter in a uniform fashion across the organization.
- Create mechanisms for tracking, trending, and reporting results of toolkit implementation
  - To involved operators to aid corrective action; and
  - To leaders / committees to empower effective oversight of compliance activities and results.

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**Hypothetical Handouts**

Three different hypothetical fact patterns, or "hypos":

1. Physician Arrangement
2. Provider-based status
3. Implantable Cardiac Defibrillator / National Coverage Determination compliance.

Each hypo contains a concern or allegation of error or misconduct.

**You are invited to consider your hypo as we discuss the next section--  
*Compliance Programs – Pieces of the Puzzle.***

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### Compliance Programs – Pieces of the Puzzle

#### U.S. Sentencing Guidelines (1991, revised 2004 and 2010)

- Controls criminal sentencing of organizations
- Sentence allows credit for “effective programs to prevent and detect violations of law”
- Risk assessments (ongoing) if credit expected
- Compliance “culture”
- Compliance standards and procedures
- Compliance obligations
- Sufficient resources
- Employee screening practices



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### Compliance Programs - Pieces of the Puzzle

#### • U.S. Sentencing Guidelines (1991, revised 2004 and 2010)

- Must have process for anonymous reporting
- “Specifically encourage prevention and deterrence of violations of the law as part of compliance programs”
- Education and Training

#### • 2010 Revisions:

- Appropriate response to the criminal conduct, including restitution to the victims, self-reporting, and cooperation with the authorities
- Organization must assess their program and make changes to make more effective.
- Encourages an independent monitor to ensure implementation of the changes.

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### Compliance Programs - Pieces of the Puzzle

#### Compliance Program Guidance Hospitals, – February 23, 1998

• SUMMARY: This Federal Register notice sets forth the recently issued compliance program guidance for hospitals developed by the Office of Inspector General (OIG) in cooperation with, and with input from, several provider groups and industry representatives. **Many providers and provider organizations have expressed an interest in better protecting their operations from fraud and abuse through the adoption of voluntary compliance programs.** The first compliance guidance, addressing clinical laboratories, was prepared by the OIG and published in the Federal Register on March 3, 1997. **We believe the development of this second program guidance, for hospitals, will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the health care industry.**

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### Compliance Programs - Pieces of the Puzzle

- Compliance Program Guidance Hospitals, 1998 - Compliance Program Elements**
- (1) The development and distribution of **written standards of conduct, as well as written policies and procedures** (adherence to included in evaluation of managers and employees)
  - (2) The designation of a **chief compliance officer and other appropriate bodies**, e.g., a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;
  - (3) The development and implementation of regular, **effective education and training programs for all affected employees**;
  - (4) The maintenance of a process, such as a **hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation**;

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### Compliance Programs - Pieces of the Puzzle

- Compliance Program Guidance, Hospitals 1998 - Compliance Program Elements**
- (5) The development of a **system to respond to allegations** of improper/illegal activities and the **enforcement of appropriate disciplinary action** against employees who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;
  - (6) The use of **audits and/or other evaluation techniques to monitor compliance** and assist in the reduction of identified problem area; and
  - (7) The **investigation and remediation of identified systemic problems** and the development of policies addressing the non-employment or retention of sanctioned individuals.

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### Compliance Programs - Pieces of the Puzzle

- Supplemental Compliance Program Guidance, Hospitals 2005 - Compliance Program Elements**
- January 31, 2005 - The supplemental CPG provides voluntary guidelines to assist hospitals and hospital systems in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts.
  - **This CPG adds Risk Assessment and evaluating effectiveness**
  - **Discusses multiple fraud and abuse risk areas**
  - **Discusses Hospital Compliance Program Effectiveness**

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### U.S. Department of Justice – Pieces of the Puzzle

**DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017**

- In the context of a criminal investigation, a corporate compliance program is evaluated applying the “Filip Factors” – the existence and effectiveness of the pre-existing compliance program and the remedial efforts to implement an effective compliance program or to improve an existing one.
- Identified several topics and questions for use in evaluation of a corporate compliance program.
- **Topics and questions have much correlation with OIG’s Supplemental Hospital Compliance Program Guidance 2005**

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### U.S. Department of Justice – Pieces of the Puzzle

**DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017**

• **Evaluation Sample Topics and Questions:**

1. Analysis and Remediation of Underlying Conduct
  - Root Cause Analysis—systemic issues identified? Who did RCA?
  - Prior Indications—prior (missed?) opportunities to detect? Why?
  - Remediation—specific changes to reduce risk of recurrence of issue or of missed detection?
2. Senior and Middle Management
  - Conduct at the Top—monitored? Senior leader encourage or discourage misconduct? Concrete actions?
  - Shared Commitment—Senior leaders demonstrate commitment to compliance, remediation efforts, sharing information?
  - Oversight—What compliance expertise and information is available to the Board? Executive sessions with Compliance?

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### U.S. Department of Justice – Pieces of the Puzzle

**DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued**

• **Evaluation Sample Topics and Questions, continued:**

3. Autonomy and Resources
  - Compliance Role—Compliance involved in training and decisions relevant to misconduct?
  - Stature—Does Compliance function experience “stature, compensation levels, rank/title, reporting line, resources, and access to key decision-makers?” Turnover rate? Compliance role in “strategic and operational decisions?”
  - Experience and Qualifications—Have Compliance personnel had the appropriate experience and qualifications?
  - Autonomy—Direct reporting lines and meetings with Board? Is senior management present during meetings? Who hires, fires, reviews, gives raises or bonuses to Compliance Officer? Has company ensured independence?
  - Empowerment—Response to Compliance concerns? Transactions or deals stopped, modified, or examined?
  - Funding and Resources—how are allocations decided? Rationale? Who outsources? How overseen?
  - Outsourced Compliance Functions—Rationale? Who decided, managed, oversees, assesses effectiveness? Access level granted to external company?

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### U.S. Department of Justice – Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 4. Policies and Procedures
  - Design and Accountability—Policies and Procedure design, implementation. Socialization?
  - Applicable Policies and Procedures—P&Ps prohibit the misconduct? Effective implementation assessed? Owners of policies held accountable for supervisory oversight?
  - Gatekeepers—Guidance or training for key gatekeepers of controls that are relevant to misconduct? Mechanism for gatekeeper communication of concerns?
  - Accessibility—P&Ps communicated to relevant employees and 3Ps? Evaluated usefulness of each P&P?
- 5. Risk Assessment
  - Risk Management Process—Method for identifying, analyzing, addressing risks faced?
  - Information Gathering and Analysis—Information, metrics used to help detect misconduct? How have the information and metrics informed the Compliance program?
  - Manifested Risk—How does the risk assessment account for the manifested risks?

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### U.S. Department of Justice – Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 6. Training and Communications
  - Risk-Based Training—Tailored training relevant to employees function? Training where misconduct has occurred? How determine who is trained on what topic?
  - Form/Content/Effectiveness of Training—Offered in form and language effective with intended audience? Effectiveness measured?
  - Communications about Misconduct—Senior management message on misconduct? Communication of terms for failure to comply (“e.g., anonymized descriptions” of the conduct that yielded discipline)?
  - Availability of Guidance—Resources available to employees on compliance policies? Assess employee knowledge of when to seek advice? Willingness to seek advice?
- 7. Confidential Reporting and Investigation
  - Effectiveness of the Reporting Mechanism—Collect, analyze, use information from reporting mechanisms? Compliance full access?
  - Properly Scoped Investigation by Qualified Personnel—Ensure proper scope, independence objectivity, documentation, and conduct?
  - Response to Investigations—Identify root causes? System vulnerabilities? Accountability lapses? Process for responding to findings? How high into company hierarchy do investigation, accountability, and response go?

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### U.S. Department of Justice - Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 8. Incentives and Disciplinary Measures
  - Accountability—What disciplinary actions were taken? Managers held accountable? Discipline for oversight failure? Ever terminate, warn, reduce bonuses?
  - Human Resources Process—Who makes disciplinary decisions on which types of misconduct?
  - Consistent Application—Are disciplinary actions and incentives fairly and consistently applied across the organization?
  - Incentive System—Is compliant and ethical behavior incentivized? Has company considered potential negative compliance implications of what is rewarded? Have compliance or ethics considerations resulted in denial of promotions or awards?
- 9. Continuous Improvement, Periodic Testing and Review
  - Internal Audit—Risks assessed, findings, remediation reported, followed by Board, management?
  - Control Testing—Program review with testing, tracking of controls, data collection and analysis?
  - Evolving Updates—Updates to Risk Assessments? Review P&Ps?

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### U.S. Department of Justice – Pieces of the Puzzle

DOJ, Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs, issued February 8, 2017, continued

• Evaluation Sample Topics and Questions, continued:

- 10. Third Party Management
  - Risk-Based and Integrated Processes—Assess enterprise risk? Procurement and vendor processes?
  - Appropriate Controls—Contract implementation, payment, work performed FMV and monitored?
  - Management of Relationships—Incentive models for 3Ps, training for relationship managers?
  - Real Actions and Consequences—Red flags from due diligence? Monitoring? Suspensions, terms?
- 11. Mergers & Acquisitions
  - Due Diligence Process—Who conducts risk review, due diligence? How? Misconduct identified?
  - Integration in the M&A Process—Is Compliance integrated into merger, acquisition, integration?
  - Process Connecting Due Diligence to Implementation—Process for tracking, remediating (risk of) misconducts identified during due diligence? How are company P&Ps implemented at acquisition?

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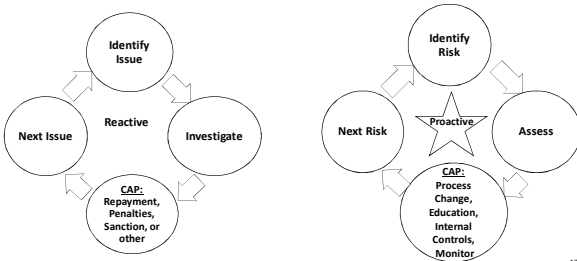
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### Hospital Compliance Program Effectiveness - Operationalize It / Complete the Puzzle

Goal: A Proactive Effective Compliance Program



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### Hospital Compliance Program Effectiveness – Operationalize It / Put The Pieces Together

A common method of assessing compliance program effectiveness is measurement of various outcomes indicators:

- Billing and coding error rates
- identified overpayments
- audit results

However, the OIG recommends *examination of program outcomes and assessment of the underlying structure and process* of each compliance program element. To accomplish:

- Begin with a baseline assessment using the OIG’s CPG Topics / Questions.
- Budget Time—
  - Time intensive;
  - May require a resource to remediate / identify corrective action and follow up.

Or this baseline assessment could be outsourced!

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**Example: Program Effectiveness Baseline Assessment Tool**

COMPLIANCE PROGRAM EFFECTIVENESS ASSESSMENT

In the Supplemental Compliance Program Guidance for Hospitals, the OIG identified a number of factors that may be useful when evaluating the effectiveness of a hospital's Compliance Program. The OIG instructed that hospitals consider these factors, as well as others, when assessing their compliance programs

6. Response to Detected Deficiencies

No.	Factor	Yes/ No	Description/Comments	Responsible Person
1	Has the hospital created a response team, consisting of representatives from the compliance, audit, and other relevant functional areas, which may be able to evaluate/investigate any detected deficiencies quickly?	Y	Individuals identified to assist in remediation efforts. SMEs also attend compliance committee per charter.	
2	Are all matters thoroughly and promptly investigated?	Y	Investigations policy XXX with tools implemented.	
3	Are corrective action plans developed that take into account the root causes of each potential violation?	Y	Consistent process implemented with tools.	
4	Are periodic reviews of problem areas conducted to verify that the corrective action that was implemented successfully eliminated existing deficiencies?	Y	Responsible individuals identified as part of CAP. Ongoing monitoring required in certain areas.	
5	When a detected deficiency results in an identified overpayment to the hospital, are overpayments promptly reported and repaid to the MAC?	Y	60-day policy implemented. Analysis of data, consistent process followed.	
6	If a matter results in a probable violation of law, does the hospital promptly disclose the matter to the appropriate law enforcement agency?	Y	Reportable Events policy, XXX implemented and staff trained on the policy.	

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**Toolkits for Operational Compliance**

**Process: Issue Identified > Investigation > Document > Discuss/Report > RCA > Remediate > CAP > Monitor > Periodic Reassessment**

- Create an investigative plan – who, when, where
- Pull resource materials – regulations, manuals, etc.
- Pertinent questions/intake analysis (What, Where, When, Who, How?)
- Get the facts – interview(s), group discussion(s)
- Supplemental facts – obtain data – review and analyze (billing, coding, referrals, etc.)
- Repeat fact gathering as necessary
- Risk Rating
- Root Cause Analysis – The 5 Whys
- Stop the leak (quick fix)
- Corrective Action Planning
- Monitor - defined parameters

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**Investigation Tools**

- Intake and Analysis
- Risk Rating
- Root Cause Analysis for Compliance Issues



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### Investigation Tools – Intake and Analysis

Intake Analysis and Investigation Tool  
Ethics and Compliance Concerns

Facility/Ethics: \_\_\_\_\_  
 FCO/ CPO Name: \_\_\_\_\_  
 Department(s) Involved in Concern: \_\_\_\_\_  
 Leader/Manager(s) of Impacted Area(s) and/or Department(s): \_\_\_\_\_  
 Date Case Was Initiated (reporter, direct phone call to CPD/FCO, email, etc.): \_\_\_\_\_  
 Risk / Severity Rating (utilize the Risk Rating Matrix): \_\_\_\_\_

**KEY INFORMATION FOR INTAKE, ASSESSMENT AND INVESTIGATION**

Summary of Concern: \_\_\_\_\_  
 Potential Interviewees: \_\_\_\_\_

**ANALYSIS AND INVESTIGATION QUESTIONS:**

1. What are processes normally happen that were interrupted or not followed and what normally happens?
2. What environmental and equipment factors contributed to the compliance failure? (i.e., equipment failure, lack of tools or resources)
3. What human factors contributed? (i.e., staffing issues, knowledge or skill deficit, communication failure, behavior)
4. What key activities and areas are impacted or involved? (Revenue/critical documentation, COP, practice reporting, etc.) Were they interrupted or not functioning or being used?
5. Is this a repetitive issue and were any trends identified? (i.e., same time of day, same area, certain staff present or not present, same equipment used, etc.)
6. What regulatory factors contributed? (New or revised standard, regulation, or requirement)
7. Include relevant policies, procedures, regulations, guidance documents, and applicable professional standards that apply and if any need to be reviewed and considered.

**RESPONSE/RESOLUTION:**

Initial mitigation efforts (Training, Reprimand, Monitoring, Policy Change, Process Change, etc.) \_\_\_\_\_

What follow up opportunities for improvement are identified and Corrective Action Initiated or taken; (attach CAP if necessary): \_\_\_\_\_

Brief Summary of Investigation Interview (attach notes if necessary): \_\_\_\_\_

\*Use this document to guide the investigation of reported or discovered Compliance concerns. May be uploaded to the case in InterLink or filed with additional investigation notes. This document is a tool that will assist in completing the InterLink Investigation and Resolution files.

### Investigation Tools – Risk Rating

Risk Rating Matrix: Patient Health Ethics and Compliance Settings

Category / Category of Risk / Potential compliance issue	1 - Low	2 - Medium	3 - High	4 - Critical/Outright
Provision of Authority	Allegation involves an individual without supervisory authority.	Allegation involves an individual with supervisory authority.	Allegation involves an individual with senior management, executive management, officer, or board-level authority.	Allegation involves executive management, board-level executives, and involving the highest level of authority.
Financial Risk	Would not exceed the entity's significant financial risk.	May exceed the entity's significant financial risk.	Significant financial risk likely.	Significant financial risk likely.
Operational Risk	Has no or minimal impact on operations or qualifications to deliver care.	Incident causes a limited disruption in some aspects of operations, but does not require significant qualification to the business.	Incident has the potential to shut down operations. Incident may require a business recovery plan for significant business.	Incident has the potential to shut down operations. Incident may require a business recovery plan for significant business.
Reputational Risk	No reputational risk.	Reputational risk may impact on reputation or operations.	Reputational risk may impact on reputation or operations.	Reputational risk may impact on reputation or operations.
Patient Safety Risk	Single or multiple events but no significant harm to patients.	Has caused or is likely to cause significant harm to patients.	Significant safety event. Single event has caused or is likely to cause significant harm to patients.	Significant safety event. Single event has caused or is likely to cause significant harm to patients.
Regulatory / Legal Risk	Allegation is not of a type that could require internal reporting or primary investigation. AND the organizational risk of liability mitigation is low.	Allegation is of a type that could require internal reporting and may require primary investigation. AND/OR the organizational risk of liability mitigation is moderate.	Allegation is of a type that could require internal reporting and would likely require primary investigation. Exposure to significant legal or regulatory risk. AND/OR the organizational risk of liability mitigation is high.	Allegation is of a type that could require internal reporting and would likely require primary investigation. Exposure to significant legal or regulatory risk. AND/OR the organizational risk of liability mitigation is very high.
Frequency (within a specific entity)	Isolated or one-time occurrence with no indication of a systemic problem.	Recurrent or repeated occurrence that suggests a systemic problem.	Recurrent or repeated occurrence that suggests a systemic problem.	Recurrent or repeated occurrence that suggests a systemic problem.
Frequency (within multiple entities)	Affects few entities in the organization.	Affects several entities in the organization.	Affects many entities in the organization.	Affects many entities in the organization.

FCO/CPD may evaluate and determine the risk rating based on the information provided. The risk rating is a tool for use in determining the level of investigation and reporting required. The risk rating does not determine the level of investigation or reporting required. The risk rating is a tool for use in determining the level of investigation and reporting required. The risk rating is a tool for use in determining the level of investigation and reporting required.

### Investigation Tools - Root Cause Analysis

Compliance RCA is an approach to identify underlying causes (not the one cause), of why an incident occurred, so that the most effective solutions can be identified and implemented. It's typically used when something goes badly, but can also be used when something goes well.

- Problem solving, incident investigation and root cause analysis are all fundamentally connected by three basic questions:
- 1. What's the problem?
- 2. Why did it happen?
- 3. What will be done to prevent it?



### Investigation Tools – Compliance Root Cause Analysis

Determine the Root Cause for ALL Compliance Issues/Investigations Using the 5 Whys technique.

- By repeatedly asking the question "Why" (five is a good rule), you can peel away the layers of symptoms which can lead to the root cause of a problem.
- Write down the specific problem. Writing the issue helps you formalize the problem and describe it completely. It also helps a team focus on the same problem.
- Ask Why the problem happens and write the answer down below the problem. Continue this step until the team is in agreement that the root cause is identified.
- Often the perceived reason for a problem will lead you to another question. Although this technique is called "5 Whys," you may find that you will need to ask the question fewer or more times than five before you find the issue related to a problem.

#### Benefits of the 5 Whys

- Helps to identify the root cause of a problem (under the surface).
- Determine the relationship between different root causes of a problem.
- One of the simplest tools.

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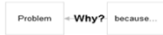
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### Investigation Tools - Root Cause Analysis

#### Cause-and-Effect- Relationship / Building Blocks

- Start on the left. Investigating a problem begins with the problem and then backs into the causes by asking Why questions.



- The questions begin, "Why did this effect happen?" The response to this question provides a cause (or causes).



- The cause that was written down last becomes the effect for the next Why question. This is fundamentally how causes and effects link together to create a chain of events. Writing down 5-Whys, shown below, is a great way to start an investigation because it's so simple.



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### Activity - Hypotheticals

- Physician Arrangement
- Provider-based status
- Implantable Cardiac Defibrillator/National Coverage Determination

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### Compliance Toolkits Examples

- Physician Arrangements
- Medicare Beneficiary Notice Delivery: Important Message From Medicare
- Charging/coding/documentation: Hydration
- Specific service regulatory compliance: Swing Bed
- Specific process for NCD compliance: Implantable Cardiac Defibrillator



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### Questions

or

Feel free to contact Anne or Barb via email

- Anne Daly: [Adaly@luriechildrens.org](mailto:Adaly@luriechildrens.org)
- Barb Martinson: [Barbara.Martinson@bannerhealth.com](mailto:Barbara.Martinson@bannerhealth.com)

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