

Chasing the Goal: How Do You Know If Your Compliance Program Is Truly Effective?

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THE ANKURA TEAM

Speakers



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- Compliance Officer
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- Compliance program expertise in academic medical center, physician practice, laboratory, long term care, including development and assessment, interim staffing, risk and effectiveness assessment, education, investigation and auditing.
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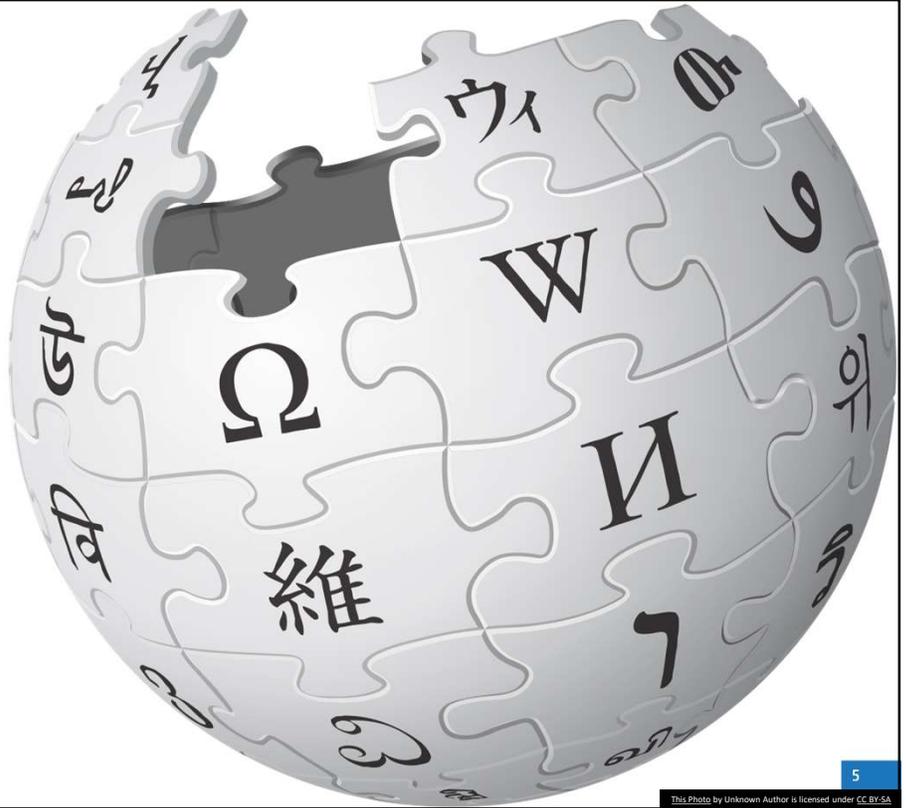
Introduction

- Why compliance program effectiveness is essential
- Challenges to achieving effectiveness
- Best practice tips to help your program achieve the effectiveness goal

Why Compliance Program Effectiveness is Essential

What is Effectiveness?

- The capability of producing a desired result. When something is deemed effective, it means it has an intended or expected outcome.
- Wikipedia
- The intended or expected outcome is identification, prioritization and mitigation of risk.



Why is Effectiveness Essential?

- “Effective” – was the standard according to the Federal Sentencing Guidelines, but had not been defined.
- [OIG Measuring Compliance Program Effectiveness: A Resource Guide](#)
 - 2017
- [DOJ Evaluation of Corporate Compliance Programs](#)
 - 2017, 2019, 2020

Intentional Assessment of and Focus on Effectiveness:



Identify Existing
Barriers



Discover
Improvement
Opportunities



Increase Overall
Program
Effectiveness

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Intentional Assessment of and Focus on Effectiveness:

Encouraged by regulatory bodies:

- FSG: Can decrease culpability score
- "Benczkowski Memo"
- DOJ: Continuous improvement, periodic testing, and review

Financial benefits:

- Cost reduction through increased efficiency
- Decreased risk of penalties
- Protects reimbursement
- Can help avoid Corporate Integrity Agreements (CIAs)

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Intentional Assessment of and Focus on Effectiveness:

Other organizational benefits:

- Promotes quality care
- Protects the organization's brand and reputation
- Increases staff awareness and understanding of compliance
- Keeps C-Suite and board engaged

Alignment of DOJ and OIG Effectiveness Documents

- DOJ – provides a high-level overview of what DOJ would look for in determining the effectiveness of a compliance program. This is part of their decision-making process for prosecution.
- OIG – provides practical guidance on how to measure effectiveness of compliance programs.
- These two documents are aligned and should be used in determining a compliance program's effectiveness.

What Does Effectiveness Look Like?

Compliance Program Elements

1. Standards, Policies, and Procedures
2. Compliance Program Administration
3. Screening and Evaluation of Employees, Physicians, Vendors and other Agents
4. Communication, Education and Training on Compliance Issues
5. Monitoring, Auditing, and Internal Reporting Systems
6. Discipline for Non-Compliance
7. Investigations and Remedial Measures

What Does Effectiveness Look Like?

Questions to ask according to the DOJ

The DOJ refers to the following three fundamental questions that should be answered by an organization:

1. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith? (In other words, is the program adequately resourced and empowered to function effectively?)
3. Does the corporation's compliance program work in practice?

Questions to Ask According to the DOJ

1) Is the corporation's compliance program well-designed?

- Explain why the organization has chosen to structure the compliance program the way it has.
- Why and how has the company's compliance program evolved over time? (i.e., provide the history of identifying, mitigating and preventing misconduct)
- How do you use lessons learned?

Questions to Ask According to the DOJ

2) Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?

- Key concepts around the compliance program being adequately resourced
- Commitment by management
- Is the Compliance Officer empowered? Can it be demonstrated?

Questions to Ask According to the DOJ

3) Does the corporation's compliance program work in practice?

- It is important to note, that the existence of misconduct does not, by itself, mean that a compliance program did not work or was ineffective at the time of the offense.
 - Consideration given to root cause analysis
- Is there continuous improvement, periodic testing and review?
- Has there been revisions to the compliance program in light of lessons learned?

Challenges to Achieving Effectiveness

Challenges to Achieving Effectiveness

- These can either be challenges or your keys to success!
- If these are gaps for you, think through how you can focus here and turn these into successes.

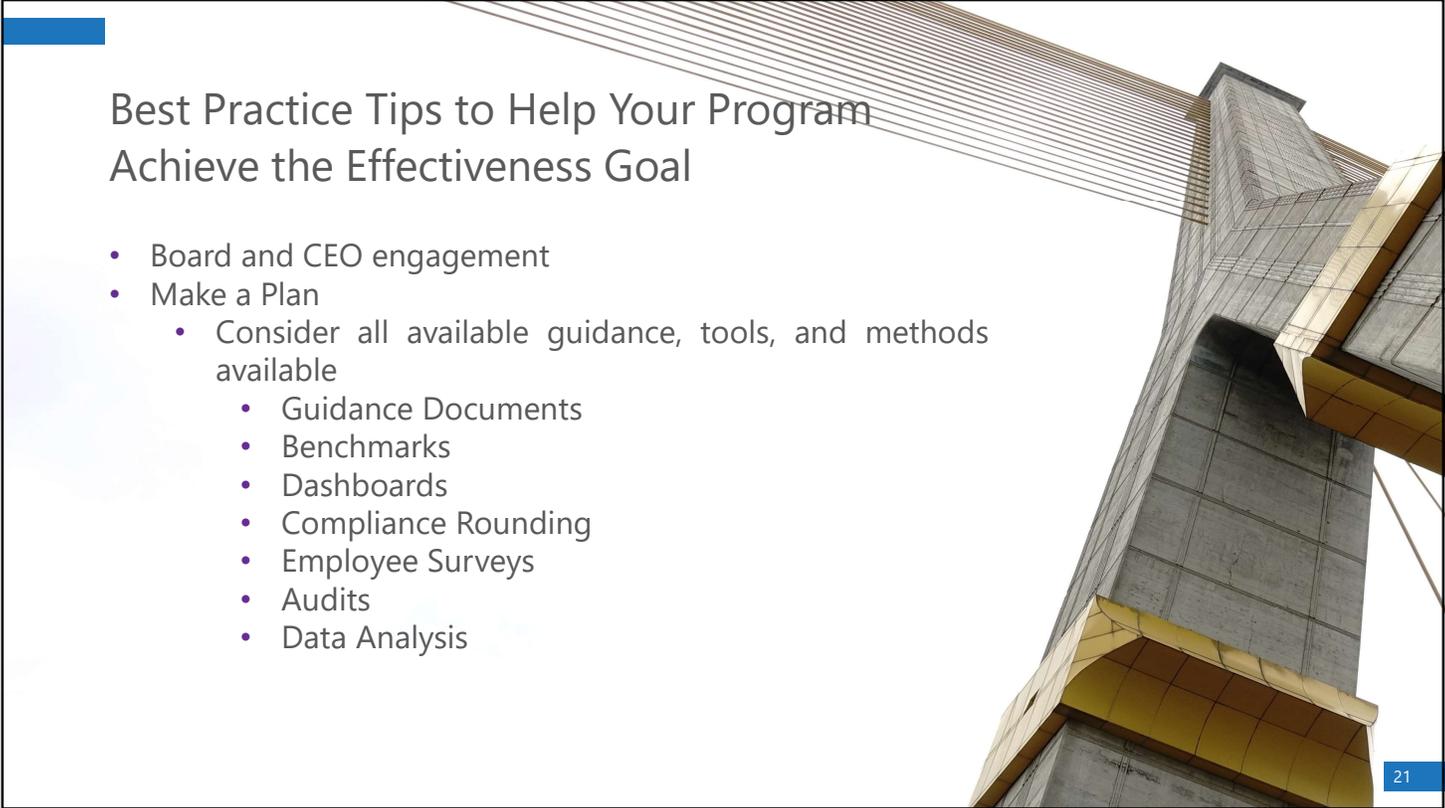
Challenges to Achieving Effectiveness

- Culture
- Understanding and buy in of Board and leadership
- Org chart/reporting structure: CCO independence and authority
- Use and integration of data
- Operations engagement in Compliance
- Leveraging partners: legal, risk, internal audit, HR, etc.

Challenges to Achieving Effectiveness

- Compliance resource sufficiency and management
- Structure and maturity of each of 7 elements
- Adequacy of risk assessment and its impact on Program
- Documentation and tracking
- Use of outside expertise

Best Practice Tips to Help Your Program Achieve the Effectiveness Goal



Best Practice Tips to Help Your Program Achieve the Effectiveness Goal

- Board and CEO engagement
- Make a Plan
 - Consider all available guidance, tools, and methods available
 - Guidance Documents
 - Benchmarks
 - Dashboards
 - Compliance Rounding
 - Employee Surveys
 - Audits
 - Data Analysis

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Best Practice Tips to Help Your Program Achieve the Effectiveness Goal

- Collaborate with compliance staff, compliance committee/operations partners, and ensure board awareness
- Consider develop SOP's, a custom tool/checklist, or even a rating plan
- Include in your work plan
- Self-assessment and outside assessment

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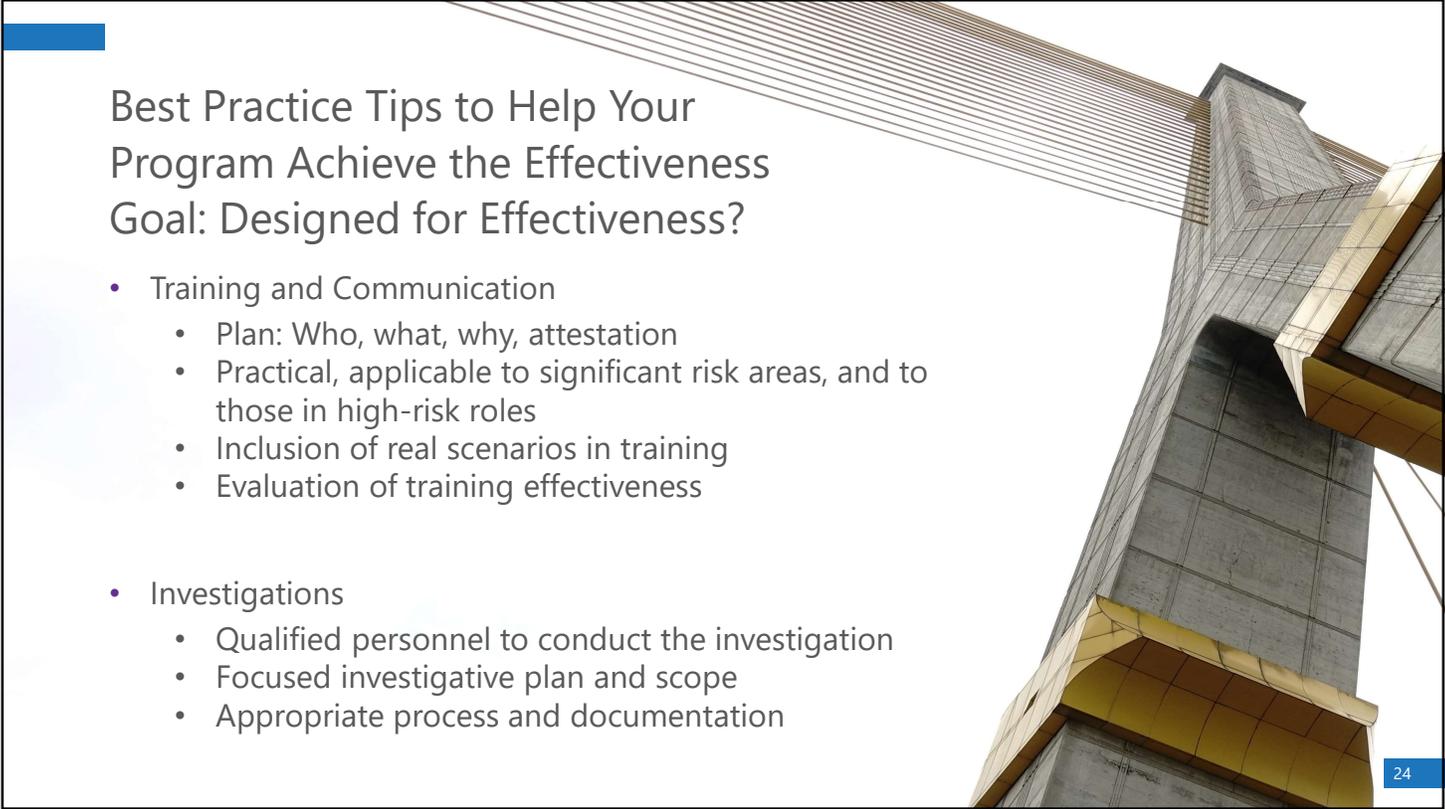


Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Designed for Effectiveness?

- Risk Assessment
 - Well-designed, documented, and ongoing
 - Compliance program tailored to your organization's risks
 - Compliance activity prioritized by risk
 - Evolving based on lessons learned
- Code of Conduct and Policies
 - Accessibility and applicability
 - Incorporated into operations
 - Appropriate for known risks

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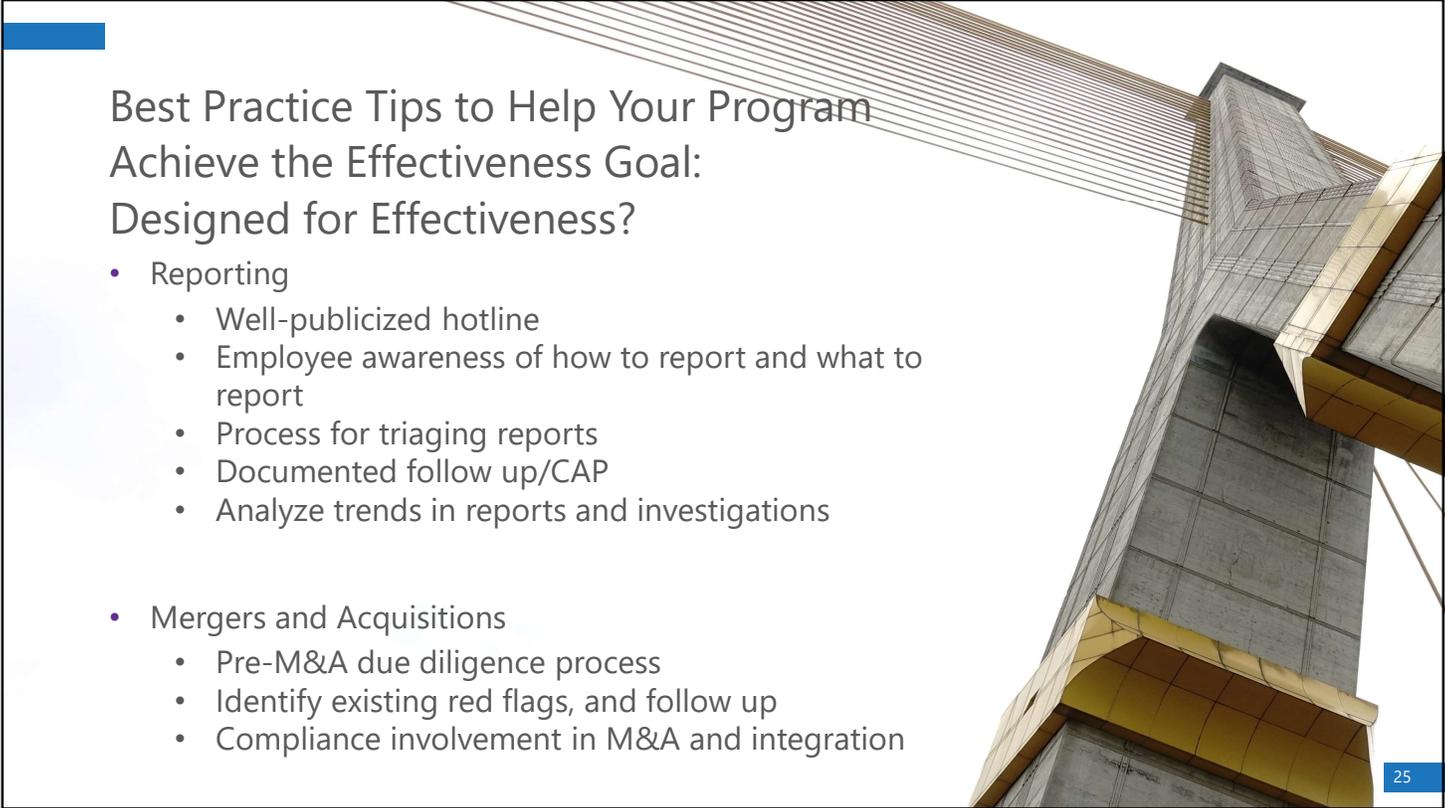


Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Designed for Effectiveness?

- Training and Communication
 - Plan: Who, what, why, attestation
 - Practical, applicable to significant risk areas, and to those in high-risk roles
 - Inclusion of real scenarios in training
 - Evaluation of training effectiveness
- Investigations
 - Qualified personnel to conduct the investigation
 - Focused investigative plan and scope
 - Appropriate process and documentation

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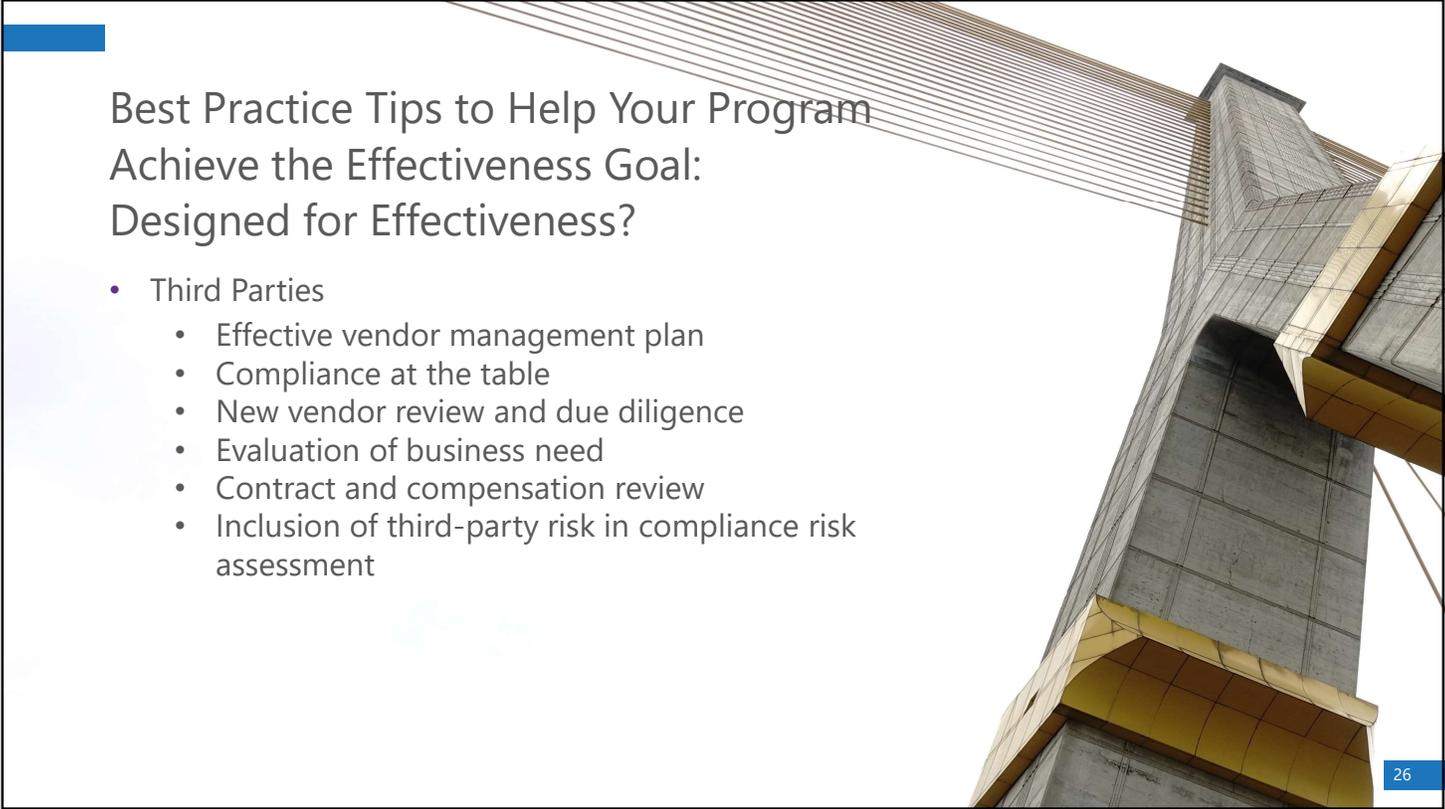


Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Designed for Effectiveness?

- Reporting
 - Well-publicized hotline
 - Employee awareness of how to report and what to report
 - Process for triaging reports
 - Documented follow up/CAP
 - Analyze trends in reports and investigations
- Mergers and Acquisitions
 - Pre-M&A due diligence process
 - Identify existing red flags, and follow up
 - Compliance involvement in M&A and integration

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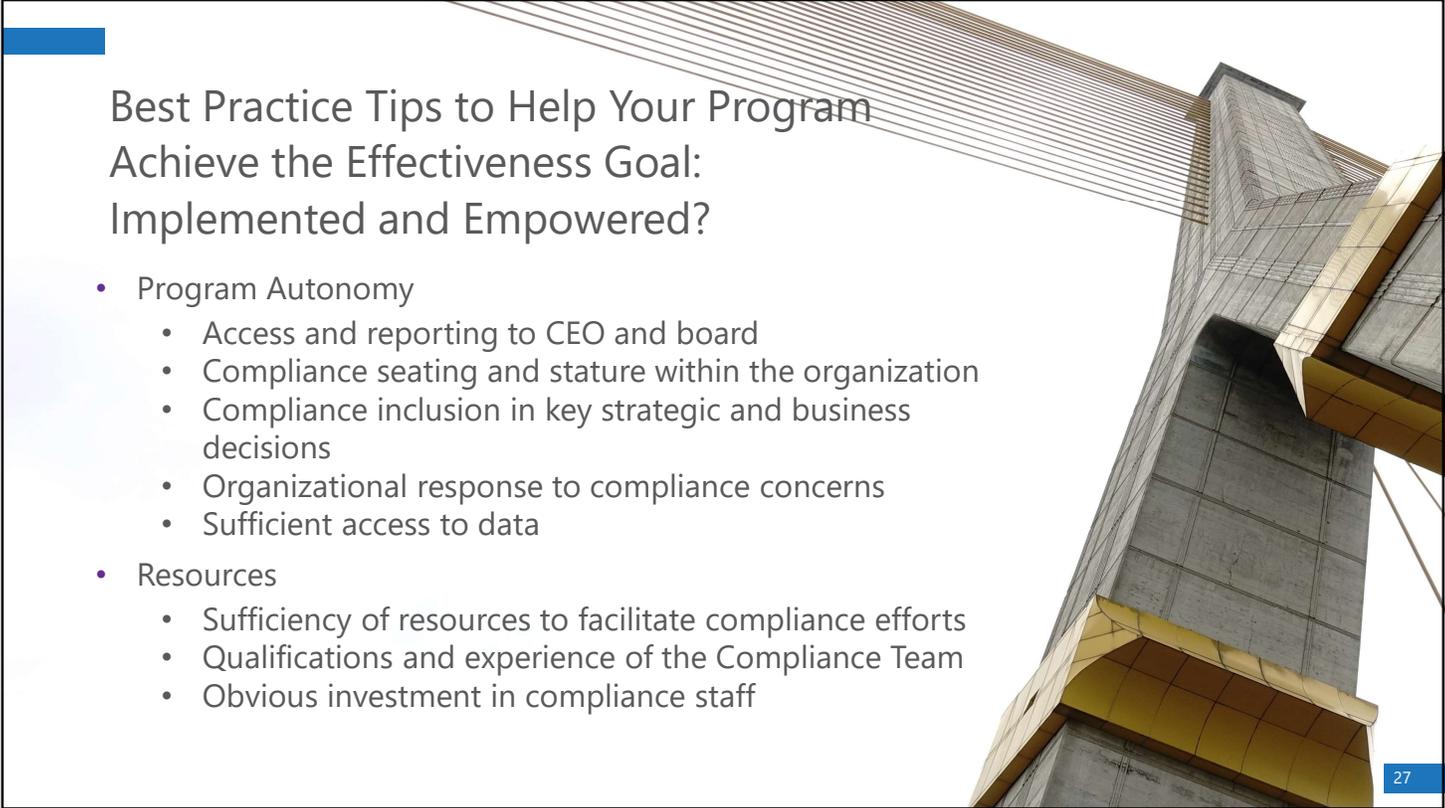


Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Designed for Effectiveness?

- Third Parties
 - Effective vendor management plan
 - Compliance at the table
 - New vendor review and due diligence
 - Evaluation of business need
 - Contract and compensation review
 - Inclusion of third-party risk in compliance risk assessment

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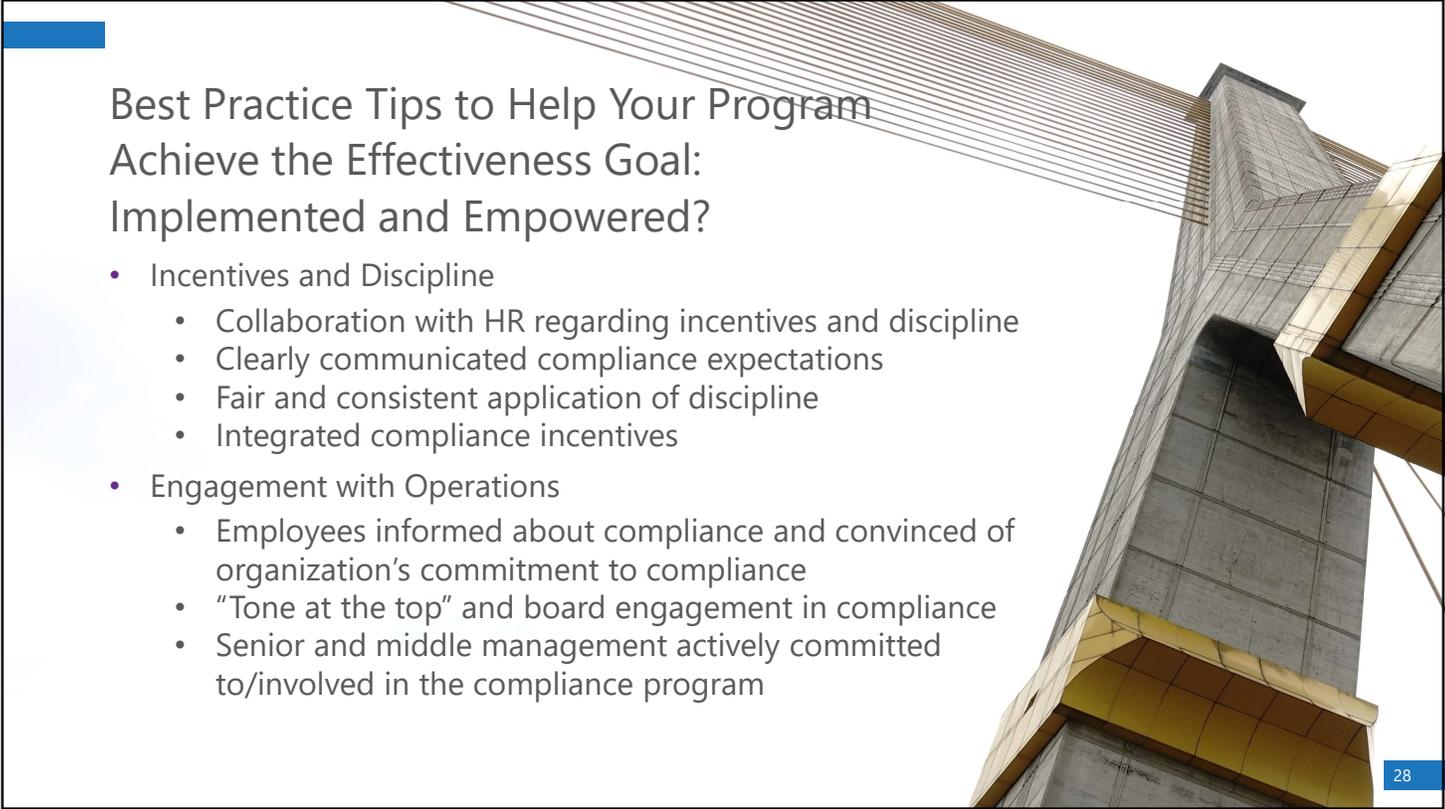


Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Implemented and Empowered?

- Program Autonomy
 - Access and reporting to CEO and board
 - Compliance seating and stature within the organization
 - Compliance inclusion in key strategic and business decisions
 - Organizational response to compliance concerns
 - Sufficient access to data
- Resources
 - Sufficiency of resources to facilitate compliance efforts
 - Qualifications and experience of the Compliance Team
 - Obvious investment in compliance staff

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Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Implemented and Empowered?

- Incentives and Discipline
 - Collaboration with HR regarding incentives and discipline
 - Clearly communicated compliance expectations
 - Fair and consistent application of discipline
 - Integrated compliance incentives
- Engagement with Operations
 - Employees informed about compliance and convinced of organization's commitment to compliance
 - "Tone at the top" and board engagement in compliance
 - Senior and middle management actively committed to/involved in the compliance program

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Best Practice Tips to Help Your Program Achieve the Effectiveness Goal: Does the Program Work?

- A Compliance Program should:
 - Evolve over time
 - Evaluate program effectiveness
 - Use root cause analysis
 - Ensure corrective action plan implementation
 - Audit high risk areas and ensure problems are fixed
 - Test and analyze controls
 - Evaluate culture of compliance and staff perceptions
 - Ensure leadership and employees held accountable with timely disciplinary response

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Conclusion

- A compliance program should be dynamic, always in motion.
- Truly effective:
 - Culture of continuous assessment and continuous improvement
 - Intentional plan to pursue effectiveness and improvement; include in your work plan!
 - Learn and implement lessons as you go
 - Formal, documented improvement and assessment
 - Flex the program as the organization evolves and the risk assessment evolves
 - Keep operations engaged

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