

Managing Compliance Program Effectiveness

Presented by:

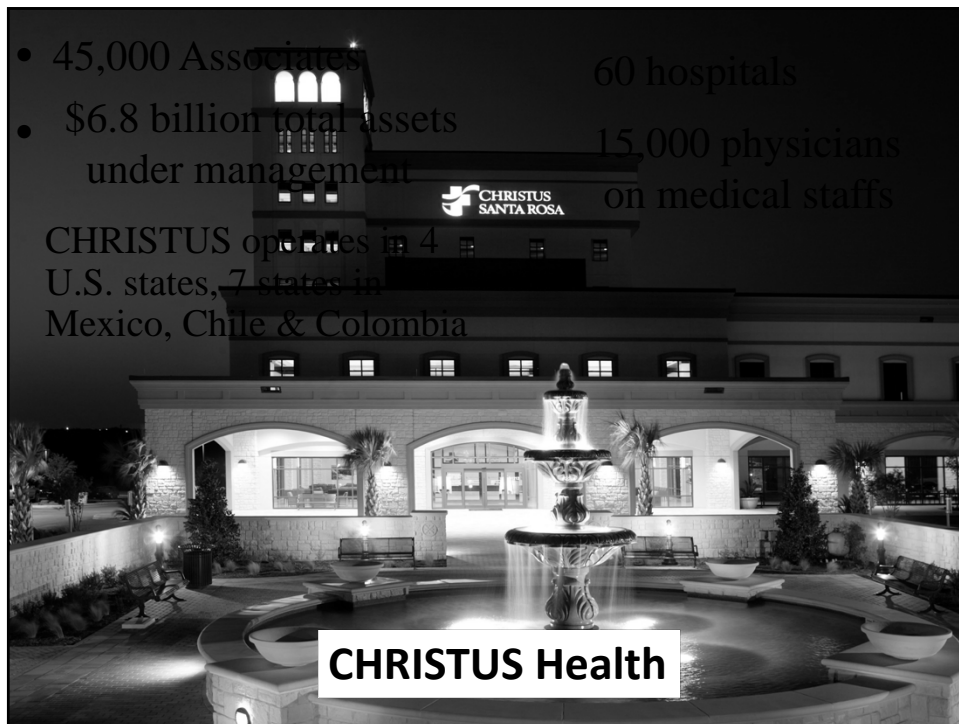
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Agenda

- ☐ Introductions
- ☐ Identify best practices for compliance programs from HCCA-OIG Compliance Program Resource Guide and DOJ Compliance on Evaluation and Compliance Programs
- ☐ Discuss compliance metrics to measure, how to measure metrics, and report to your Leadership and the Board.
- ☐ Examine the impact of recent healthcare fraud settlements on the structure and operation of internal compliance operations.
- ☐ Review approaches for addressing different compliance risks such as Stark Law, AntiKickback, HIPAA, and Payor contractual obligations.
- ☐ Final Thoughts
 - What Gets Measured . . . Improves



Recent Compliance Program Guidelines

HCCA – OIG March 27, 2017, “Measuring Compliance Program Effectiveness: A Resource Guide”

DOJ, February 8, 2017, “Evaluation of Corporate Compliance Program”

Expectation of an Effective Compliance Program

Medicare Advantage – Prescription Drug (MA-PD) Plan and Medicare-Medicare Plan (MMP) require the Managed Care Organization to implement an effective system for routine monitoring and identification of compliance risks. (Medicare Managed Care Manual, Chapter 21, Section

Office for Civil Rights (HIPAA) Security Rules require covered entities and business associates to have both Security Management Process – Risk Analysis and Risk Management

Office of Inspector General (OIG) Compliance Program Guidelines

US Federal Sentencing Guidelines (e.g., guiding principles of an effective Compliance Program)

Department of Justice (DOJ) – 11 Evaluation Categories of an effective Compliance Program

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OIG/HCCA Resource Guide

WHAT THE OIG/HCCA RESOURCE GUIDE **IS** . . .

- A tool in your toolbox (list of many compliance program ideas)
- A more objective view of what OIG might be looking for in assessing effectiveness

WHAT THE OIG/HCCA RESOURCE GUIDE **ISN'T** . . .

- A self-explanatory tool (“Let the organization choose which ones best suit its needs.”)
- A guarantee that your program will be deemed effective if you measure and trend everything

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DOJ Evaluation of Corporate Compliance Programs

- DOJ issued memo on February 8, 2017 for evaluation of compliance programs in context of criminal charging decisions.
- Operationalizes DOJ's Principles of Federal Prosecution of Business Organizations.
- Provides a very useful and practical set of benchmarks to evaluate compliance program effectiveness.
- The parameters in the DOJ memo could impact the investigation of an individual's reckless disregard or willful blindness for purposes of a civil or criminal prosecution.

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DOJ February 2017 Guidance

- Contains 11 topics that shift the analysis from examining how the alleged misconduct could have occurred, the organizations response – to the alleged misconduct and the current state of the compliance program.
- For example, the “Policies and Procedures” category ask “whether existing policies addressed alleged misconduct” and “whether policies and procedures could have prevented the alleged misconduct.”

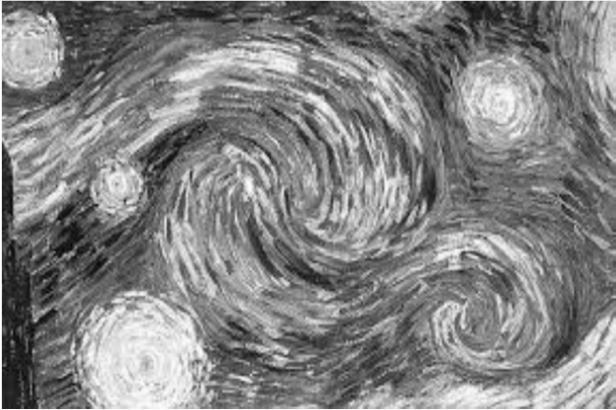
Differences Between OIG Positions and DOJ Guidance

- DOJ 2017 Guidance does not address the reporting relationship between the compliance officer and the General Counsel, and whether they can be the same person.
- DOJ Guidance instead emphasizes compliance officer's stature in the organization, access to resources, experience and qualifications, independence, access to board, etc...
- Attorneys will need to be able to articulate the areas targeted in the DOJ's memo's questions.

Starry Night

By Van Gogh



<p>Starry Night By Van Gough</p> <p>A little closer look . . .</p>	
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<p>Code of Conduct</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Does HR actively use the Code of Conduct in their investigations, sanctions, etc? <input type="checkbox"/> Is it used throughout the organization during orientation? Annual training? <input type="checkbox"/> Do all employees know how and where to access it? <input type="checkbox"/> Do staff attest to reading and understanding it? <input type="checkbox"/> How often is it reviewed and updated?
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<p>Compliance Plan Documents</p>	<ul style="list-style-type: none"> <input type="checkbox"/> How often are they reviewed / updated? <input type="checkbox"/> Who is the intended audience? Regulators, Leadership, Compliance Team, etc. <input type="checkbox"/> How does the CCO / Compliance Team use the compliance plan throughout the year?
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<p>Policies and Procedures</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Content of Policies <ul style="list-style-type: none"> • Consider developing a “policy on policies” • Definition Dictionary for terms used in policies • Help Tools / Resources for “quick answers” <input type="checkbox"/> Policy Approval Process <ul style="list-style-type: none"> • Are policies reviewed and approved by impacted stakeholders prior to implementation? • Who is responsible for training? • How are new/revised policies communicated throughout the organization? <input type="checkbox"/> Policy Maintenance <ul style="list-style-type: none"> • How do we maintain version control? • Do we train our employees how and where to access policies? <input type="checkbox"/> Compliance Department Policies <ul style="list-style-type: none"> • Updates. Process for ensuring current regulatory citations are updated in policies? • Create an Annual Compliance Dept “Activity Tracker” to ensure activities /commitments are addressed
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DOJ Evaluation Questions

Policies and Procedures

- Designing Compliance Policies and Procedures
- Applicable Policies and Procedures
- Accessibility
- Payments systems
- Approval/certification process
- Vendor management

Risk Assessment

- Information Gathering and Analysis
- Manifested Risks
 - How has the company's risk assessment process accounted for manifested risks?

DOJ Compliance Program Memo

- The DOJ Compliance questions look at the organization's existing compliance policies, and:
 - The assumptions, methodology, design and judgments in the compliance policies;
 - The proactive character and predictive accuracy of those policies;
- These inquiries may call into question compliance advice received from in-house legal counsel and outside legal counsel.

2018 Compliance Policy Activity Tracker

#	Policy Requirement	P&P Ref	Page #	Owner	Verification Method	Verified by	Start Date	Expected Completion Date	Actual Completion Date
1	Establish a Service Verification Policy and assure a quarterly verification that services were delivered to Members.	COM 10	6	J. Smith	Select 50 paid claims monthly. Contact member to validate services were delivered. Must make three attempts at different times of the day.	J. Doe	2/1/18	3/15/18	
2	Ensure that all employees are aware of the standards for business conduct and ethical behavior that is expected CPHL.	COM 2	10	J. Doe	Select 10 new employees within the last quarter and validate the Code of Conduct acknowledgement form is complete and on file.	M. Smith	4/15/18	4/30/18	
3	Ensure Conflict of interest Disclosure Forms have been completed for all Management staff and above.	COM 3	12	H. Brown	Randomly select five management staff and validate: 1. Validate COI training was completed with sign-in sheets, and 2. The completed COI Disclosure form has been completed for 2018 and it in the HR File.	B. Able	4/15/18	4/30/18	
4	ETC.								

Compliance Program Administration

- ☐ Reporting structure and access to senior leadership
- ☐ Access to governing body / Education to governing body about their compliance responsibilities
- ☐ Staffing / Budget
 - Qualified staff / Ongoing education
 - Sufficient to align with identified risks
 - Sufficient Tools to accomplish the objective
 - Program administration costs
- ☐ Support for Compliance Committees
 - Exec Compliance Committee
 - Operational Compliance Committee
 - Hospital Compliance Committees
- ☐ Open lines of communication

<p>Committee Charters and Meeting Agendas</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Charter Templates <ul style="list-style-type: none"> • Purpose. Be descriptive. What are we asking the Committee Members to do? • Composition and Meetings. Who, What, When, Where, Why • Reporting Structure. Who will receive this report and when? <input type="checkbox"/> Agendas / Meeting Invites. <ul style="list-style-type: none"> • Include copy of charter when emailing meeting invites as a good reminder. Refer to it regularly.
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DOJ Evaluation Questions

- Analysis and Remediation of Underlying Misconduct
 - Root Cause Analysis
 - Prior Indications
 - Remediation
- Senior and Middle Management
 - Conduct at the top
 - How does the company monitor its senior leadership behavior?
 - How has senior leadership modelled proper behavior to subordinates?
 - Shared Commitment
 - What specific actions have senior leaders and other stakeholders taken to demonstrate their commitment to compliance, including their remediation efforts?
 - Oversight
 - What compliance expertise has been available on the board of directors?

DOJ Evaluation Questions

- Autonomy and Resources
 - Compliance Role
 - Stature
 - What role has compliance played in the company's strategic and operational decisions?
 - Experience and Qualifications
 - Autonomy
 - Have the compliance and relevant control functions had direct reporting lines to anyone on the board of directors?
 - How often do they meet with the board of directors?
 - Does the Compliance Officer attend Board meetings?
 - Empowerment
 - Have there been specific transactions or deals that were stopped, modified, or more closely examined as a result of compliance concerns?
 - Funding and Resources
 - How have decisions been made about the allocation of personnel and resources for the compliance and relevant control functions in light of the company's risk profile?
 - Outsourced Compliance Functions (wholly, partially)

Open Lines of Communication (with BOD, Executives, and Other Leaders)

- ☐ Take advantage of each and every contact and reporting opportunity
- ☐ Reliability builds credibility
- ☐ Know your audience
 - Don't lose them with too much detail
 - Before you begin, know your goal and then tell "your story"
- ☐ Educate, Educate, Educate
- ☐ Consistency Matters
 - Standard reporting formats for Exec and BOD Committee reports
 - Use templates for minutes and activity trackers

<p>Screening (COI, Exclusion, Licensing) Effectiveness</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Do you have a conflict of interest policy? <input type="checkbox"/> Do you require new hire / annual COI disclosure? <ul style="list-style-type: none"> • Who must complete? All Staff Physicians or Just Leaders? BOD members? • Who documents results and actions taken? • Do you audit or refer back to COI disclosures, as appropriate? <input type="checkbox"/> How is exclusion screening conducted (e.g., centralized in compliance, conducted by a vendor, or carried out in various areas such as HR, medical staff, vendor management / contracting)? <ul style="list-style-type: none"> <input type="checkbox"/> Frequency <input type="checkbox"/> What process exists if an excluded individual is identified? <input type="checkbox"/> Do you have a role in auditing licensure / certification requirements of licensed staff?
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<p>Exit Interviews</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Does the organization conduct exit interviews? <ul style="list-style-type: none"> • Routine? Only for high risk employees? • Vendors? <input type="checkbox"/> Who conducts the exit interviews? <ul style="list-style-type: none"> • HR? Compliance? External firm? • Are you involved? Are compliance questions included? • If an employee declines an exit interview, who is notified?
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<p>Compliance Training</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Do you maintain a training schedule and / or policy? <input type="checkbox"/> Do all employees receive compliance training at hire? Annually thereafter? <ul style="list-style-type: none"> • Is comprehension tested? • Do you train them (1) how to report a compliance issue and (2) non-retaliation? • How is it tracked? <input type="checkbox"/> What additional role-based or high risk department training do you provide? <input type="checkbox"/> Do you mix in live training? <input type="checkbox"/> How do vendors (FDRs) receive compliance training? How is content determined? <input type="checkbox"/> How is compliance training documentation maintained?
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DOJ Evaluation Questions

- Training and Communications
 - Risk-Based Training
 - Form/Content/Effectiveness of Training
 - Communications about Misconduct
 - Availability of Guidance
- Confidential Reporting and Investigation
 - Effectiveness of the Reporting Mechanism
 - Properly Scoped Investigation by Qualified Personnel
 - Response to Investigations
- Incentives and Disciplinary Measures
 - Accountability for misconduct
 - Human Resources Process
 - Consistent Application of disciplinary actions

<h2>Processes for Implementing New Laws / Regulations</h2>	<ul style="list-style-type: none"> <input type="checkbox"/> Who in the organization is responsible for tracking new laws / regulations? Is there a centralized intake process? <input type="checkbox"/> Who monitors implementation of new laws / regulations? <input type="checkbox"/> How are stakeholders convened, if at all, to understand multidisciplinary impacts of new laws / regulations?
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<h2>Internal Reporting Systems</h2>	<ul style="list-style-type: none"> <input type="checkbox"/> How can staff / others report concerns? <ul style="list-style-type: none"> • How do you build awareness for how to report concerns? • How is your compliance hotline staffed? • Do you assess whether employees trust the reporting system? • How do you monitor if retaliation has occurred? <input type="checkbox"/> How are reported concerns tasked to appropriate investigators? <input type="checkbox"/> How do you track timeliness of response to reported concerns? <input type="checkbox"/> Do you report hotline volumes and category of concerns to your executive compliance committee and BOD? <input type="checkbox"/> Do you maintain documentation of all reported concerns?
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<p>Monitoring and Auditing Work Plans</p>	<ul style="list-style-type: none"> <input type="checkbox"/> What is your process for developing, monitoring, and auditing Work Plans based upon Risk Assessment results? <ul style="list-style-type: none"> • Who develops your Work Plan? Compliance? Do others provide feedback? • Are all audits conducted by individuals with appropriate independence? <input type="checkbox"/> How are Work Plans approved? <input type="checkbox"/> How is the audit process conducted? <ul style="list-style-type: none"> • Does each audit begin with identifying purpose, scope, and sample size? • Do audit reports have a consistent format including findings, conclusions, and recommendations? <input type="checkbox"/> Are audit results tracked and trended? <input type="checkbox"/> Who receives notice of audit results? <ul style="list-style-type: none"> • Are the results presented to your Compliance Committees? BOD?
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<p>Investigation Processes</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Is there a policy to drive the process? <input type="checkbox"/> Does compliance have the authority to take immediate steps during the investigation (i.e., stop billing)? <input type="checkbox"/> Who are your investigators? (Compliance team, HR, Legal, others?) <ul style="list-style-type: none"> • Are they adequately trained? <input type="checkbox"/> Is the process transparent? <ul style="list-style-type: none"> • When do you place it under attorney-client privilege? <input type="checkbox"/> How are investigations documented? <input type="checkbox"/> How do you ensure timely completion of the investigations? <input type="checkbox"/> Do you monitor investigations (QA activities) to ensure adherence to the policy?
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<h2>Corrective Actions</h2>	<ul style="list-style-type: none"> <input type="checkbox"/> How is accountability established for developing corrective action plans? <input type="checkbox"/> How is the corrective action plan assessed or approved? <ul style="list-style-type: none"> • Who are your Action Plan Owners, Action Plan Executives, etc? <input type="checkbox"/> How is timeliness of corrective action plan completion tracked / reported? <ul style="list-style-type: none"> • How do you assess whether CAP was successful? Change in controls? New Policy?
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<h2>Reporting Investigation Outcomes</h2>	<ul style="list-style-type: none"> <input type="checkbox"/> How are investigation outcomes communicated? <input type="checkbox"/> Consider including an Action Plan Executive section in your investigation documentation and using this to address communication needs at the conclusion of the investigation. <input type="checkbox"/> Do you maintain meeting minutes of executive compliance committee that includes notation of closed investigations and corrective actions? <input type="checkbox"/> Do you report on timeliness of investigation closure?
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CORRECTIVE ACTION PLAN		
FINDING	RECOMMENDATION	MANAGEMENT RESPONSE
<p>Risk Rating: Medium ●</p> <p>1. Provider Enrollment / Credentialing Timeliness, Completeness and Accuracy</p>		<p><u>Action Plan Owner(s):</u></p> <p><u>Action Plan Executive(s):</u></p> <p><u>Executive Sponsor(s):</u></p> <p><u>Target Completion Date:</u></p> <p><u>Management Action Plan(s):</u></p>

<p>Compliance as an Expectation of Employment</p>	<p><input type="checkbox"/> Do all training materials stress compliance as an expectation of employment?</p> <ul style="list-style-type: none"> • Is it included in job description? • Is it included in performance evaluations? <p><input type="checkbox"/> How are staff made aware of compliance's role in ensuring the fairness and consistent application of HR processes, including non-retaliation obligations from management.</p> <p><input type="checkbox"/> Do you track the number of disciplinary actions taken for non-compliance and the nature of the violation?</p>
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EFFECTIVENESS REVIEWS

IF YOU WERE ASSESSING YOUR OWN PROGRAM . . .

- Where do you start?
- What questions will you ask?
- With whom would you like to speak?
- What records will you review?
- What will you measure?
- *Is it a maturity model or task oriented (is the item present or not)?*
- How will you know if you have an effective program?

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DOJ Evaluation Questions

- Continuous Improvement, Periodic Testing and Review
 - Internal Audit
 - Control Testing
 - Evolving Updates to the Compliance plan
- Third Party Management
 - Appropriate Controls of 3rd parties
- Mergers and Acquisitions (M&A)
 - Due Diligence Process (risk identification)
 - Integration in the M&A Process of the Compliance function
 - Process Connecting Due Diligence to Implementation (risk remediation)

Effectiveness Review and Your Annual Work Flow

Don't work harder . . . Work smarter!

- Incorporate your effectiveness review into an existing compliance work flow item. **Operationalize!**
- Conduct your effectiveness review with your annual risk assessment.



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Example of Building Metrics

Focus Area:
Conflicts of Interest Form
Completion

Baseline:
45% of employees
complete their annual
COI; no formalized
process to monitor or
enforce

Data:
HR can provide COI
completion data

Activity:
New employees will
receive education about
COIs and requirement to
submit. Existing employees
will receive an email
explaining requirement to
complete
COI by March 1. COI
policy will be reviewed
and updated with
enforcement/discipline for
non-completion.

Target:
80% will complete by
April 30th

Measurement:
Percent of employees that
complete COI before
April 30th of each year

Dashboard:
Features COI completion
percentage at bi-weekly
measurement and
compares year over year.

Demonstrate Effectiveness

- Established compliance program goals and metrics to track progress on those goals
- Evidence that the compliance program
 - identified risk areas and assessed compliance with those areas
 - identified problems before outside sources brought them to provider's attention
 - responded quickly, thoroughly, and appropriately when a problem was identified

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Recent Fraud Settlements: Lessons for Compliance Programs

- (March 2018) Sightline Health and Integrated Oncology Network Holdings agreed to pay \$11.5 million to settle a FCA suit based on alleged Anti-Kickback violations.
- Sightline allegedly paid physicians profits through investments in leasing companies to induce them to refer patients to Sightline cancer treatment centers.
- Settlement included a 5-year Corporate Integrity Agreement with:
 - Internal and external monitoring of relationships with referring physicians

Sightline Settlement: Corporate Integrity Obligations

Compliance Obligations in Sightline's 5-year CIA included:

- Management Certifications by listed "certifying employees", including the CEO, COO, CFO, Director of Compliance, and business development officers.
- Established a fair market value review and oversight process.
- Required reviews of investments and rates of return.
- Verification that any discounts (e.g., prompt pay discounts, electronic payment discounts), write-offs, etc... are not improper and provided in accordance with applicable policies and procedures.

Recent Fraud Settlements: Lessons for Compliance Programs

- (March 2018) UPMC Hamot and Medicor Associates agreed to pay \$20,750,000 to settle a FCA suit based on alleged Anti-Kickback and Stark Law violations.
- Alleged that hospital paid cardiology group up to \$2 million per year for 12 physician and administrative services arrangements to secure referrals.
- FCA suit alleged that hospital had no legitimate need for the service agreements and in some instances the services were either ***duplicative or not performed***.
- A March 2017 federal district court ruling had held that 2 of the arrangements violated the Stark Law.

Compliance Strategies: Requirements from Corporate Integrity Agreements

- OIG “Focus Arrangements Procedures” in corporate integrity agreements
- Maintain a centralized tracking system
- Tracking remuneration to and from all parties
- Monitoring the use of leased space, medical supplies, medical devices, equipment, etc...
- Written review and approval process
- Track service and activity logs
- Track the fair market value determination of remuneration.

FINAL THOUGHTS

- **WHAT GETS MEASURED . . . IMPROVES**
- **Begin With the End in Mind . . . Create Your Story With the End in Mind**
- There will be no effectiveness without a strong compliance structure
- Engaging the Board and senior leadership in compliance is critical
- Demonstrate effectiveness through risk assessment, proactive internal audit, and quick response to issues
- Creating a culture of transparency and accountability will increase effectiveness

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